food supplements europe

The application of the Nutrition and Health Claims Regulation 1924/2006

Guidance for food operators
June 2013

The application of the Nutrition and Health Claims Regulation 1924/2006 – Guidance for food operators

Introductory statement

These guidelines are intended to assist food operators when applying the principles and requirements of the Nutrition and Health Claims Regulation 1924/2006 (NHCR).[1]

Many aspects of this legislation may be open to interpretation and for a number of the provisions, a common application has not yet been agreed by the Member States. It is therefore necessary to develop some guiding principles to help food operators, in particular small and medium sized companies, understand and apply this legislation in a responsible way and in a way that is most likely to follow the enforcement practices of the Member States. The aim is to have these principles applied throughout the EU as a means of supporting harmonization, one of the objectives of the NHCR.

Given the complexity of the legislation and the room for interpretation left, it is not possible in all cases to provide black and white answers. In addition the context of the use of a claim is of primary importance to judge its status and the requirements applicable. This guidance therefore intends to offer to food operators the necessary elements for making a reasoned judgment when using a specific claim and to develop sound arguments to support the approach chosen.

These guidelines are not intended to replace legislation or modify its intention. They are intended to help food operators to apply the rules in the spirit and within the scope of what was intended. Several aspects of the NHCR are very clear and should not be interpreted in more lenient ways. Other aspects however leave room for appreciation and should also not be interpreted in more restrictive ways than what is provided. The EC, Member States and EFSA have already issued guidance on a number of aspects of the NHCR. Although such guidance has no legal authority, it provides strong indications on how the provisions of the NHCR will be applied. Any deviation from such guidelines should be well considered by food operators and justification provided to ensure that the aims and objectives of the NHCR are kept, in particular by ensuring consumer protection and fair competition. It is ultimately up to the relevant Courts to judge on any interpretation of EU legislation.

This guidance should be used in conjunction with the various documents that are available from the European Commission, Member States and EFSA. An overview of relevant documents is included in Annex 1 of these guidelines.

These guidelines will be regularly revised and updated following developments and practices established with the implementation of the NHCR after the end of the transition period for the Article 13 claims on 14 December 2012. [Art 2 of Reg 432/2012]

[1] Corrigendum to Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. Official Journal of the European Union: L12/3, 18 January 2007

Important Notice

Every effort has been made to ensure that the principles in this guidance are based on and justified by the provisions of the legislation. Legislation however often involves legal uncertainty and differences of interpretation. Food Supplements Europe shall therefore have no liability whatsoever for any loss or damage resulting from the use of these guidelines or the information contained herein. When applying these guidelines, in view of linguistic, cultural and interpretation differences between the Member States, food operators should ensure that the interpretations are valid in the country in which the claim is made and justify the use of a claim with the necessary documentation.

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Executive summary

1. Elements to be checked when making nutrition and health claims

Elements to be checked to ascertain that the NHCR is applicable:

1. Is the statement a nutrition or health claim under the definitions of the NHCR?
2. Is the statement referring to a food intended to be delivered as such to the final consumer?
3. Is the statement made in a '*commercial communication*'?

A positive answer to those 3 questions clearly confirms that the NHCR is applicable. If only one or two answers are positive, then an additional check is needed to assess the likelihood of application of NHCR based on this guidance.

Elements to be checked to ascertain the correct use of nutrition and health claims:

1. Is the nutrition or health claim allowed?
    - Check the EU Register on the EC website.
2. Is the nutrition or health claim in accordance with the specific conditions of use?
    - Check the EU Register on the EC website.
3. Are the requirements and additional labelling requirements of the NHCR applied?
    - Check the NHCR and appropriate guidance documents.
    - Ascertain the claim is made in accordance with national enforcement interpretations.
    - Have the necessary justification available for inspection.

It is recommended to have a structure or system in place for the use of nutrition and health claims in the same way as other legal requirements are verified and validated.

2. Statements that fall or are likely to fall under the NHCR

Statements that fall or are likely to fall under the NHCR

1. Nutrition and health claims in conformity with the definitions of the NHCR

- The nutrition claims mentioned in the annex to the NHCR

  Remark

  Refer to the 2007 EC guidance document for clarification on the borderline with claims describing or referring to the role of a nutrient or other substance in growth, development and the functions of the body (Article 13 claims).

- The following health claims, defined or referred to in the NHCR
  - Health claims describing or referring to the role of a nutrient or other substance in growth, development and the functions of the body. [Art 13.1.a]

    Remark

    Refer to the 2007 EC guidance document for clarification on the borderline with nutrition claims, claims referring to children development and health and reduction of disease risk claims.

  - Health claims describing or referring to psychological and behavioural functions. [Art 13.1.b]
  - Health claims describing or referring to slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.
  - Reduction of disease risk claims. [Art 14.1.a]

    Remark

    Refer to the 2007 EC guidance document for clarification on the borderline with claims describing or referring to the role of a nutrient or other substance in growth, development and the functions of the body (Article 13 claims).

  - Claims referring to children's development and health. [Art 14.1.b]

    Remark

    Refer to the 2007 EC guidance document for clarification on the borderline with claims describing or referring to the role of a nutrient or other substance in growth, development and the functions of the body (Article 13 claims).

2. Nutrition and Health Claims acceptable without the need for authorisation

- References to general, non-specific benefits of a nutrient or food for overall good health or health-related well-being. [Art 10.3]

  Remark

  These statements must be accompanied by an approved specific health claim that should relate to the context of the product's presentation [e.g. on a product containing folate the approved claim should also relate to folate].

- Trade marks, brand names or fancy names which may be construed as nutrition or health claims. [Art 1.3]

  Remark

  These statements must be accompanied by an approved nutrition or health claim that is related to the effect expressed in the trade mark, brand name or fancy name.

- Recommendations of or endorsements by national associations of medical, nutrition or dietetic professionals and health-related charities. [Art 11]

  Remark

  Applicable national rules should be complied with.

3. A number of specific claims that are not allowed. [Art 12]

- Claims which suggest that health could be affected by not consuming the food
- Claims which make reference to the rate or amount of weight loss
- Claims which make reference to recommendations of individual doctors or health professionals and other associations not referred to in Article 11

4. Statements of fact

- Statements of fact are factually true and do not refer to a beneficial physiological effect.

  Remark

  Food operators wanting to use such factual information to inform consumers about the nature of their products should ensure that the information is factual and that no benefit is suggested. Whether the use of such statements is admissible will depend on the context in which the statement is being made.

3. Statements that do not fall or are not likely to fall under the NHCR

Statements that do not or may not fall under the NHCR

1. Statements that cannot be considered as beneficial physiological effects

- Statements relating to the composition and quality of a product

  Remarks

  This includes information on product composition and product properties, e.g. statements that a product contains specific ingredients and specification of the nature of such ingredients (e.g. natural origin, organic, etc).

  Such ingredients could have known beneficial properties for health (e.g. milk or soy). The wording should therefore be carefully chosen and the context be such that these statements are not considered as implied health claims.

- Statements referring to beauty

  Remarks

  This includes statements for which EFSA has indicated they could not be considered as physiological effects.

  It can be argued that these statements are not covered by the NHCR. The wording and context should be carefully considered so as not to state or imply that the claimed effect is a physiological benefit.

  Such statements should be scientifically justified and in accordance with applicable national provisions.

- Statements relating to bioavailability

  Remarks

  Bioavailability is a property of a nutrient or other substance that can be established by accepted scientific methodologies. It is a statement of fact and does not express a relationship with health.

  Only when a higher bioavailability is linked to a beneficial effect for health, would such information fall under the scope of the NHCR. Some of such claims have been included in the EU Register of rejected claims.

- Statements relating to glycaemic index

  Remarks

  Glycaemic index is a property of a food that can be established by accepted scientific methods. It is a statement of fact that as such would not fall under the provisions of the NHCR.

  Several claims relating to glycaemic index have been included in the EU Register of rejected claims, mainly because the food was not sufficiently characterised for an assessment of the scientific evidence.

  Depending on the context, a statement on glycaemic index of a food could be considered as

an implied health claim. The glycaemic index of a food ingredient also depends on the matrix of the food and on other factors. The correctness of such statements within the context of the food should be justified.

- Statements relating to pro- and prebiotics

  Remarks

  The 2007 EC guidance indicates that the words 'probiotic' and 'prebiotic' are to be considered as health claims, needing approval (or be accompanied by an approved claims in case they are used as non-specific statements).

  If used to indicate that a product contains live microorganisms that survive passage through the gut in sufficient numbers, the terms 'probiotic' could be considered acceptable by some Member States.

  Likewise the use of the term 'prebiotic' as indication of the growth promoting effect on gut bacteria, as long as no further health effects are mentioned.

  These properties need demonstration with generally accepted scientific methodologies and the results of these tests kept available for national enforcement authorities.

  Not all national authorities may be of the same opinion and national acceptance should be verified.

2. Information that is mandatory or for which specific requirements are specified in EU or national legislation

- Food labelling
  - Sales name and Qualitative Ingredient Declaration (QUID)

    Remarks

    The sales name is a legal name, a customary name or a descriptive name (e.g. fermented milk drink with lactobacillus X and vitamin C).

    The sales name should only be mentioned once on the label, be neutral in appearance and should not go beyond what is necessary to describe and characterise a product's true nature and distinguish it from other products.

- Foods for particular nutritional uses (PARNUTs)
  - For infant formulae, the nutrition and health claims specifically allowed. [Annex 4 Dir 2006/141/EC]
  - For slimming products, the specific claims accepted. [Art 5.3 of Dir 96/8/EC]
  - For Foods for Special Medical Purposes, the statement 'For the dietary management of…' where the blank is to be filled in with the diseases, disorders or medical conditions for which the product is intended and the description of the properties and/or characteristics that make the product useful in particular, as the case may be, relating to the nutrients which have been increased, reduced, eliminated or otherwise modified and the rationale of the use of the product. [Art 4.4.a and c of Dir 1999/21/EC]
  - For other PARNUT products, the indication of the particular nutritional characteristics and the particular elements of the qualitative and quantitative composition or the special manufacturing process which gives the product its particular nutritional characteristics. [Art 9.1 and 2 of Dir 2009/39/EC]
  - For specific not harmonised PARNUTs categories, any statement required under national legislation.

Remarks

The above statements are the only ones that fall outside the scope of the NHCR. All other non-mandatory nutrition and health claims made for PARNUT products need to be approved under the NHCR.

Also for the statements above sufficient justification needs to be available for national enforcement authorities.

The conditions of use of nutrition claims can be adapted to the specific nutritional requirements of PARNUT populations on the basis of generally accepted scientific evidence.

It should be noted that the PARNUT legislation will be fundamentally changed in 2016 due to an in-depth revision (Regulation 609/2013 abolishing the PARNUTS concept and retaining 4 categories of products intended for sensitive population groups).

Some clarification on the application of the NHCR to PARNUTS legislation is provided in the 2007 EC guidance.

- Foods supplements
  - An indication of the names of the categories of nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances. [Art 6.3.a of Dir 2002/46/EC]

Remarks

This statement can be equivalent to a nutrient 'contains' claim but is exempted from the NHCR. Nevertheless such statements must not go beyond the scope of informing consumers about the type or nature of the nutrients or substances that characterise the product and the indication be factual and devoid of any highlighting.

If the name of the nutrient or other substance is included in a trade mark or brand name, the appropriate requirements for trade marks and brand names apply (See point 2.2 above).

- Novel foods
  - Specific labelling requirements as part of a novel food authorisation. [Art 8.1 of Reg 258/97]

3. Non-beneficial nutrition claims and factual nutrition information

Remarks

Non-beneficial properties are not covered by the NHCR (e.g. high content in salt, fat, sugar, energy) in as far as the context would not make these statements being perceived as beneficial (e.g. for people doing sports).

Factual nutritional information, such as 'this product contains 5 g of fat' would not be considered as nutrition claim as it does not specify a beneficial property. The context is important. National acceptance should be verified.

Nutrition labelling will become mandatory for all foods from 13 December 2016.

4. Claims relating to the content of gluten and lactose

Remarks

The rules for the labelling of gluten are covered by Reg 41/2009.

There is no EU legislation setting harmonised levels for lactose. National requirements apply.

4. Commercial communications

What is or is likely to be considered as a food to be delivered as such to the final consumer?

Remarks

Foods that are intended to be delivered as such to the final consumer include foods offered for sales in the regular retail channels and via internet and direct sales.

It also includes **non-prepackaged foodstuffs** (including fresh products such as fruit, vegetables or bread).

The NHCR applies also to **foods intended for supply to restaurants**, hospitals, schools, canteens and similar mass caterers.

Foods to be delivered to the final consumer can be both specific and general. Specific products are usually branded with trade marks or brand names. The NHCR also covers **generic advertising** relating to unbranded products (e.g. milk, meat).

This indicates that the NHCR would cover primarily communications to the final consumer and not to professionals.

Communications that are or are likely to be considered as commercial communications

1. Promotional materials (e.g. labelling, brochures, websites, advertising)

Remarks

Any form of communication designed to **directly or indirectly promote the sales of foods** is a commercial communication. It includes labelling, brochures, websites, advertising, publicity, sales guides, folders, catalogues, and even verbal communication.

A communication is likely to be considered as commercial if its **primary objective is to influence consumer choice** to purchase a product or is likely to lead to **benefits for the food operator**, distributor or seller of a product.

However, materials or communications that are **outside the responsibility or supervision of food operators** or where no financial or commercial relationship with the food operator exists, should not be covered.

Food operators should have a justification if they would consider certain communications as non-commercial.

The NHCR only covers commercial communications when they relate to foods to be delivered as such to the final consumer.

Communications that are not or may not to be considered as commercial communications

1. Business to Business (B2B) communications

Remarks

The NHCR does not contain specific provisions relating to B2B communication.

Commercial communications relating to **raw materials and food ingredients** between professionals (e.g. a raw material supplier and his customer) fall out of the scope of the NHCR.

Nutrition and health claims made for **nutrients and substances in general** fall under the NHCR when such information is linked to a food intended to be delivered as such to the final consumer and communicated for commercial purposes to the consumers, but not to professionals operating within a professional context.

Communication between professionals (e.g. between a manufacturer and a retailer), relating to **products destined to be delivered to the final consumer** would not fall under the scope of the NHCR provided the product as such and the communication intended for the consumer, is in conformity with the NHCR.

In cases where it is not possible to prevent access to information for professionals by the general public, necessary information should be given to indicate it is not intended for the general consumer and where possible, explicit consent for access should be sought (e.g. use of disclaimers, pop-ups asking for explicit acceptance of use, password protection, etc).

Below are general principles. Conformity with individual practices will need to be assessed case by case.

General principles

Content	Nature of the communication	Scope of the NHCR
• Raw material / ingredient	• Supplier – Manufacturer • Supplier – Health professional	Professional communications out of scope.
• Raw material / ingredient	• Supplier – Consumer • Manufacturer – Consumer	Out of scope when no direct link with a product destined to be delivered as such to the final consumer.
• Final product	• Supplier – Manufacturer • Manufacturer – Retailer • Manufacturer – Health professional	Professional communication out of scope provided the recipient of the information is properly informed that the communication to the final consumer is or must be in compliance with the NHCR.
• Final product	• Supplier – Consumer • Manufacturer – Consumer • Retailer – Consumer	Within scope of the NHCR when included in commercial communications.

2. Communications to health care professionals

Remarks

Health care professionals are persons that are active in the health care sector and can cover anyone who is representing him/herself, or is understood by the consumer, as having expertise in the field of health or nutrition and include primarily physicians, family doctors, dieticians, pharmacists, etc.

The NHCR does not contain specific provisions relating to communication to health care professionals. The focus of the NHCR on information destined to the consumer does not intend to restrict communication to professionals.

Information on health benefits for **foods that are intended to be delivered as such to consumers**, should be correct and contain sufficient information on the legal status. The food as such needs to be in conformity with the NHCR.

It is recommended to indicate clearly on relevant materials that they are exclusively intended for medical professionals and should not be passed on to consumers.

The number of copies of such materials developed and distributed should be proportionate to the use in the target group envisaged and available for control authorities when requested.

3. Communications by third parties

Remarks

As with food information, **responsibility of information** relating to a product primarily lies with the food operator responsible for the product, i.e. the operator under whose name the food is marketed or the importer. Other food business operators, within the businesses under their control, shall ensure compliance with the requirements of food information law and shall verify that such requirements are met.

Food operators should not be held accountable for information relating to **health benefits of their foodstuffs, made by third parties** in as far as no contractual or financial relationship exist between both parties.

- Information in press, media or public domain

Remarks

The NHCR is not intended to cover **information in the press**. [Recital 4]

Promotional information originating from food operators can be considered as commercial communication. The same applies to promotional information originating from company employees or other parties that have contractual obligations to the company (e.g. advertising or public relations agencies, distributors, sellers, etc).

Information that is intended for the press (e.g. press releases, briefings, interviews, etc) when relating to foods intended to be delivered as such to the final consumer should also comply with the NHCR.

Press releases relating to company activities, stock value and corporate governance are not likely to be considered as commercial communications.

- Communications of a generic nature

Remarks

The NHCR applies to **generic advertising of food and promotional campaigns**, such as those supported in whole or in part by public authorities. [Recital 4]

Non-profit organizations acting on behalf of food operators should ensure that communication on nutritional and health benefits destined for consumers and relating to foods intended to be delivered as such to the final consumer is in conformity with the NHCR requirements.

Non-profit organisation that are not linked to commercial interests and provide information on foods, food composition and health benefits should not be considered to fall under the scope of the NHCR. However, organizations providing such information are encouraged to verify the truthfulness of the information.

Information of a generic nature covering broad classes of food, e.g. meat, milk, dairy products, fruits and vegetables, etc.) should not be covered by the NHCR as these food categories are insufficiently characterised to enable a claim to be assessed and approved.

Information relating to **individual food components that are not considered foods intended to be delivered as such to the final consumer** should not be considered as commercial communication so long as it is not of a commercial nature and not directly linked to a food containing the component.

Any **direct financial relationship** between an organization and a food operator or sector organisation having a direct commercial benefit from the communication could lead to communications being considered as commercial.

Information originating from **official government bodies** is not considered as commercial communications.

4. Communications intended for or originating from non-EU countries

Remarks

The NHCR only applies in the EU Member States. **Foods that are exported and information on these foods** should comply with national rules in the country of import.

Communication on websites, intended for third countries but accessible also by EU consumers can relate to products that are also marketed in the EU. They must be in conformity with the rules in the country the information is intended for. Food operators have to ensure that consumers are informed of the regional relevance of the communication.

Communication on websites that are intended for both EU and non-EU citizens (e.g. distant selling) need to be in conformity with the EU NHCR in as far as it concerns products that are intended to be sold to consumers in the EU.

5. Communications of scientific study results

Remarks

The NHCR is not intended to cover information in scientific publications. [Recital 4]

Information by independent researchers on the outcome of their research should therefore not to be considered as commercial communication, not even if it relates to products that are known by consumers.

It is acceptable for scientists to be financially or materially supported to present their work to the scientific community. However, presentations at events accessible by the general public could be considered as commercial.

Information on study outcomes, dissemination of scientific publications, overviews of study results developed and communicated by food operators, however, when linked to their products and intended for the consumer may be considered as commercial communications.

When used in relation to foods without an accepted nutrition or health claim the use of such materials is likely to be considered as a breach of the NHCR, except if such materials are exclusively intended for professionals and necessary measures have been taken to avoid such materials being made available to consumers.

5. Specific cases of nutrition and health claims

Specific cases of nutrition and health claims

1. Trade marks and brand names

Remarks

Trade marks, brand names and fancy names that can be construed as nutrition or health claims can be used without authorisation when accompanied by a related nutrition or health claim. [Art 1.3]

Trade marks, brand names or fancy names are not defined, therefore general definition apply. Slogans or whole or partial sentences expressing a nutrition or health claim will in general not be considered as trade marks or brand names, unless they are registered as such.

There is no requirement that trade marks or brand names need to be registered or restricted for use to only one product.

The accompanying nutrition or health claim must specifically relate to the claim that is mentioned in or as part of the trade mark, brand name or fancy name.

The precise location of the accompanying claim is not specified by the NHCR. The most appropriate place should be chosen in function of consumer understanding. Member States prefer that this related claims in next to the trade mark of brand name.

Products bearing trade marks or brand names (but not fancy names) existing before 1 January 2005 which do not comply with the NHCR benefit from a transition period until 19 January 2022. This would also apply if such products are part of advertising and publicity.

The use of trade marks or brand names as such, without an associated product, in advertising and publicity must always be accompanied by a related accepted nutrition or health claim.

2. Generic descriptors

Remarks

Generic descriptors are denominations, which have traditionally been used to indicate a particularity of a class of foods or beverages. Some of them could imply an effect on human health (e.g. cough drops).

Unless a derogation has been authorised, generic descriptors must be treated in the same way as trade marks, brand names and fancy names.

3. Flexibility of the wording

Remarks

A certain degree of flexibility of the wording of an approved claim is acceptable. The wording can be modified depending on the context as long as the meaning for the consumer remains the same.

The degree of flexibility allowed will depend on the context of the claim, cultural and linguistic aspects and the appreciation by enforcement authorities on a case by case basis.

The following principles may apply:

- A claim should be **made for the nutrient or substance** it is intended for and not for a food as such.

  It should not be implied that that the product's 'specific' formulation is relevant for the claimed effect or that the product has been 'specifically' developed to achieve a specific effect unless the product has obtained a claims permission as formulated.

- **'Contribute claims'** should not be presented in absolute ways.

  As an example, it would be acceptable to state that the nutrient plays a role in or supports a physiological function, but not that it is necessary or has a particular importance for the physiological effect.

- **'Maintenance claims'** should not be presented in a way that they imply an improvement of the physiological function.

  As an example, in this context it would not be acceptable to indicate that a nutrient or any other substance improves, strengthens, stimulates or optimizes a physiological effect, unless these effects were specifically approved.

- **References to 'health'** should be used with care.

  The appropriateness of replacing the word '*normal*' by '*healthy*' or '*good*' is an appreciation that needs to be considered in relation to the context of individual claims.

- **Statements of fact** can be used in as far as they are supported by indisputable scientific evidence and remain within the context of the approved claim.

  When citing elements from EFSA opinions to help consumers understand the health benefit, care must be taken that the claim remains within the scope of the approved wording. Appreciation by national enforcement authorities may differ.

- **Generalisations and extrapolations** are generally not acceptable.

  It would not be appropriate to extend an accepted health claim with elements that were not part of the assessment.

- **Focusing on one or more elements or sub-functions of a health** effect is possible on condition that these sub-functions are recognized to belong to the more general approved health effect.

  Care should be taken that it is not implied that the intake of the nutrient or other substance is of specific relevance only for these sub-functions (e.g. learning and memory are part of normal psychological functions).

- Combining the effect of nutrients or other substances is to be considered acceptable in case the nutrients or other substances have a similar or identical health benefit accepted. (e.g. Iodine and Magnesium contribute to normal functioning of the nervous system).

  It should not be implied that the particular combination of these nutrients or other substances has a stronger effect or has particular advantages or characteristics that go beyond the claimed effect of the individual substances.

The claimed effect should also not be extended to combinations of nutrients or other substances if it has only been accepted for one or a few of the nutrients or other substances mentioned.

- **Medicinal claims** remain prohibited (i.e. claims referring to the prevention, treatment or cure of diseases).

  EFSA has confirmed many effects as beneficial physiological effects. Such effects are therefore not considered to be medicinal effects. However, the context of use of these claims will be of importance, as well as the appreciation of national authorities.

- **Not all wordings** contained in the submission can be used; only accepted wording or wording expressing the same benefit.

  For approved claims, the wording is explicitly included in the authorisation. However, for on hold claims the use of correct and appropriate wording is of particular relevance. Not all examples of wording contained in the submission would be acceptable.

4. References to general, non-specific benefits for health and health-related wellbeing

Remarks

Reference to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being may only be made if accompanied by a specific approved health claim. [Art 10.3]

Food operators are expected to justify the link between the general reference and the accompanying permitted health claim.

Some **claims were judged to be too general or non-specific for evaluation** by EFSA and have been included in the EU Register as rejected claims. Such claims could still be used lawfully as general references, when accompanied by a specific approved claim.

Food operators will have to judge on the **appropriate location** of the accompanying claim to ensure that the general statement is not misleading for consumers. The specific authorised health claim accompanying the statement making reference to general non-specific health benefits, should be made 'next to' or 'following' the statement.

5. Recommendations and endorsements

Remarks

The NHCR accepts **recommendations of or endorsements by national associations of medical, nutrition or dietetic professionals** and health-related charities under national rules. [Art 11] Claims, which make reference to recommendations of individual doctors or health professionals and other associations are not allowed. [Art 12.c]

In the absence of national rules, recommendations or endorsements covering health-related organizations or charities can be considered as health claims, except when the use of an organisation's logo or name is not related to a nutrition or health benefit or is used for a purely non-commercial purpose (e.g. for fund raising).

Enforcement authorities may also accept to include supra-national and international associations.

Individual health care professionals (e.g. doctors, dieticians) may obviously continue to recommend the use of products to patients. These would be considered as non-commercial communications.

Information provided as part of presentations and public appearances could be considered as commercial communications if they are part of a commercial event or sponsored by a food operator, destined for the general public or intended to promote the sales of products. Justification of the commercial or non-commercial nature of the event must be considered.

Health care professional that are sellers, such as pharmacists, are responsible for the information within the context of the businesses under their control. They have to comply with the NHCR but can recommend products to consumers.

Endorsements or recommendations by other persons than health care professionals (e.g. celebrities) are allowed. Nutrition or health benefits in such statements must be approved and used under the accepted conditions of use.

Testimonials, meaning statements by consumers on their experiences with a certain product, should be in conformity with the NHCR when these statements concern benefits of the food for health.

Testimonials of consumers referring to their weight loss, including 'before and after' pictures that state or imply a rate or amount of weights loss are only accepted if they relate to other mechanisms of weight reduction than diet (e.g. physical activity).

The NHCR is not intended to cover **official recommendations by public health authorities** and bodies. [Recital 4]. References to such recommendations are acceptable, provided they are correct, relevant for the product and not misleading. Any accompanying information on the benefit of specific nutrients or other substances would need to be approved.

6. Claims relating to products intended for children

Remarks

The 2007 EC guidance explains which claims will be considered as claims referring to children's development and health (Art 14):

- Health claims solely referring to the development and health of children, with the scientific substantiation only valid for children.

- Health claims used on PARNUT products (intended exclusively to infants and young children).

The guidance also explains that the following claims are not to be considered as Article 14 claims, but as Article 13 claims:

- Claims for which the scientific substantiation covers the entire life span, or more than the children population group.

Claims that are valid for the general population, but made on products that are aimed principally at children, must remain within the remit of authorised claims and not be presented as of specific importance for children only.

7. Restrictions for the use of claims on particular products

Remarks

In principle approved claims can be used on any food in compliance with the conditions of use, except when otherwise specified.

When a claim is restricted to specific categories of foods by the conditions of use, it cannot be used on another category.

Nutrient profiles may in future further restrict the use of claims on specific products.

Claims that are approved with **proprietary data protection** can only be used by the applicant the decision is addressed to, unless other operators have obtained explicit permission from that operator.

8. Claims that remain on hold

Remarks

A number of claims, mostly relating to **botanicals** have been put on hold pending a decision. Only these claims remain possible provided they comply with the general requirements of the NHCR and existing national provisions until a final decision is taken.

The list of claims that are on hold is published on the website of the EC. Full information on these submissions can be found in the EFSA database of claims.

Most of these claims relating to botanicals have not been assessed. The wording that can be used must be verified and justified.

6. General conditions for the use of nutrition and health claims

How to use the EU Register of accepted and rejected claims

Remarks

The EU Register is not a legally binding instrument but provides a helpful tool for operators and Member States.

This EU register contains all the **accepted** nutrition and health claims and their conditions of use.

Some flexibility of wording of the claim is possible. See the section on flexibility of wording for more guidance.

The EU Register also contains those claims that have been **rejected**. Some of these can still be considered as referring to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being and can be used if they are accompanied by an approved health claim listed in the EU Register.

In case of overlap between a rejected claim and a claim still on hold for a specific substance, the on hold claims remains possible.

Specific **national rules** relating to the use of other substances (restrictions or prohibitions) remain applicable irrespective of an approved claim for the substance. However the principles of mutual recognition also apply.

General conditions for the use of nutrition and health claims

1. Basis for using nutrition and health claims

Remarks

Nutrition and health claims must refer to the **food ready for consumption** in accordance with the manufacturer's instructions.

For dehydrated **foods that need reconstitution**, the basis for a claim is the rehydrated product. For foods that can be consumed as such, the basis for the claim is the food as such.

Claims on **foods that are not eaten as such** but are used as ingredient in other foods should be considered case by case.

Weight loss or gain during preparation at home should not be considered unless there are reasons to suspect that this will influence significantly and in a systematic way the content and/or availability of the food component subject of the claim.

The application of **tolerances** for deviations from the declared label values, applying also to the conditions of use of nutrition and health claims is subject to a specific guidance document developed by the European Commission.

2. Beneficial effect required

Remarks

The presence, absence or reduced content of a nutrient or any other substance in respect of which the claim is made must have been shown to have a **beneficial nutritional or physiological effect**, as established by generally accepted scientific evidence.

Approved nutrition or health claims in the EU Register meet this requirement.

Trade marks, brand names or fancy names and **references to general, non-specific benefits** of the nutrient or food for overall good health or health-related well-being must be accompanied by an approved claim.

'Contains' nutrition claims can only be made for nutrients or substances for which a beneficial effect has been demonstrated. In case no health claim has been approved, this must be justified by the food operator. This does not apply if a 'contains statement is not referring to nutritional benefits or is mandatory information (e.g. on food supplements).

3. Significant quantity

Remarks

The nutrient or other substance for which the claim is made must be contained in the final product in a **significant quantity**.

This can be defined in legislation (e.g. for nutrients) or, if not, must be established by generally accepted scientific evidence. The significant quantity is in most cases included in the conditions of use of nutrition and health claims. If the quantity can be expressed per 100 g or 100 ml or 100 kcal, the choice of the most appropriate value must be justified.

Food supplements are concentrated foods. 15% of the Nutrient Reference Value (NRV) per 100 g could result in insignificant quantities ingested per day. It is therefore recommended practice for food supplements to consider the minimum quantity per portion of the product as recommended for daily consumption and not per 100 g.

For **beverages**, the significant quantity has been reduced to 7.5% of NRV by virtue of the new Food Information legislation. Beverages with more than 1,2 % of alcohol are not allowed to bear any health claim. This excludes liquid food supplements.

When a **target group differs from the general population** in terms of its nutritional needs (e.g. children), the conditions of use may result in inappropriate values. The choice of the significant quantity must be justified by the food operator.

For **'contains' nutrition claims** for nutrients, the same condition of use as for 'source of' nutrition claim applies. In case no daily recommended amount has been established, the choice of the significant quantity must be justified by the food operator.

4. Availability

Remarks

The nutrient or other substance for which the claim is made must be in a form that is available to be used by the body.

Systematic verification of **bioavailability** is not required for nutrients that are included in permitted lists for use in foods [Annex II of Reg 1925/2006], food supplements [Annex II of Dir 2002/46] or dietetic foods [Reg 953/2009].

For substances that are not subject to such lists, availability should be ascertained on the basis of available knowledge.

Relevant EFSA opinions may indicate factors that might affect the availability of the food component.

5. Quantity that can reasonably be ingested

Remarks

The quantity of the food that can reasonably be expected to be consumed must provide a significant quantity of the nutrient or other substance to which the claim relates (see point 3 on significant use).

In cases where the conditions of use for a claim specify the minimum quantity of the nutrient or substance in the food, it should be assessed if this quantity is sufficient in relation to the claimed effect.

If the food contains only part of what is needed, but it is reasonable to assume that consumers will obtain sufficient intake also through other sources in the diet, this would be sufficiently covered.

However, if the food can be considered to be the only source of the nutrient or substance, the full amount needed for the claimed effect would need to be present. In this case the number of servings required to be consumed must be reasonable and realistic.

Additional labelling requirements

1. Full nutrition labelling

Remark

For food: either as specified in Dir 90/496 (until 13 December 2016) or in Reg 1169/2011.

For food supplements: as specified in Dir 2002/46.

2. Explicit additional labelling requirements

- A statement indicating the importance of a varied and balanced diet and a healthy lifestyle. [Art 10.2.a]
- The quantity of the food and pattern of consumption required to obtain the claimed beneficial effect. [Art 10.2.b]
- Where appropriate, a statement addressed to persons who should avoid using the food. [Art 10.2.c]
- An appropriate warning for products that are likely to present a health risk if consumed to excess. [Art 10.2.d]
- For reduction of disease risk claims: a statement indicating that the disease to which the claim is referring has multiple risk factors and that altering one of these risk factors may or may not have a beneficial effect. [Art 14.2]

3. General food information legislation remains applicable

Consumer understanding

Remark

Nutrition and health claims should be understood by consumers. This is an assessment that needs to be part of the elements to be considered when making nutrition and health claims. It may require flexibility of wording (See section on flexibility of wording).

Introduction

The Nutrition and Health Claims Regulation 1924/2006 (NHCR) became applicable on 1 July 2007. It harmonises legislation on nutrition and health claims across the EU, including the establishment of a list of permitted claims, general conditions of use and premarketing authorisation procedures. The general principle of this legislation is that all nutrition and health claims made in relation to foodstuffs must be authorised before they are allowed to be used.

The main objectives of the NHCR are consumer protection and fair competition. Food operators should keep these objectives in mind at all times when applying the requirements of this legislation and make nutrition and health claims. Using claims that are not permitted, implying health benefits without these being in conformity with the NHCR provisions or trying to avoid restrictions imposed are to be considered as deliberate breaches of this legislation.

The NHCR only covers nutrition and health claims for foodstuffs when made on a voluntary basis. Therefore, its principles are applicable when food operators choose to communicate the nutritional and/or health properties of their products or the ingredients that they contain, but it does not oblige food operators to provide such information.

The NHCR is therefore not intended to affect the marketing of products that do not carry nutrition or health claims. As expressed on several occasions by the European Commission (EC), the rejection of a nutrition or health claim should not result in products or food ingredients being banned or consumer choice otherwise restricted. The only consequence of a claims rejection would be that nutrition and health claims could no longer be used in consumer marketing activities.

There are three elements that are of importance in deciding if the NHCR is applicable to a certain type of information:

- The information must be considered as a **nutrition or health claim** covered by the NHCR.
- The information must be made in **commercial communications**. If not, the NHCR does not apply.
- The information must relate to a **product destined to be delivered to the final consumer** or intended for supply to restaurants, hospitals, schools, canteens and similar mass caterers.

These three aspects are covered by these guidelines.

In addition **the general conditions of use** for nutrition and health claims are also covered by these guidelines.

The approved and rejected nutrition and health claims can be found in a compiled form in a Register on the website of the European Commission[2]. This Register contains the most complete information and should be consulted by food operators wishing to use nutrition and health claims. Information on how to use the Register is included in this guidance. However, this Register is not legally binding and does not replace the legal texts. It's a tool to help food operators and Member States by bringing relevant information together.

[2] http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm

The application of the NHCR is a complex matter with many nuances and elements to be considered. Whether a claim complies or not with the requirements of the NHCR will depend on how the claim is worded, what the claim covers and the context in which it is used. This will often need to be assessed case by case. The same wording may be correct in a certain context but inappropriate or misleading in another context. It is highly recommended that food operators establish and implement a structure within their business to ensure that nutrition and health claims are made in a responsible way, in conformity with the applicable rules.

This structure should include a system for validation of nutrition and health claims before they are made. This system should be part of the auto-control of food operators in the same way as the system to verify and validate other legally required information in the labelling of foods.

1. Which claims are covered by the NHCR?

1.1. Introduction

The NHCR covers nutrition and health claims.

- A **nutrition claim** is defined as "*any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to the energy (calorific value) it provides, provides at a reduced or increased rate, or does not provide; and/or the nutrients or other substances it contains, contains in reduced or increased proportions, or does not contain."* [Art 2.2.4]

  It is very simple to identify if a nutrition claim is allowed or not, as the only allowed nutrition claims are those specified in the annex of the NHCR. Nutrition claims that are likely to have the same meaning for the consumer as those listed in the annex are also acceptable.

- A **health claim** is defined as *"any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health."* [Art 2.2.5]

  This definition is intentionally very broad. '*Health*' is not defined in the NHCR. However, there is a WHO general definition of health[3], which states that:

  " *Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. "*

  Application of this broad interpretation to the NHCR is supported by the fact that the NHCR permits *"references to general, non-specific benefits of a nutrient or food for overall good health or health-related well-being"*, which can be used if accompanied by a specific health claim that has been specifically authorised. [Art 10.3]

  Nevertheless, the scope of the health claims that are covered by the NHCR is limited to those for which specific provisions are foreseen.

1.2. Claims covered by the NHCR

Art 2.2.1 of the NHCR defines what is meant by a 'claim': *"any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics."* [Art 2.2.1]

This clearly spells out that the NHCR not only covers nutrition and health claims in written form but also pictures, symbols or graphic representations that could be viewed as health messages by consumers.

1.2.1. Claims for which a possibility for approval is covered in the NHCR

In the framework of the NHCR the concept of health claims is limited to the categories of claims for which specific provisions are foreseen. As the principle of the NHCR is that claims can only be allowed when authorised, it can only cover those claims for which authorisation procedures have been established. In addition, Article 12 covers those claims that are specifically not allowed.

[3] Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948.

The claims explicitly covered by the authorisation procedures include:

- *Health claims describing or referring to the role of a nutrient or other substance in growth, development and the functions of the body.* [Art 13.1.a]

  These claims cover so-called physiological effects, which may both refer to maintenance or improvement of such functions [EC Terms of reference Article 13 claims][4]

- *Health claims describing or referring to psychological and behavioural functions.* [Art 13.1.b]

  These claims cover so-called psychological effects.

- *Health claims describing or referring to slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.* [Art 13.1.c]

- *Reduction of disease risk claims.* [Art 14.1.a]

- *Claims referring to children's development and health.* [Art 14.1.b]

Except for reduction of disease risk claims, none of these claims have been specifically defined by the NHCR. The decision if a certain claim falls into one of these categories will therefore be open to a certain interpretational discretion.

As an example, in the 2007 guidance[5], the use of the term '*antioxidant*' has been considered by the Member States as being a health claim and therefore cannot be used unless specifically approved for specific foods or food compounds, as has been the case for a number of nutrients. [Reg 432/2012]

1.2.2. Claims that are acceptable without the need for authorisation

Some nutrition and health claims do not need explicit authorisation under the terms of the NHCR. These are covered by the requirements of the NHCR and include the following:

- *References to general, non-specific benefits of a nutrient or food for overall good health or health-related well-being.* [Art 10.3]

  Such claims may only be made if accompanied by a specific approved health claim. The location of this accompanying claim is not specified by the NHCR but has been clarified in guidance published in 2013 by the EC: The specific authorised health claim accompanying the statement making reference to general non-specific health benefits, should be made 'next to' or 'following' the statement.[6]

  It may be difficult in some cases, especially on smaller packs, to accommodate the text accordingly. In such cases the food operator may be considering alternatives, such as linking the general and the specific claim by a symbol (e.g. a star). The association between both should nevertheless be clear to the consumer.

[4] European Commission request to the European Food Safety Authority for scientific advice on: the Community list of permitted health claims pursuant article 13 of Regulation 1924/2006 on nutrition and health claims made on foods http://www.efsa.europa.eu/en/ndaclaims13/docs/ndaart13tor.pdf

[5] Guidance on the implementation of regulation n° 1924/2006 on nutrition and health claims made on foods conclusions of the standing committee on the food chain and animal health. 14 December 2007. http://ec.europa.eu/food/food/labellingnutrition/claims/guidance_claim_14-12-07.pdf

[6] Commission Implementing Decision of 24 January 2013 adopting guidelines for the implementation of specific conditions for health claims laid down in Article 10 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council. Official Journal of the European Union: L22/25, 25 January 2013

- *Trade marks, brand names or fancy names which may be construed as nutrition or health claims.* [Art 1.3]

  Such statements may be used without undergoing the authorisation procedures provided they are accompanied by a related nutrition or health claim.

- *Recommendations of or endorsements by national associations of medical, nutrition or dietetic professionals and health-related charities.* [Art 11]

  Such statements are subject to relevant national rules.

- *A number of specific claims that are not allowed.* [Art 12] These are:
  - Claims which suggest that health could be affected by not consuming the food.
  - Claims which make reference to the rate or amount of weight loss.
  - Claims which make reference to recommendations of individual doctors or health professionals and other associations not referred to in Article 11.

1.2.3. Statements of fact

Statements of facts present a problematic area when assessing if their use is permitted or not. In addition Member States may have different appreciations as to the acceptability or not.

The NHCR intends to cover all claims that state, suggest or imply that a relationship exists between a food category, a food or one of its constituents and health. One of the guiding principles of the NHCR is that claims should only be accepted if it is ensured that the substances for which a claim is made have been shown to have a beneficial nutritional or physiological effect. [Recital 14, Art 5.1.a]

A number of statements relating to the role of a nutrient or other substance are well established in scientific literature. Examples include:

- *Riboflavin is a precursor of certain essential coenzymes such as flavin mononucleotide (FMN) and flavin-adenine dinucleotide (FAD), in which riboflavin functions as a catalyst for oxidation and reduction reactions and electron transport.*
- *L-Tyrosine is the starting point for the synthesis of all catecholamines. L-Tyrosine is hydroxylated to form dihydroxy-L-phenylalanine (also known as levodopa or L-dopa) via the enzyme tyrosine hydroxylase.*
- *Carnitine is required for the transport of fatty acids from the cytosol into the mitochondria for beta-oxidation. L-carnitine is the form commonly used in food supplements.*
- *Glucosamine is a structural component of several glycosaminoglycans other than chondroitin sulphate which is an important structural component of joint cartilage and in part responsible for its resistance to compression.*
- *Lutein is one of the carotenoids found in the macula of the human eye.*

Such statements are factually true and confirmed in the relevant EFSA opinions but have generally not been subject to an assessment. They have either been assessed as part of a broader beneficial role of a nutrient (mainly in relation to vitamins and minerals, e.g. Riboflavin contributes to the protection of cell constituents from oxidative damage) or have not been considered as a beneficial physiological effect per se (as for most other substances). The reason is that the scope of the Article 13 claims has been determined by the assessment approach applied. This approach focuses on improvements of physiological functions and benefits of supplementation, rather than on maintenance of health and has resulted in factual statements on the structural role of a substance not being assessed or considered beneficial. In this context it could be argued that such statements per se could be considered not to state a relationship with health and be permissible given that they are unquestionably true and provided they have not been assessed as a health benefit by EFSA.

The use of such statements in relation to an authorised claim for a nutrient or other substance covering a broader scope can be defended (see section 3.3. on flexibility of wording). However, the use of such statements when a related claim was not accepted is more critical.

A number of such statements could be useful to inform consumers on the nature of the product. However, even though such statements are factually true, their use may mislead consumers to think that intake has a benefit and therefore result in such statements becoming unauthorised health claims. Food operators wanting to use such factual information to inform consumers about the nature of their products should therefore ensure that the information is factual and that no benefit is suggested. Whether the use of such statements is judged admissible will depend on an assessment of the context in which the statement is being made, which is an assessment to be made by national enforcement authorities on a case-by-case basis.

In addition, consumer understanding is important. In a limited number of cases such statements have been specifically assessed (e.g. L-tyrosine contributes to normal synthesis of catecholamines). However, in these cases discussions have focused on consumer understanding and conditions of use, resulting in claims being kept on hold or rejected, even though they are factually true.

In a number of cases effects of intake of nutrients or other substances that have not been considered per se as beneficial health effects by EFSA express the result of an intervention (e.g. an increase or decrease of a function, biomarker or risk factor).

As these effects relate to changes of physiological functions, these effects cannot be considered as statements of fact and therefore their use is only permissible either if specifically authorised as a health claim or when it is part of the biological mechanism underlying an authorised health claim (See section 3.3. on flexibility of wording).

Examples of such situations include:

- *Reduction of gastric acid*
- *Increasing parameters of the immune system (e.g. non-specific IgA secretion, natural killer cell activity, cytokine production (e.g. TNF-alpha and IFN-gamma)*
- *Increasing body stores of certain nutrients.*

The use of statements of fact has to be carefully assessed. When in addition EFSA indicates in one of its opinions that the effect is not beneficial, additional care should be taken and it is recommended not to use such statement unless a strong justification is provided to substantiate its use.

1.3. Claims not covered by the NHCR

As already indicated, the concept of a '***claim***' is defined as "*any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics.*" [Art 2.2.1]

This concept is broader than the concept of '*health claim*', which is only a subcategory of the claims concept. Therefore not all claims can be considered as '*health claims*'.

Provided that no relationship between a food category, a food or one of its constituents and health is stated, suggested or implied, it can be concluded that the following statements would not be covered by the provisions of the nutrition and health claims. Nevertheless, even though those statements are out of the scope of the NHCR, they are covered by the general requirements of food law and should not mislead the consumers.

1.3.1. Statements relating to the composition and quality of a product

This includes information on product composition and product properties. Statements that a product contains specific ingredients and specification of the nature of such ingredients (e.g. natural origin, organic, etc) are not covered by the scope of the NHCR, not even if such ingredients would have known beneficial properties for health (e.g. milk or soy). In this case, the wording should be carefully chosen and the context be such that these statements are not considered as implied health claims.

1.3.2. Statements referring to beauty

It was confirmed by EFSA that a number of claims submitted in the Article 13 authorisation process could not be considered as physiological effects since they referred exclusively to the maintenance of the structure or appearance of skin, nails, hair, etc. These claims therefore were considered to be out of the scope of the NHCR.

These claims were subsequently put on hold by the EC pending further discussion. The conclusion in the end was that these beauty claims fall under the scope of the NHCR but that a physiological or psychological effect needs to be demonstrated to justify them. On 12 June 2013, when the next Regulation on the article 13 list was published, these claims were included in the Register of rejected claims for non-compliance with the NHCR because on the basis of the scientific evidence assessed, the claimed effect has not been linked to a function of the body, as required by Article 13 of the Regulation. This obviously related to the claims that had been submitted.

It can be argued that other statements that relate to beauty but do not refer to a function of the body have not been submitted because they do not fall under any of the categories of health claims included in the NHCR. Their use could be justified to fall outside the scope of the NHCR. However a valid justification should be available. Food operators should consider carefully the wording and context of these statements so as not to state or imply that the claimed effect is a physiological benefit. In addition food operators should ensure that such statements are scientifically justified under their own responsibility and in accordance with applicable national provisions and opinions where applicable.

1.3.3. Statements relating to bioavailability

Bioavailability is a property of a nutrient or other substance that can be established by accepted scientific methodologies. It is a statement of fact and does not express a relationship with health.

Only when a higher bioavailability is linked to a beneficial effect for health, would such information fall under the scope of the NHCR. Such situations need to be assessed case by case. Some claims relating to bioavailability have been included in the EU Register of rejected claims. However, these claims go beyond the mere provision of information as to the bioavailability of a food or food ingredient. As a consequence, these rejected health claims should not be used.

1.3.4. Statements relating to glycaemic index

Glycaemic index is a property of a food that can be established by accepted scientific methods. It is therefore a statement of fact, of interest to particular consumers and when used as such it would not fall under the provisions of the NHCR.

Several claims relating to glycaemic index have been assessed and included as non-accepted in the EU Register of rejected claims. In many cases the foods have been defined in terms of their glycaemic index and this has been considered by EFSA as not appropriate for the purpose of characterising a food. In the EU Register, these claims are therefore indicated as '*not validated*'. In other cases, the evidence has been considered without taking note of the glycaemic index of the food or food component. The rejected claims are therefore not related to the glycaemic index of the food as such.

Nevertheless, as the glycaemic index of a food implies to consumers a slower release of glucose in the blood, it can easily be considered as an implied health claim relating to glucose metabolism. In addition, the glycaemic index of a food ingredient may differ depending on the matrix of the food in which it is used. Context of use, composition of the meal and other factors (e.g. extend of chewing before ingestion and biological variation in rates and extent of digestion and absorption) may all affect and modify glycaemic values of foods reported. When stating glycaemic index value on a food or food components, food operators are encouraged to justify the correctness of the stated value within the context of the food to ensure that consumers are not being misled.

1.3.5. Statements relating to pro- and prebiotics

The use of the words '*probiotic*' and '*prebiotic*' is still an area of debate. In its 2007 guidance document the EC and Member States have agreed on a common interpretation that the terms '*probiotic*' and '*prebiotic*' should be considered as health claims, as they are understood by the consumer to convey a health benefit. Obviously, these terms are not sufficiently defined to allow a scientific assessment. They could therefore only be considered as references to general, non-specific benefits of nutrients or foods for overall good health or health-related well-being and as a consequence they are allowed when accompanied by a specific approved health claim.

This would be the case if such terms are used in the context of a health benefit. However, the terms have also been traditionally used in the EU to indicate products containing specific strains of bacteria (mainly

belonging to the groups of bifidobacteria and lactobacilli) that can be shown to pass through the gastro-intestinal tract and arrive in the colon in sufficient numbers. This is a property of the product that can be demonstrated by generally accepted scientific methodologies. Such passage and survival is not a physiological effect, nor does it describe any role in growth, development and the functions of the body. Used in this context, the terms '*probiotic*' and '*prebiotic*' could be judged as admissible.

This is also the case with factual information relating to the passage and survival of the microorganisms. This is corroborated by EFSA stating in its various opinions that an increase in the numbers of gastro intestinal microorganisms is not a beneficial physiological effect per se.

Information referring to the passage, survival and increased numbers of bacteria through the gastro-intestinal tract could therefore be considered as a statement of fact that falls outside the scope of the NHCR. Nevertheless, any statement going beyond the factual information and implying a health benefit would be considered as a health claim and would need to be approved before its use is allowed.

The same would apply for food compounds that have been demonstrated to promote the growth of bifidobacteria and lactobacilli in vivo (prebiotics) in so far as the only effect referred to is its growth promoting properties on these bacteria in the gut.

In both cases the effects referred to above need to be demonstrated with generally accepted scientific methodologies and the results of these tests kept available for national enforcement authorities.

1.3.6. Information that is mandatory by EU or national legislation

Information that is mandatory by EU or national legislation falls out of the definition of a claim. [Art 2.2.1] Aspects that are mandatory under food labelling (e.g. the indication of the name and description of the product and quantitative ingredient declaration) or vertical legislation relating to specific product (e.g. foods for particular nutritional uses or food supplements) can therefore not be considered as nutrition or health claims, even though they would fully fall within the definitions of the NHCR. Obviously this would only apply to the extent that the wording used is necessary and does not go beyond what is required to comply with the mandatory requirements.

a. Food labelling

The indication of the name of the product and quantitative ingredient declaration are mandatory particulars in food labelling. [Reg 1196/2011 Art 9.1.a and d, Art 17, Art 22][7]

Highlighting specific ingredients is permitted provided the quantity of such ingredients is indicated.

The name of the food must be its legal name[8], or in the absence of such a name, a customary name[9], or, if there is no customary name or the customary name is not used, a descriptive name[10]. [Art 17.1 of Reg 1169/2011]

[7] Regulation (EC) no 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers […] Official Journal of the European Union: L304/18 22 November 2011

[8] 'legal name' means the name of a food prescribed in the EU provisions applicable to it or, in the absence of such Union provisions, the name provided for in the laws, regulations and administrative provisions applicable in the Member State in which the food is sold to the final consumer or to mass caterers. [Art 1.2.n of Regulation 1169/2011]

[9] 'customary name' means a name which is accepted as the name of the food by consumers in the Member State in which that food is sold, without that name needing further explanation. [Art 1.2.o of Regulation 1169/2011]

[10] 'descriptive name' means a name providing a description of the food, and if necessary of its use, which is sufficiently clear to enable consumers to know its true nature and distinguish it from other products with which it might be confused. [Art 1.2.p of Regulation 1169/2011]

A product name like '*orange juice with added vitamin C*' would therefore not be considered as a nutrition claim. This would also be the case for a product description like '*fermented milk drink with lactobacillus X*'. However, such descriptions should not go beyond what is necessary to describe and characterise a product's true nature and distinguish it from other products with which it might be confused. The information should be given in a neutral and factual way (e.g. no highlighting, same font, same size, same color…). Any mention of a health effect is likely to be considered as a health claim.

It is noted that the sales name must feature on the label only once to satisfy the requirement of mandatory information. Repeating this name is possible but, when used in a particular context or highlighted, this could be considered as a means of attracting particular attention to the product description. If this description could be construed as a nutrition or health claim, it could be considered no longer as mandatory information but as a nutrition (or health) claim, subject to the rules of the NHCR.

b. Foods for particular nutritional uses (PARNUTs)

The NHCR applies without prejudice to the framework Directive relating to foodstuffs for particular nutritional uses [now Dir 2009/39][11] and Directives adopted on specific categories of dietetic products. [Dir 2006/141 on infant and follow on formulas, Dir 2006/125 on cereal based weaning foods and baby foods, Dir 96/8 on slimming foods and Dir 1999/21 on foods for special medical purposes][12,13,14,15]

Any specific requirements relating to claims included in these Directives take precedence over the requirements of the NHCR. Also any mandatory information required by these Directives falls outside of the scope of the NHCR.

These include:

- The nutrition and health claims specifically allowed for infant formulae. [Annex 4 Dir 2006/141/EC]
- The specific claims accepted for slimming products. [Art 5.3 of Dir 96/8/EC]
- For Foods for Special Medical Purposes, the statement '*For the dietary management of…*' where the blank is to be filled in with the diseases, disorders or medical conditions for which the product is intended and the description of the properties and/or characteristics that make the product useful in particular, as the case may be, relating to the nutrients which have been increased, reduced, eliminated or otherwise modified and the rationale of the use of the product. [Art 4.4.a and c of Dir 1999/21/EC]
- For other PARNUT products it is mandatory to accompany the designation under which the product is sold by an indication of its particular nutritional characteristics. For products intended for infants and young children in good health this would need to be a reference to the purpose for which the product is intended. [Art 9.2 of Dir 2009/39/EC]

[11] Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses. Official Journal of the European Union: L124/21 20 May 2009

[12] Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC. Official Journal of the European Union: L401/1 30 December 2006

[13] Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children. Official Journal of the European Union: L339/16 6 December 2006

[14] Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction. Official Journal of the European Union: L55/22 6 March 1996

[15] Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes. Official Journal of the European Union: L91/29 7 April 1999

- In addition, for PARNUTs products that are not the subject of a specific Directive, the particular elements of the qualitative and quantitative composition or the special manufacturing process which gives the product its particular nutritional characteristics must be given in the labelling. [Art 9.3.a of Dir 2009/39/EC]
- It should be noted that also statements that could be considered as health claims, imposed by national legislation also fall out of the scope of the NHCR. [Art 2.2.1] This can cover the intended use of specific PARNUTS, e.g. sports foods and target populations for which the product is intended as specified in national rules.

In the context of PARNUTs, the above statements are the only ones that, when construed as nutrition and health claims, fall outside the scope of the NHCR because their indication in the labelling of the products concerned is mandatory. All other nutrition and health claims made for PARNUT products need to be in conformity with the NHCR and therefore subject to an authorisation before they can be used.

In addition, the fact that the above statements fall outside the requirements of the NHCR does not mean that sufficient justification does not need to be at hand to justify the mandatory statements in accordance with applicable PARNUT rules. National enforcement authorities can request such information for further scrutiny.

The use of nutrition claims in the annex of the NHCR refers to the healthy population. The conditions of use refer to the reference intake values specified in the general labelling requirements. These are not relevant for population groups with particular nutritional requirements (including pregnant and lactating women, children and adolescents, patients with medically induced requirements, etc). It is therefore defendable that the conditions of use, relating to the reference quantities refer to specific values that are appropriate for the target populations under consideration provided such deviation is justified on the basis of generally accepted scientific data. Such information would need to be part of the scientific work and data establishing the product's compliance with PARNUT rules and the particular nutritional suitability of the product. If such work is contained in a readily available publication, a reference to this publication should be sufficient. [Art 11.1.c of Dir 2009/39/EC] National enforcement authorities can request such information for further scrutiny.

It should be noted that the PARNUT legislation has been completed revised. Reg 609/2013 has been published on 29 June 2013. It includes a transition period of 3 years during which the EC needs to adopt a number of delegated acts.[17] This new framework substantially differs from the current situation. The whole concept of PARNUTS disappears and only a limited number of categories of foods for sensitive population groups remain as specific legislation. These include:

- Infant formula and follow-on formula;
- Processed cereal-based food and baby food;
- Food for special medical purposes;
- Total diet replacement for weight control.

17 Regulation 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009. Official Journal of the European Union: L181/35, 29 June 2013

The rules relating to the use of the statements 'gluten-free' and 'very low gluten' [Currently included in Reg 41/2009] will be included in the Food Information to Consumers legislation [Regulation (EU) 1169/2011] as will be new rules on the use of statements indicating the absence or reduced presence of lactose.

The other categories of the existing PARNUTS will fall under general food law and therefore the NHCR will apply. A transition period of 3 years after the date of the entry into force of this Regulation (20 July 2016) is foreseen for both products that fall in or out the scope of the new Regulation provided they are in conformity with the current rules. Given the new Regulation is likely to be published by mid 2013, this means that the current situation can continue to exist for PARNUTS until mid 2016. After that point, only stocks may be sold until exhausted and claims will need to be in conformity with the NHCR.

In addition the new framework also foresees that the Commission may adopt implementing acts to decide whether or not a given food falls within the scope of this Regulation or to which specific category a given food belongs. It will be very important to be able to justify the positioning of each product with regards to the remaining product categories in scope.

Some clarification on the relationship between the NHCR and PARNUTs legislation is provided in the EC 2007 guidance document.

c. Food supplements

The NHCR applies, without prejudice, to the food supplement Directive. [Dir 2002/46][18] The only aspect exempted from the scope of the NHCR in this Directive is the requirement to indicate in the labelling "*the names of the categories of nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances*". [Art 6.3.a of Dir 2002/46/EC]

Such statement could be equivalent to a '*contains*' nutrition claim, listed in the annex of the NHCR. However, since it concerns mandatory information this annex is not applicable.

As the food supplement legislation does not specify the place of such information in the labelling, nor its format, it is acceptable for food operators to choose the most appropriate place on the label. Nevertheless, care must be taken to avoid that such indications go beyond the scope of informing consumers about the type or nature of the nutrients or substances that characterise the product. This risk is minimized when this statement is part of the product description (e.g. '*food supplement with vitamins and minerals', 'food supplement with acerola and lutein'*) and presented in a neutral and factual way.

When a product consists of more characterising substances, highlighting one may also increase the risk that consumers are misled about the nature of the product.

If the name of a nutrient or other substance is part of a trade mark or brand name, the relevant requirements of the NHCR relating to trade marks and brand names apply (See section 3.1. on trade marks and brand names).

Food supplements presented in a liquid form and containing more than 1,2 % by volume of alcohol are not considered as beverages under the NHCR. [Recital 13] This means that nutrition and health claims are possible for ethanol-containing food supplements under the same conditions as for all other food supplements.

[18] Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. Official Journal of the European Union: L136/85, 12 July 2002

d. Novel foods

Specific labelling requirements can be part of a novel food authorisation. [Art 8.1 of Reg 258/97][19] Such information can cover nutritional value or nutritional or physiological effects. When included in the authorisation, this information is mandatory and falls out of the scope of the NHCR.

e. Concluding remarks

While it can be justified that the above claims do not fall within the scope of the NHCR, the specific context of their use, taken together with the other communication, publicity and presentation of the food, could still imply a link to the health of the consumer that goes beyond the provision of the mandatory information and therefore result in such statements being considered as implied health claims, making such information fall within the scope of the NHCR. The assessment of the context of the use of a certain claim falls within national enforcement. Although uniform application of harmonized provisions is essential to secure the free movement of goods, such assessments could be different between the Member States and depend on local attitudes and historic and cultural factors. Nevertheless a priori judgments on the status of a certain claim without considering its context on a case-by-case basis would not be considered as proper enforcement practice.

It must also be noted that although the above claims do not fall within the scope of the NHCR, they remain subject to the general provisions of the misleading advertising legislation. [Dir 1984/450/EEC][20] Member States have therefore the competence to verify that claims are not misleading and may demand from the company justifiable proof of the correctness of any of the statements used. Member States may also choose to submit such evidence to appropriate national advisory bodies for assessment. Companies should therefore at all times have sufficient proof at hand as to the correctness of the information used in the labelling, presentation and advertising of their foods.

In this respect the following elements are considered specifically as misleading for consumers and are prohibited under food law: [Art 7.1 of Reg 1169/2011]

- To mislead consumers as to the characteristics of a food and, in particular, as to its nature, identity, properties, composition, quantity, durability, country of origin or place of provenance, method of manufacture or production.
- To attribute to the food effects or properties which it does not possess.
- To suggest that the food possesses special characteristics when in fact all similar foods possess such characteristics, in particular by specifically emphasizing the presence or absence of certain ingredients and/or nutrients.

  The NHCR obviously allows the use of claims for foods that naturally meet the conditions of use specified for a specific claim.
- To suggest, by means of the appearance, the description or pictorial representations, the presence of a particular food or an ingredient, while in reality a component naturally present or an ingredient normally used in that food has been substituted with a different component or a different ingredient.

[19] Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. Official Journal of the European Union: L043/1, 14 February 1997

[20] Council Directive 1984/450/EEC of 10 September 1984 concerning misleading and comparative advertising. OJ L250/17 19 September 1984

1.3.7. Non-beneficial nutrition claims and factual nutrition information

The NHCR only covers nutrition claims that state, suggest or imply that a food has particular beneficial nutritional properties. This implies that non-beneficial properties are not covered by the NHCR. This covers indications of undesirable nutrients on foods (e.g. high content in salt, fat, sugar, energy). The indication of such statements would be permitted.

Care should be taken however of the context. If used in a context in which a claim relating to a high content in salt, fat, sugar, energy, … would be perceived as beneficial (e.g. for people doing sports), such statements could still be considered as nutrition claims, and since they are not included in the annex, as not authorised.

Factual nutritional information, such as *'this product contains 5 g of fat*' would also not be considered as nutrition claim as it does not specify a beneficial property. However, also in this case the context will be important and any indication that such a statement would be beneficial should be avoided (e.g. *'this product contains only or less than 5 g of fat'*) and acceptance on national level should be verified.

Nutrition labelling will become mandatory for all foods with the application of Regulation 1169/20011 on food information to consumers from 13 December 2016. This mandatory and factual information is not covered by the NHCR.

1.3.8. Claims relating to the content of gluten and lactose

Claims relating to lactose and gluten content are clearly intended to fall outside the scope of the NHCR. Conditions for claims such as '*lactose-free*' or '*gluten-free*', addressed to a group of consumers with specific disorders, are currently dealt with by the PARNUTS legislation. [Recital 22]

The rules for the labelling of gluten are covered by Regulation 41/2009[21]. There is no EU legislation setting harmonised levels for lactose.

It is noted however that the revision of the dietetic legislation agreed will result in claims such as '*lactose-free*' or '*gluten-free*' to be regulated under the Food Information to Consumers Regulation [Reg 1169/2011] in future, with specific conditions of use. This is not the case yet and given Recital 22, it is logic to assume that such claims are currently out of the scope of the NHCR and can be made in accordance with applicable EU or national legislation.

[21] Commission Regulation (EC) No 41/2009 of 20 January 2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten. Official Journal of the European Union: L16/3, 21 January 2009

2. What information is covered by the NHCR?

The scope of the NHCR contains a number of elements that determine when the requirements of the NHCR apply to a nutrition or health claim and when not.

Art 1.2. states "*This Regulation shall apply to nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer* ".

The following elements are important for the interpretation of this article:

- The NHCR applies only to **Commercial Communications**, which covers labelling, presentation and advertising of foods.
- The NHCR covers only commercial communications of **foods to be delivered as such to the final consumer.**

The NHCR covers both **pre- and non-prepacked foodstuffs**. However some labelling requirements for both are different.

The NHCR also applies in respect of **foods intended for supply to restaurants, hospitals, schools, canteens and similar mass caterers.**

2.1. Commercial communications

Although there is no definition in the NHCR, it is acceptable to look into other legislation to address the scope of commercial communications.

One example is the Directive on services in the internal market. [Dir 2006/123/EC][22]

This Directive defines commercial communications as: " *any form of communication designed to promote, directly or indirectly, the goods, services or image of an undertaking, organisation or person engaged in commercial, industrial or craft activity or practicing a regulated profession* ". [Art 4.12 of Dir 2006/123/EC]

The key element of commercial communication is therefore that its intention is to promote directly or indirectly the goods that it concerns.

However, the Directive also indicates that the following do not in themselves constitute commercial communications:

- Information enabling direct access to the activity of the undertaking, organisation or person, including in particular a domain name or an electronic-mailing address.

[22] Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market. Official Journal of the European Union: L376/36 27 December 2006

- Communications relating to the goods, services or image of the undertaking, organisation or person, compiled in an independent manner, particularly when provided for no financial consideration.

When using the above principles, it would be appropriate to consider that any material made by, under the responsibility or supervision of, or financed by, a food operator that directly or indirectly promotes a food is covered by the concept of commercial communications. This therefore covers product labels, leaflets, brochures, folders, publicity, broadcasts, advertising, websites, in-store brochures, catalogues and all forms of electronic communication and direct mail.

Also any use of a nutrition or health claim in a promotional context, even in verbal communications, is likely to be considered as commercial communications. The context and the reason for the use of a claim should be carefully considered by the food operator. A communication is likely to be considered as commercial if its primary objective is to influence consumer choice to purchase a product. Also if such communications are likely to lead to benefits for the food operator, distributor or seller of a product, either financially or in terms of image or reputation, these elements should be consider when judging whether these communications are commercial or not. When not considered as commercial communications, a justification should be available.

It should be remembered that websites are likely to be considered as commercial communication when they refer to foods destined to be delivered, as such, to the final consumer. Any information, relating to health featured on a website and directly linked to such a product should be checked for conformity with the NHCR. This also applies to links to other websites, to scientific or magazine articles or to other relevant information. If such information would be provided without a direct link to the food in question, it could be considered as outside the scope of commercial communications.

Communications on branded ingredients whose brand can be found in the communication of foods intended for the final consumers should be carefully checked when such information is publicly available.

2.2. Foods to be delivered as such to the final consumer

The fact that the NHCR restricts its scope to foods to be delivered as such to the final consumer, indicates that there are possibilities for nutrition and health claims to be used on foods which are not intended to be delivered as such to the final consumer.

It has been debated if this provision would mean that the NHCR would only cover nutrition and health claims made in communications to the final consumer and not to professionals. The focus on products intended to be delivered to the final consumer indicates that this is indeed its primary focus. Otherwise the NHCR would have contained more specific provisions covering the use of nutrition and health claims to other target groups.

The application of the nutrition and health claims rules clearly cover more than only activities by food operators. These rules are applicable to "*all nutrition and health claims made in commercial communications, including inter alia generic advertising of food and promotional campaigns, such as those supported in whole or in part by public authorities*". This is therefore irrespective of whether the originator of a commercial communication is a food operator or not. The only exemptions mentioned are that the NHCR should not apply to claims which are made in non-commercial communications, such as dietary guidelines or advice issued by public health authorities and bodies, or non-commercial communications and information in the press and in scientific publications. [Recital 4]

The intended population that the NHCR is targeting is obviously narrower. The rules are developed to protect, on the one hand, consumers against misleading information and, on the other hand food operators against unfair competition.

That communication on nutrition and health claims is intended to cover only information destined to consumers is corroborated by its scope and by a number of elements contained in the NHCR itself:

- The legislation is motivated to a large extent by a high level of protection of consumers and adequate to facilitate choice by adequately labelling. [Recitals 1 and 9]
- It is constructed as a set of rules that complement general labelling provisions. [Recital 3] These rules cover specifically food information to consumers.
- The focus on the importance of consumer understanding throughout the text. [e.g. Recitals 10, 11, 16, 22, 29, 36 and Art 1.1, 1.2, 5.2, 13.1, 27]
- The limitation of the scope of the NHCR to foods destined to be as such delivered to the final consumer, this being defined as "*the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity*." [Art 3.18 of Reg 178/2002][23]
- Nowhere in the text the NHCR covers impact, requirements of consequences of the use of nutrition and health claims on professionals.

Foods to be delivered to the final consumer can be both specific or general. Specific products are usually branded with trade marks or brand names. However, the NHCR also covers generic advertising relating to unbranded products (e.g. milk, meat or specific food ingredients).

2.3. Communication to professionals

The NHCR does not contain provisions relating to communications to professionals. Given the focus on commercial communications and foods intended to be delivered as such to the final consumer, it is likely that communication to professionals, acting within their professional context would not be limited by the provisions of the NHCR.

[23] Regulation (EC) no 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. Official Journal of the European Union: L31/1, 1 February 2002

2.3.1. Business to business communication (B2B)

The NHCR does not contain specific provisions relating to B2B communication. The main principle is that it covers commercial communications for foods intended to be delivered as such to the final consumer. It can be argued therefore that commercial communications relating to raw materials and food ingredients between professionals (e.g. a raw material supplier and his customer) falls out of the scope of the NHCR. This is also important given that restricting this type of information in a professional context would not be justified.

In the vast majority of cases nutrition and health claims refer not to foods, but to individual nutrients and substances. Therefore, nutrition and health claims made for these nutrients and substances fall under the provisions of the NHCR when such information is communicated for commercial purposes to consumers is linked to products that are destined to be delivered as such to the final consumer. When such information is restricted to professionals operating within a professional context, such information could be argued not to be covered by the restrictions of the NHCR.

In cases where it is not possible to prevent access by the general public, necessary information should be given to indicate that the information is not intended for the general consumer and in as far possible, explicit consent for access should be sought (e.g. accepting the conditions of use for accessing websites).

When acting within their professional activities, it would also be logic that communication between professionals relating to products destined to be delivered to the final consumer (e.g. between a manufacturer and a retailer), would not fall under the scope of the NHCR provided the product, as such, and the communication intended for the consumer, would be in conformity with all aspects of the NHCR.

If, in B2B communication, information is given relating to nutrition and health benefits that would not be accepted under the NHCR when destined at consumers, it would be prudent to inform the reader by use of disclaimers or other means that compliance of the information with the NHCR needs to be ascertained when used in the labelling, presentation or advertising of foods destined to be delivered as such to the final consumer. In the case the information is conveyed through means that are also accessible for consumers (e.g. web pages), it is recommended that appropriate measures are taken to prevent access or inform consumers that the information is only intended for professional contacts.

2.3.2. Communication to health care professionals

There is no harmonized definition of what constitutes health care professionals on EU level. National definitions can differ and go beyond medicine or nursing. Nevertheless, it would appear logic to assume that for the purpose of this guidance health care professionals are persons that are active in the health care sector and can cover anyone who is representing him/herself, or is understood by the consumer, as having expertise in the field of health or nutrition and include physicians, family doctors, dieticians, pharmacists, etc.

The NHCR does not contain specific provisions relating to communication to health care professionals. The main principle is that it covers commercial communications for foods intended to be delivered as such to the final consumer. Health care professionals, because of their professional activities need to be informed and it would not be appropriate to restrict the nature of this information to what is pertinent for consumers. Nevertheless, information on health benefits should be correct and contain information to inform health care professionals on the legal status of accepted or rejected claims.

In principle any communication that relates to a product that is intended to be delivered to the final consumer could be considered to fall under the provisions of the NHCR. Any product as such, subject to communication should therefore be in conformity with the NHCR rules.

However the NHCR and its aims and objectives do not contain elements that indicate that communication should be restricted to professionals who are not the final purchasers of the product. Materials developed therefore for information purposes for health care professionals who because of their knowledge and background should be able to understand the context and are not commercially linked to promote the sales of a specific food should fall outside of the NHCR.

If such communication relates to nutritional or health benefits of a specific food destined to be delivered as such to the final consumer, information that would go beyond the scope of accepted or rejected claims, should be accompanied by sufficient information on the correct legal status of the health benefits covered.

It would be recommended to indicate clearly on materials that they are exclusively intended for medical professionals and should not be passed on to consumers. In cases where it is not possible to prevent access by the general public, necessary information should be given to indicate that the information is not intended for the general consumer and in as far as possible, explicit consent for access should be sought (e.g. accepting the conditions of use for accessing websites or protecting the web site section by means of passwords).

For control purposes, the number of copies of such materials developed and distributed should be proportionate to the use in the target group envisaged. Enforcement authorities should have access to such information where requested.

2.3.3. In summary

For communication of health claims between professionals it is justified that the requirements of the NHCR relating to foods intended to be delivered to the final consumer are balanced with the requirements for professional information to provide all necessary and useful information within a professional context, as long as the products concerned, when intended to be delivered to the final consumer, are in conformity with the provisions of the NHCR.

Any question as to the appropriateness of a specific communication in the context of such professional exchanges will need to be judged in relation to its form, content and target and on a case by case basis. A number of general principles can be proposed:

Content	Nature of the communication	Scope of NHCR
Raw material / ingredient	Supplier – Manufacturer Supplier – Health professional	Professional communications out of scope.
Raw material / ingredient	Supplier – Consumer Manufacturer – Consumer	Out of scope when no direct link with a product destined to be delivered as such to the final consumer.
Final product	Supplier – Manufacturer Manufacturer – Retailer Manufacturer – Health professional	Professional communication out of scope provided the recipient of the information is properly informed that the communication to the final consumer must be in compliance with the NHCR.
Final product	Supplier – Consumer Manufacturer – Consumer Retailer – Consumer	Within scope of the NHCR when included in commercial communications.

The above presents general principles. Conformity with individual practices will need to be assessed case by case.

2.4. Communication by third parties

The NHCR is set up to complement food labelling rules. The responsibility of information relating to a product primarily lies with the food business operator responsible for the product, i.e. the operator under whose name or business name the food is marketed or, if that operator is not established in the EU, the importer into the Union market. [Art 8.1 of Reg 1169/2011] Other food business operators, within the businesses under their control, shall ensure compliance with the requirements of food information law and shall verify that such requirements are met. No obligations are specified in relation to third parties. In principle food operators should not therefore be held accountable for information relating to health benefits of a foodstuff made by third parties in as far as it can be demonstrated that no contractual or financial relationship exist between the third party and the food operator involved.

2.4.1. Information in press, media or public domain

The NHCR is not intended to cover information in the press. [Recital 4] Nevertheless, promotional information originating from food business operators intended for press and media can be considered as commercial communications.

Food operators should therefore take care that promotional information originating from company employees or other parties that have contractual obligations to the company (e.g. advertising or public relations agencies, distributors, sellers, etc) remain in conformity with the requirements of the NHCR. This is of particular relevance for communication via social media.

In addition, food operators should make sure that promotional information that is intended for the press (e.g. press releases, briefings, interviews, etc) is in conformity with the NHCR when relating to products intended to be delivered as such to the consumer and it can reasonably be expected that such information will be taken over by the media and communicated to consumers. Press releases relating to company activities, stock value and corporate governance are not likely to be considered as commercial communications. Nevertheless food operators will usually be held accountable for information of a commercial nature containing nutrition and health claims relating to products destined to the final consumer, that can be traced back as originating from the food operator.

This would, in general, not apply to information that is not relating to foods intended to be delivered, as such, to the consumer, or has no commercial value or intention.

Food operators would generally not be held accountable for information published in media or press which falls out of the remit of the food operator and is not based on materials that have been provided by the company or has been put into a commercial context despite the original material being objective and non-commercial. Nevertheless, if food operators would quote or refer back to such information in the context of foods intended to be delivered to the final consumer, this is likely to be considered as a commercial communication and should comply with the NHCR rules.

As the NHCR also applies to generic advertising, non-profit organizations acting on behalf of food operators should ensure that communication on nutritional and health benefits destined for consumers and relating to foods intended to be delivered as such to the final consumer is in conformity with the NHCR requirements.

2.4.2. Communications of a generic nature

The NHCR is very explicit in that it should apply to all nutrition and health claims made in commercial communications, including inter alia generic advertising of food and promotional campaigns, such as those supported in whole or in part by public authorities. [Recital 4] It is clear therefore that '*generic advertising*' of foods is intended to be covered by the requirements of the NHCR.

Still, the NHCR is also intended to complement food information for foods intended to be delivered as such to the final consumer (for both pre- or non-prepacked foods), when voluntary nutrition and health claims are being made. Whether the information relates to a food intended to be delivered as such to the final consumer or not is therefore a crucial element for judging whether the information is covered or not under the NHCR rules.

There are private organization, not linked to commercial interests that provide information on foods, food composition and health benefits. The information provided by such organisations is not of a commercial

interest although some information could be construed as nutrition and health claims for foods that are intended to be delivered as such to the final consumer. Such information should not be considered to fall under the scope of the NHCR.

However, organizations providing such information are encouraged to verify the truthfulness of the information they disseminate, in particular if they have knowledge of health benefits that have been rejected under the Regulatory framework. In such cases the reason for rejection is an important element to consider.

Some information of a generic nature covers broad classes of food, e.g. meat, milk, dairy products, fruits and vegetables, etc. Experience with the applications under Article 13 has shown definitively that claims for such categories of foods cannot be assessed under the methodology adopted because they cannot be sufficiently characterised for the purpose of assessing the scientific evidence. It can therefore be defended that information relating to food categories as such is not covered by the NHCR as it is not possible to obtain approval for such health claims under the current assessment system. Nevertheless, the more detailed the food group is the more it will become possible to characterise the foods and in those cases compliance with the HNCR may become appropriate.

In some cases generic information is provided on individual food components that are not considered foods intended to be delivered to the final consumer. Although such food components may be included in concentrated form in foods, e.g. food supplements, it can generally be considered that when such information is not of a commercial nature and not directly linked to a food containing the component, it should not be considered as a commercial communication. Also in this case organizations providing such information are encouraged to consider regulatory rejections and their reasons.

If a direct financial relationship exists between an organization engaged in the communications as described above and a food operator or sector organisation having a direct commercial benefit from the communication for the products covered, the non-commercial nature of the information may be more difficult to defend.

Information originating from official government bodies is not considered as commercial communications. Nevertheless, information provided by non-government bodies, financially or otherwise supported by public money, could still be considered as commercial communication if the information could be considered as '*generic advertising*'.

2.5. Information intended for or originating from non-EU countries

It is obvious that the NHCR only applies in the EU Member States. While Non-EU countries can also opt to apply EU rules, this is not the case in the vast majority of other jurisdictions. Regulation 178/2002 specifies that food exported or re-exported from the EU for placing on the market of a third country shall comply with the relevant requirements of food law, unless otherwise requested by the authorities of the importing country or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country. [Art 12.1 of Reg 178/2002]

This means that in general communication on or about foods manufactured in or outside of the EU intended for marketing in a non-EU country will need to abide local rules relating to nutrition and health claims. Also in case no specific rules exist in the third country, local practice prevails and the requirements of the EU NHCR do not necessarily apply.

In the modern day era of communication it cannot be avoided that communication on websites, intended for third countries is accessible to EU consumers. Such communication can relate to products that are also marketed in the EU. As the content of such communication needs to be in conformity with the requirements of the country the communication is intended for, such communication may be perceived in breach with NHCR rules, in particular when non-approved nutrition or health claims are being made. Food operators therefore have to ensure that consumers are informed of the regional relevance of the communication. This is of particular relevance when websites originate from within the EU Member States and are in one of the official languages of the EU and feature products also available in the EU.

Websites that are intended for both EU and non-EU citizens (e.g. distant selling) need to be in conformity with the EU NHCR in as far as it concerns products that are intended to be sold to consumers in the EU.

2.6. Communication of scientific study results

The NHCR is not intended to cover information in scientific publications. [Recital 4]

Information by independent researchers on the outcome of their research should therefore not to be considered as commercial communication, not even if such communication would relate to products that are known by consumers. This relates to the publications, press releases and presentations at symposia or in the media.

It is also acceptable for scientists to be financially or materially supported to present their work at symposia and congresses within the scientific community. Presentations at events accessible by the general public could be considered as commercial when supported by the food operator.

Information on study outcomes, dissemination of scientific publications, overviews of study results developed and communicated by food operators, however, when linked to their products and intended for the consumer may be considered as commercial communications. When such materials are used in the promotion of foodstuffs with an accepted nutrition or health claim and remain within the context of that authorisation, the use of such materials could be acceptable.

When used in relation to foods without an accepted nutrition or health claim the use of such materials is likely to be considered as a breach of the NHCR. This would not apply if such materials are exclusively intended for professionals and if necessary measures have been taken to avoid such materials being made available to consumers.

3. Specific cases of nutrition and health claims

3.1. Trade marks and brand names

The NHCR clearly applies to trade marks and brand names that can be construed as nutrition or health claims. [Recital 4]

It accepts however that "*a trade mark, brand name or fancy name appearing in the labelling, presentation or advertising of a food which may be construed as a nutrition or health claim is used without undergoing the authorisation procedures, provided that it is accompanied by a related nutrition or health claim in the labelling, presentation or advertising which complies with the provisions of the NHCR.*" [Art 1.3]

The following elements need therefore to be considered:

- As there is no definition of what is a trade mark, a brand name or a fancy name in the NHCR, generally applicable definitions of these concepts apply and it is up to the food operator to justify that a certain terminology is a trade mark, brand name or fancy name. Slogans or whole or partial sentences expressing a nutrition or health claim will in general not be considered as trade marks or brand names, unless they are registered as such. In any case to be permissible in relation to food products they would need to be accompanied by a related approved claim.
- A brand name, trade mark or fancy name is linked to a product (food or food ingredient when the food ingredient brand name is communicated to consumers e.g. in co-branding activities). However, the nature of the product can vary and the same name can be applied to several, even largely different product concepts. Trade marks, brand names and fancy names are, in principle, used to create product identification and to prevent confusion in the eyes of consumers as to the identity of a specific food and with similar or competing products by other food operators. They can be used for different products over time. As the NHCR covers claims, the provisions on trade marks, brand names and fancy names concern the names as such and not the products they are allowed to be used on.
- A trade mark or brand name can be registered but this is not a requirement for the application of the requirements of the NHCR, including the application of the transitional period provisions.
- The accompanying nutrition or health claim must specifically relate to the claim that is mentioned in or as part of the trade mark, brand name or fancy name.
- The exact location of the accompanying approved nutrition or health claim on the product label or in the presentation or advertising is not specified by the NHCR, which indicates that a certain flexibility is acceptable. Accompanying can therefore be considered as one of the following possibilities:
    - As part of the trade mark, brand name of fancy name, either with the same font size and typeset or not
    - In close proximity
    - In the same field of vision
    - In the same label of material

The context of the claim and its potential to mislead consumers will need to guide food operators to choose the most appropriate place for the positioning of an accompanying claim.

As this approved claim should be '*related*' it will need to have the same meaning to the consumer as the trade mark, brand name or fancy name it accompanies. Therefore food operators will need to check that the general consumer understanding of the intended use of the product on the basis of the trade mark, brand name or fancy name is correct if the accompanying claim is not immediately apparent. In case consumer understanding would not be correct, the accompanying claim should be included in the same field of vision or in close proximity to the trade mark, brand name or fancy name. Member States generally prefer that the accompanying claim is put near or next to the trade mark or brand name.

The NHCR has foreseen a transition period for products bearing trade marks or brand names (but not fancy names) existing before 1 January 2005 which do not comply with the NHCR. These products may continue to be marketed until 19 January 2022. It should be noted that this only applies to the use of these trade marks and brand names on products.

This transition period does not apply to the use of trade marks or brand names used as such, without any product associated to it, in advertising and publicity. In such cases these trade marks and brand names must still be accompanied by a related accepted nutrition or health claim. Since the transition period is not limited to the placing on the market but covers the marketing of products bearing trade marks or brand names existing before 1 January 2005, which do not comply with the NHCR, advertising and other ways marketing of that brand name or trade mark when associated to the product the transition period applies to, is obvious permitted.

3.2. Generic descriptors

Generic descriptors are denominations, which have traditionally been used to indicate a particularity of a class of foods or beverages. Some of them could imply an effect on human health (e.g. cough drops).

The NHCR considers such generic descriptors as trade marks, brand names or fancy names, but provides for the possibility of a derogation to enable such descriptors to be used without being accompanied by a related approved claim.

Application for such derogations must be introduced via a national competent authority of a Member State. Implementing rules are still under development, being discussed by the Standing Committee on the Food Chain and Animal Health and no generic descriptor derogation has yet been authorised.[24]

Unless a derogation has been authorised, generic descriptors must be treated in the same way as trade marks, brand names and fancy names.

[24] Standing Committee on the Food Chain and Animal Health. Section General Food Law. Agenda. 12 June 2013

3.3. Flexibility of the wording

The NHCR applies to all nutrition and health claims. It is however recognized that not every wording or variation of a food/health relationship would need to be approved. Flexibility of the wording of a claim is also recognized as necessary for consumer understanding as it shapes the context under which a claim can be made.

In the authorisations of the various nutrition and health claims it is specified that one of the objectives of the NHCR is to ensure that health claims are truthful, clear and reliable and useful to the consumer, and that wording and presentation have to be taken into account in that respect. Therefore where the wording of claims has the same meaning for consumers as that of an authorised health claim as they demonstrate the same relationship that exists between a food category, a food or one of its constituents and health, they should be subject to the same conditions of use indicated therein.

This means that the wording of an accepted claim can be modified depending on the context of the claim is as long as the meaning for the consumer remains the same.

This obviously is a matter of subjective appraisal and carries the risk that the claim is formulated in a way that it infers upon the consumer a benefit that goes beyond what has been established. Therefore when food operators chose to deviate from the accepted wording of a claim, it is highly recommended to have a rationale to justify such deviation and demonstrate that the wording to the consumer is equivalent to the original wording. Verification of consumer understanding of claims wording falls under the remit of national enforcement, taking into account the context in which the claims are being used and where appropriate linguistic and cultural aspects.

Although no guidance exist on EU level, a number of Member States have developed guidance documents on national level. In addition, a document presenting general principles on flexibility of wording for health claims has been developed by 17 Member States based on an informal meeting in Brussels on 19 June 2012.[25] It is advisable to consult such guidance where available when considering flexibility of wording.

In this context the following principles can be of importance:

- **A claim should be made for the nutrient or substance it is intended for and not for a food as such.**

  The vast majority of approved claims relate to health effects of nutrients or other substances. A claim when used on a food that contains any of these should therefore only refer to the nutrient or other substance and not to the food as such. Statements implying that the food as such has the beneficial effect while in fact it is relevant only for one of its components would be misleading. This would also be the case with statements that imply that the product's '*specific*' formulation is relevant for the claimed effect or that the product has been '*specifically*' developed to achieve a specific effect.

  As an example, the statement 'Product X is a source of Vitamin C and contributes in that way to the normal functioning of the immune system' would be acceptable. The statement '*Product X contributes to the normal functioning of the immune system and is a source of Vitamin C*' would not.

[25] General Principles on Flexibility of Wording for Health Claims. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/156287/health-claims-flexibility-of-wording-principles-UK-19-Dec-2012.pdf.pdf

Stating the nature of the ingredients that characterise the product is obviously accepted in as far as the claimed effect is only linked to the ingredient for which the claim has been approved and not to the others or to the combination of these ingredients.

- **'Contribute' claims should not be presented in absolute ways.**

  Many approved claims relate to the fact that intake of a nutrient or other substance contributes to a physiological function. The terms '*contribute to*' is critical for the context of a specific claim. It inherently indicates that the intake of the nutrient or other substance is a contributing factor but not the only one determining a physiological function. Any alternatives for or flexibility of this kind of wording will need to respect this context. As examples, it would be acceptable to state that the nutrient or other substance plays a role in or supports the physiological function. It is likely not to be considered an appropriate equivalent to state that the nutrient or other substance is necessary or has a particular importance for the physiological effect.

- **'Maintenance' claims should not be presented in a way that they imply improvement of the physiological function.**

  Many approved claims relate to the maintenance of a certain physiological function. The term '*maintenance*' is critical. It indicates that the intake of the nutrient or other substance is beneficial for maintaining specific physiological function. Such claims should therefore not be worded in a way that indicates that the nutrient or other substance improves, strengthens, stimulates or optimizes the physiological effect. This would only be acceptable in cases where a specific claim relating to an increase or decrease of a physiological function or risk factor has been authorised (e.g. lowering of cholesterol).

- **Reference to 'health' should be used with care.**

  Many approved claims relate to the '*normal*' functioning of the body. Member States have discussed if '*normal*' would be equivalent to '*healthy*' and the general consent of these discussions is that it not always is. The appropriateness of replacing the word '*normal*' by '*healthy*' or '*good*' is an appreciation that needs to be considered in relation to the context of individual claims. Food operators should justify the reason in case they refer to '*healthy*' in the context of a specific physiological function.

There are situations where food operators would want to explain a certain health benefit to the consumer or where such explanation is necessary or at least helpful to guide consumer understanding of the health benefit. Such explanations need to be considered with care as they inherently carry the risk that the claim is being portrayed in a way that goes beyond its scope and validity as expressed in the opinion by EFSA.

Referring to statements in the EFSA opinion appears to be a useful and correct way for explaining the broader context of a beneficial effect. However, extracting statements from an EFSA opinion could alter the meaning of the claimed effect. To be acceptable, therefore, food operators should ensure that such statements are correctly presented and remain within the context of the accepted claimed effect. Appreciation of such statements by national enforcement authorities may differ.

- **Statements of fact,** in principle, can be used in as far as they are supported by undisputable scientific evidence and remain within the context of the approved claim. Statements of fact that are not considered health claims are also possible (See section 1.2.3. on statements of fact).

- **Generalisations and extrapolations** are generally not acceptable as they are likely to convey a broader meaning to the beneficial physiological effect of a nutrient or other substance. It would also not be appropriate to extend an accepted health claim with elements that were not part of the assessment. Consulting the EFSA opinion of the claim is a useful tool to ascertain the scope of the accepted health benefit.
- **Focusing on one or more elements or sub-functions** of a health effect is possible on condition that these sub-functions are recognized to belong to the more general health effect and that this is made clear in the wording of the claim. Care should be taken that it is not implied that the intake of the nutrient or other substance is of specific relevance only for these sub-functions (e.g. learning and memory are part of normal psychological functions. It could be considered misleading to state that a nutrient or other substance specifically contributes to normal learning and memory, whereas the approved claim is for contribution to normal psychological functions).
- **Combining the effect of nutrients or other substances** is likely to be considered acceptable in case the nutrients or other substances have a similar or identical health benefit accepted (e.g. Iodine and Magnesium contribute to normal functioning of the nervous system).

  It should not be implied however that the particular combination of these nutrients or other substances has a stronger effect or has particular advantages or characteristics that go beyond the claimed effect of the individual nutrients or other substances as approved.

  The claimed effect should also not be extended to combinations of nutrients or other substances if it has only been accepted for one or a few of the nutrients or other substances mentioned.
- **Medicinal claims remain prohibited.**

  Food operators should be careful that a claim does not refer to the prevention, treatment or cure of a disease. References to disease signs and symptoms and deficiency states must be considered with care as they may be considered as medicinal claims in certain circumstances. In this context in its opinions, EFSA has identified a whole range of health effects that are considered as beneficial physiological effects. Such effects are therefore not considered to be medicinal effects. However, the context of use of these statements will be of importance, as will be the appreciation of national authorities.
- **Not all wordings contained in a submission can be used.** Food operators should be careful that additional wording to explain an authorised claim is appropriate and covered by the assessment of the claim.

  It is obvious that for approved claims, the beneficial physiological effect is contained in the wording of the approved claim. In such cases the EFSA opinion may also contain information as to which wordings of a claimed effect have been considered and which have not because of a variety of reasons (e.g. because they do not present a beneficial effect, because they are formulated in a too general way, etc). These elements need to be considered when using additional wordings to explain accepted claims.

  However, for claims that remain on hold and therefore remain acceptable under the transition period until a decision is taken, the use of correct and appropriate wording is of particular relevance. It should be noted that not all examples of wording contained in the EFSA database for a certain submission that remains on hold would be acceptable.

In some cases the EC and Member States have not followed the recommendation of EFSA for the proposed wording of a claim. This may have been because of consumer understanding or because of sensitivity relating to the use of specific wording. Information as to the reasons for such deviations is not included in the authorising regulation and therefore not obvious in most cases. Nevertheless, food operators should take care to assess consumer understanding and other relevant factors (e.g. whether the claims could be considered as an (implied) medicinal claim relating to the prevention, treatment or cure of a disease).

3.4. References to general, non-specific benefits for health and health-related wellbeing

Reference to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being may only be made if accompanied by a specific approved health claim. [Art 10.3] These are easy, top-line statements conveying more consumer-friendly messages that the approved wording of a claim (e.g. '*for good health*').

Although it is not imposed by the NHCR that the accompanying approved claim must be related, it is nevertheless specified in the 2013 EC guidance that it should bear some relevance to the general reference. Given the often general nature of such statements, various approved health claims could be eligible to accompany it. Food operators therefore should justify the link between the reference to general, non-specific benefits and the specific, accompanying, permitted health claim.

Some claims submitted for authorisation were judged to be too general or non-specific for evaluation by EFSA during their scientific assessment. These claims could not be authorised and are therefore included in the list of the non-authorised claims in the EU Register. This does not exclude that those claims could still be used lawfully as general, non-specific benefits of the nutrient or food for overall good health or health-related well-being when they are accompanied by a specific approved claim.

The location of this accompanying claim is not specified. As in the case of trade marks (see section 3.1. on trade marks) different possibilities exist. The food operator will therefore have to judge on the appropriate location to ensure that the general statement is sufficiently clear not to be misleading for consumers. The EC 2013 guidance indicates that the specific authorised health claim accompanying the statement making reference to general non-specific health benefits, should be made 'next to' or 'following' such statement.

3.5. Recommendations and endorsements

The NHCR accepts recommendations of or endorsements by national associations of medical, nutrition or dietetic professionals and health-related charities under national rules (in compliance with the provisions of the Treaty). [Art 11]

On the other hand, the NHCR explicitly prohibits claims which make reference to recommendations of individual doctors or health professionals and other associations not referred to in Article 11. [Art 12.c]

It is not defined what is covered by recommendations or endorsements, which means that the normal usage of these terms in daily language can be considered: a 'recommendation' is usually understood as "*a suggestion or proposal as to the best course of action, especially one put forward by an authoritative body"* [Oxford Dictionaries online]. This means that such recommendations or endorsements can give a strong signal to consumers on the importance of the food in the daily diet, which clearly falls within a commercial context.

In the vast majority of cases there are no specific national rules. Therefore, such recommendations or endorsements, when they cover health-related organizations or charities and are used in a commercial context (e.g. on product labels or in promotional materials) are likely to be considered as health claims in particular when the name or logo of such associations contains a notion of a nutritional or health benefit for the consumer (e.g. a heart symbol).

Only when the use of an organisation's logo or name is not related to a nutrition or health benefit or is used for a purely non-commercial purpose (e.g for fund raising) its use could be considered to be acceptable. Food operators should therefore make clear what the intention of the use of such endorsements or recommendations is and have such information available in case they would be challenged.

Although Article 11 only refers to national associations, enforcement authorities may also include supra-national and international associations given that the NHCR seeks to harmonise rules throughout the EU.

It can also safely be assumed that the intention of the NHCR is not to restrict, limit or curtail information that can be given by health care professionals in the context of their normal professional activities. Individual doctors may obviously continue to recommend the use of products to patients. Dieticians can obviously advise people on the nutritional and health properties of foods and diets. These would be considered as non-commercial communications.

However, information provided as part of presentations and public appearances could be considered as commercial communications in certain situations. In this respect the context, the audience and the intention of the messages is important.

- If such messages are given as part of a commercial event or sponsored by a food operator, they would likely be considered as commercial communications and thus as requiring conformity with the NHCR rules. However, if this were undertaken privately and independently from the company concerned, it may not be considered as a commercial communication.
- If such messages are destined for an audience of the general public, they are more likely to be considered as commercial communications than when they are destined for a professional audience. However, communication to the general public can also be undertaken as private initiatives and independently of the companies concerned.
- If the intention of the messages is to promote the purchase of specific products, directly or indirectly, they are likely to be considered commercial communication. If, however, the messages are intended to provide objective information on the nutritional or health benefits of foods, they may be considered as non-commercial.

If food operators are involved in such events, whether as sponsor, exhibitor or presenter, justification of the commercial or non-commercial nature of the event and appropriateness of the messages given should be considered.

A specific case of endorsement or recommendations by individual health professionals is presented when the seller of a product is a health care professional, such as is the case with a pharmacist in a pharmacy. In principle, sellers are considered as food business operators and responsible for the information within the context of the businesses under their control. [Art 8.5 of Reg 1169/2011]

This implies that they have to apply and abide by the requirements of the NHCR relating to authorised or rejected claims to promote products to consumers. In the case that the seller is a health care professional, however, the prohibition of art 12.c does not mean that they would not be entitled to recommend any product to a consumer. Art 12.c envisages only the prohibition of claims which make reference to recommendations of individual doctors or health professionals, not the recommendation or endorsement itself.

Endorsements or recommendations by other persons than health care professionals (e.g. celebrities) in commercial communications are obviously allowed. If such endorsement or recommendations cover nutrition or health benefits, these will need to be in compliance with the rules of the NHCR (i.e. approved and used in conformity with the conditions of use).

Testimonials, meaning statements by consumers on their experiences with a certain product, are likely to be considered as commercial communications when used in the presentation and/or advertising of a food destined to be delivered as such to the final consumer. In this context any statement that can be considered as a nutrition or health benefit should be in conformity with the NHCR.

As claims which make reference to the rate or amount of weight loss are specifically prohibited, testimonials of consumers referring to their weight loss, including '*before and after*' pictures that state or imply a rate or amount of weights loss when this is associated with specific foods or diets would be considered to fall under this prohibition. Such presentation may still be permissible however if it relates to other mechanisms of weight reduction than diet (e.g. physical activity as part of a slimming program).

The NHCR is not intended to cover official recommendations by public health authorities and bodies. [Recital 4] It would therefore appear permissible to refer to such recommendations provided they are correct, relevant for the product and not misleading in the context in which they are used. Any accompanying information on the benefit of specific nutrients or other substances for health would however be considered as health claims and need to be approved under the NHCR.

3.6. Claims relating to products intended for children

In its December 2007 guidance the EC has explained which claims will be considered as claims referring to children's development and health and as a consequence need to be specifically approved before they can be used (Article 14 claims).

The guidance explains that the term '*children*' is not defined in the NHCR and should be understood as reaching the end of the growth period, with an indicative age limit of 18 years. It should be noted that the guidance also states that this indication does not intend to define children in the frame of the NHCR.

Infants and young children are considered as sub groups of children, with the following definitions (drawn from Directive 2006/141/EC):

- '*infants*' means children under the age of 12 months;
- '*young children*' means children aged between one and three years;

The guidance explains that the following claims should be considered as Article 14 claims:

- Health claims solely referring to the development and health of children, and where the scientific substantiation is only valid for children. In this case, the scientific substantiation consists of data obtained on studies conducted with children.

  Example: '*calcium is good for children's growth*'
- Health claims used on products intended exclusively to children, like follow on formulae, processed cereal-based foods and baby foods, as defined by Directive 2006/141/EC and Directive 2006/125/EC.

The guidance also explains that the following claims are not to be considered as Article 14 claims, but as Article 13 claims:

- Claims referring to the role of a nutrient or other substance in growth, development and to the functions of the body where the scientific substantiation covers the entire life span, or more than the children population group. In this case, applications, EFSA opinions and conditions for the use of the claim should specify precisely the consumer group for which the claim is scientifically substantiated and valid.

  Example: for the reference '*for children and pregnant women*', an Article 13 claim is only possible if the scientific substantiation covers the children population group as well as the pregnant women population group.

This classification is therefore performed mainly on the basis of the scientific evidence submitted for the substantiation of the claims.

As the NHCR covers claims and not products, any approved claim can therefore be used on any product unless the conditions of use specify otherwise. However, care should be taken, when using claims that are

valid for the general population but are provided on products that are aimed principally at children, that the claim remains within the remit of authorised claims and is not presented as of specific importance for children only. It is up to the food operator to justify the use of a claim with the necessary documentation. [Art 6.2]

3.7. Restrictions for the use of claims on particular products

In a few cases the use of a claim is restricted to specific categories of foods as specified in the conditions of use. Using such a claim for another category is therefore not allowed. Companies should have the necessary arguments at hand to justify that the product concerned belongs to the category of products for which these claims are allowed.

Nutrient profiles may be set to govern the use of nutrition and health claims on foods and determine which foods will be allowed and which foods not to use nutrition and health claims based on their composition in terms of fat, sugar and salt. The reason is that foods promoted with claims may be perceived by consumers as having a nutritional, physiological or other health advantage over similar or other products to which such nutrients or other substances are not added. This might encourage consumers to make choices, which directly influence their total intake of individual nutrients or other substances in a way which would run counter to scientific advice. To address this potential undesirable effect, the concept of nutrient profiles is foreseen to limit the use of claims to products that from a nutritional point of view meet certain criteria relating to their content in certain components as salt, fat and sugar. [Recitals 10-12, Art 4]

Until nutrient profiles are established, claims remain possible on all foodstuffs (except alcoholic beverages) as long as the conditions of use of the specific claims are respected. [Art 4]

In addition, food operators should verify that the overall composition of their product would be valid for a specific claim to be truthful. In case other components of a food are known to affect a physiological effect or risk factor in a negative way, such products should not use claims implying a positive effect on these functions or risk factors.

Claims approval is generic. This means that all food operators can use the claim for their products in accordance with the conditions of use. However, some claims may be approved with protection of proprietary data. Although only the data is protected, this means in practice that the claim can only be used by the original applicant which is the owner of the protected data. Decisions to allow such claims are addressed to this applicant, so other food operators are not allowed to use this claim unless they obtain an approval based on an application that does not contain the protected data.

The owner of the data can obviously grant permission or license to other operators to use its approved claim. This is likely to be under the form of a contractual agreement.

3.8. Claims that remain on hold

The first Regulation authorising article 13 claims was published on 25 May 2012 [Reg 432/2012].[26] At that moment the claims that had not been approved were included in the Register of rejected claims. Those did not include all article 13 claims. A number of claims had been put on hold pending a decision during the process of the implementation of the NHCR. These covered a number of claims where specific concerns had been raised and claims relating to botanicals. On 12 June 2013 a second Regulation was published extending the list with a further 6 authorised claims [Reg 536/2013].[27] At that moment another batch of rejected claims was added to the register of rejected claims, including a number of claims relating to beauty and probiotics. The use of these claims remains possible until 2 January 2014. This is indicated in the Community Register of Claims.

Claims still on hold at that moment included claims for the following categories:

- Plant, herbal or botanical substances
- Foods for use in very low calorie diets
- Foods with reduced lactose content
- Caffeine
- Carbohydrates

The use of these claims remains possible, provided they comply with the general requirements of the NHCR and existing national provisions applicable to them, until a final decision will be taken, even in those cases where EFSA has delivered a negative opinion.

It is noted that only the claims for which a submission was made and have subsequently been put on hold benefit from this possibility. All other claims, including claims for botanicals that have never been submitted and claims that are not on the on hold list, are prohibited.

The list of claims that are on hold, as identified by their ID number, is published on the website of the EC.[28] Full information on the content of these submissions can be found in the EFSA database of claims.[29]

As noted before, most of the claims relating to botanicals that have been put on hold, have not been assessed. No information is therefore available as to the acceptability and correctness of the claims and the examples of wording submitted. Some of these wordings may be medicinal; other wordings may not refer to beneficial effects. In order to judge that a specific wording complies with the criteria of the NHCR, consulting other EFSA opinions can be useful. In particular EFSA has identified many physiological functions that are considered to be beneficial. These can be used, provided evidence is at hand that these effects are pertinent for the substances under consideration. Evidence from scientific and traditional sources is acceptable for this purpose during the period the claim remains on hold. It falls onto the food operator to assess these submissions and to justify any claim made. [Art 6.2]

[26] Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health. Official Journal of the European Community L136/1, 25 May 2012

[27] Commission Regulation (EU) No 536/2013 of 11 June 2013 amending Regulation (EU) No 432/2012 establishing a list of permitted health claims made on foods other than those referring to the reduction of disease risk and to children's development and health. Official Journal of the European Community L160/4, 12 June 2013

[28] http://ec.europa.eu/nuhclaims/

[29] http://www.efsa.europa.eu/en/topics/topic/article13.htm

4. General Conditions for the use of nutrition and health claims

4.1. How to use the EU Register of accepted and rejected claims

The most direct way to know what claim is appropriate for a certain product or food ingredient is to consult the EU Register of accepted and rejected claims. This register contains the accepted nutrition and health claims and their conditions of use. Using such a claim under the conditions of use specified would constitute conformity with the NHCR.

Food operators should note that it is not allowed to use a claim that has been approved on the basis of proprietary data protection, unless an agreement exist between the applicant to whom the authorisation is addressed and the food operator wanting to use the claim. Whether a claim has been accepted on the basis of proprietary data is not immediately apparent from its entry in the EU Register. This should be considered by consulting the legal text authorising the claim.

The disclaimer to the Register specifies that some flexibility of wording of the claim is possible provided its aim is to help consumer understanding taking into account factors such as linguistic and cultural variation and the target population. Adapted wording must have the same meaning for the consumer as the authorised claim in the EU Register. For further information how to apply this, see section 3.3. on flexibility of the wording.

Claims that are not authorised and listed in the EU Register should as a principle not be used. However, the EU Register of rejected claims is for information purposes only. Following the assessments of EFSA there have been several reasons why a certain claim did not receive a positive opinion. A distinction can be made between claims for which the scientific justification has been assessed and those that have been rejected because the submission did not fit the format and requirements of the process without the scientific evidence having been revised. The nature of the rejection is listed in the entry in the EU register.

Some claims have been listed in the rejected register because they concern claims that are worded in a general unspecific way preventing EFSA from characterising the claimed effect. For these claims the relationship is indicated as '*not validated*' in the EU Register. In these cases the use of such claims could still be possible provided they can be considered as references to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being. Such claims can be made if they are accompanied by an approved health claim (not a nutrition claim) listed in the EU Register.

It is noted that the scope of the wording of certain claims is quite broad and may overlap with claims that have been specifically approved or claims that are still on hold. In such cases it is still possible to use the claim provided that it corresponds with the conditions of use of either the accepted claim or the claim that is still on hold.

The claims that are on hold are not listed in the Register but in separate documents on the same EC webpage. They are only indicated with their ID number, so all details must be retrieved from the EFSA database. Such claims can continue to be made in conformity with national legislation applicable, until a final decision is taken.

It should however be noted that this possibility only exists for the claims that are on hold and under the conditions specified in these submissions. In addition not all proposed wordings would seem to be acceptable. See section 3.7. on hold claims for further information.

Member States may have specific national rules relating to the use of other substances. This may be under the form of positive and negative lists, specific legislation or administrative practice. These rules are in principle not affected by the NHCR. If a claim is approved for a certain substance, Member States may still apply national restrictions or prohibitions or consider that the use of a certain substance is restricted to medicinal products. It is strongly recommended to verify national regulations relating to the use of other substances in foods and food supplements, even in case a health claim has been approved. Mutual recognition in accordance with Regulation 764/2008 does not apply to the use of nutrition and health claims as this area is fully harmonized.[30] However it does apply to national rules and practices relating to the use of other substances. More information on the application of mutual recognition in relation to food supplements can be found in EC guidance.[31]

4.2. General conditions for the use of nutrition and health claims

When making nutrition or health claims, food operators not only need to select an approved claim from the EU Register of claims and apply the specific conditions of use for these claims, they will also need to comply with the general requirements for the use of claims and apply any relevant additional labelling requirements. [Art 5, 7, 10]

4.2.1. Basis for using nutrition and health claims

Principle 1: Nutrition and health claims shall refer to the food ready for consumption in accordance with the manufacturer's instructions. [Art 5.3] In most cases this is obvious, as many foods are pre-packed ready for consumption without further handling or preparation required.

However, in some cases it may not be straightforward to assess if a food is ready for consumption or not. A dehydrated soup powder obviously is not, as water needs to be added before it is consumed. A breakfast cereal however is often recommended for consumption with added milk, but it can also be eaten as such. Rice is usually not consumed as such but cooked before consumption. However, as such, rice is fit for human consumption and it can also be prepared with milk. Flour also is not usually eaten as such but used for the manufacture of a variety of foodstuffs and bakery wares, according to various recipes. Nevertheless the product as such is fit for human consumption and it would be impossible to accommodate the conditions of use of a claim to all the various uses imaginable.

It is clear therefore that in some cases a pragmatic approach must be taken and that the basis for use will need to be justified by the food operator.

As a rule of thumb, where products are not consumed as such and where there is a clear and unique instruction included in the labelling of the product on how to reconstitute or prepare it, nutrition and health claims should relate to the reconstituted or prepared state.

[30] Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC. Official Journal of the European Union: L218/21 13 August 2008

[31] EC Guidance document: The application of the Mutual Recognition Regulation to food supplements. 2 October 2010. http://ec.europa.eu/enterprise/policies/single-market-goods/files/mutual-recognition/food-supplements/food-supplements_en.pdf

Products that can be consumed as such, despite a recommendation to consume them with other foods or beverages, should carry nutrition and health claims that relate to the product as such.

Claims on products that are not eaten as such but are used as ingredient in other foods should be considered case by case. The nutrition and health claim must be relevant to the consumer. Therefore a significant quantity must be available in the final food as consumed. If this can be guaranteed for the quantity of the food that is usually incorporated into recipes, taking into consideration the number of portions in the recipe, it would seem acceptable to express nutrition and health claims on the product as such. The portion that would contain a significant quantity should be determined with care and justified.

Finally, foods may lose or gain weight during preparation. Weight loss can be caused by the removal of inedible parts (e.g. cleaning of vegetable) or evaporation of water during frying or baking (e.g. meat, bread). Weight gain can be the result of absorption of water or fat during preparation (e.g. rice, fries). Furthermore during processing nutrients and other substances can be lost in cooking liquids or destroyed by heating or other processing. These factors are in general unpredictable. The nutrition labelling rules do not consider such factors. They specify that nutrition labelling shall refer to 100 g or 100 ml amounts (and, if appropriate, additional portion-based declarations are accepted). [Art 32.2 of Reg 1169/2011] It also specifies that the energy value and the amounts of nutrients shall be those of the food as sold. However, where appropriate, the information may relate to the food after preparation, provided that sufficiently detailed preparation instructions are given and the information relates to the food as prepared for consumption. [Art 31.3 of Reg 1169/2011] As nutrition labelling is obligatory in case a claim is made and the conditions of use of many nutrition claims refer to nutritional labelling legislation where a significant quantity is specified, it seems acceptable and logical from consumer understanding and enforcement control point of view to apply the same basis for both nutrition labelling as for the use of nutrition and health claims. Nevertheless, if there are reasons to suspect that the food matrix or the processing will influence significantly and in a systematic way the content and/or availability of the food component that is the subject of the claim, the food operator should adjust the conditions of use to account for this and ensure that the quantity of the substance that is required for the beneficial effect is valid.

In all cases justification of the choice made by the food operator should be available.

The application of tolerances for deviations from the declared label values, applying also to the conditions of use of nutrition and health claims is subject to a specific guidance document developed by the European Commission.[32]

4.2.2. Beneficial effect required

Principle 2: the presence, absence or reduced content in a food or category of food of a nutrient or other substance in respect of which the claim is made must have been shown to have a beneficial nutritional or physiological effect, as established by generally accepted scientific evidence. [Art 5.1.a]

As the legislation specifies that no nutrition or health claim can be used unless it has been authorised, the only way of demonstrating that this principle is met is to revert to an approved nutrition or health claim listed in the EU Register. In some cases the flexibility in the wording of a claim allows to deviate from the wording as specified, but still the claim must retain the same meaning (See section 3.3. on flexibility of wording).

[32] Guidance document for competent authorities for the control of compliance with EU legislation […] with regard to the setting of tolerances for nutrient values declared on a label. http://ec.europa.eu/food/food/labellingnutrition/supplements/documents/guidance_tolerances_1212_en.pdf

This is not the case for trade marks, brand names or fancy names and for references to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being as these are exempted from the authorisation requirements. However, when such statements are accompanied by a (related) health claim, this accompanying claim will justify that the claimed effect is beneficial.

This is also not the case for '*contains*' nutrition claims. From the definition of a nutrition claim and Article 5.1.a is appears that it is only possible to use a contains statement as a nutrition claim in relation to nutrients or substances for which a beneficial effect has been demonstrated as established by generally accepted scientific evidence. Some have therefore concluded that such a 'contains' nutrition claim is only possible for nutrients or substances for which at least one health claim has been approved. The EFSA assessment would constitute proof that the nutrient or substance has a beneficial nutritional or beneficial effect. This may however not be correct application of the NHCR in terms of proportionality.

As nutrition claims are not health claims and the NHCR does not require approval of a health claim as a condition for the use of a 'contains' nutrition claim, it can be deduced that 'contains' claims would also be acceptable for nutrients or substances for which no health claim has been explicitly approved. In that case the food operator would be responsible to have verifiable information available to demonstrate that the substances have a beneficial nutritional or physiological effect for the conditions of use proposed. It is noted that this could be challenging in case EFSA has delivered a negative opinion relating to a health benefit for a certain food compound. It is obvious that any further information about health effects should be explicitly approved as a health claim.

It is also possible that a '*contains*' statement is not a nutrition claim in case such statement is made in the context of indicating that the product contains an ingredient. Obviously if the subject of such a claim is a nutrient (vitamin or mineral) or when it is accompanied by a qualifier as to a nutritional or physiological effect, it is likely to be considered as a nutrition claim and not as a 'contains' statement.

In addition, it is legally imposed upon food supplements to indicate in the labelling the names of the categories of nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances. [Art 6.3.a of Dir 2002/46] Such statements therefore obviously fall outside the scope of the NHCR (See section 1.3.6. on Information that is mandatory by EU or national legislation for further information).

4.2.3. Significant quantity

Principle 3: the nutrient or other substance for which the claim is made:

- (i) is contained in the final product in a significant quantity a defined in Community legislation or, where such rules do not exist, in a quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence; or
- (ii) is not present or is present in a reduced quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence. [Art 5.1.b]

What constitutes a significant quantity is in most cases included in the conditions of use of nutrition and health claims contained in the EU Register. Annex 2 of this guidance gives an overview of the quantities needed for making '*source of*' and '*rich in*' claims. Following these requirements will result in conformity with these provisions in the vast majority of cases.

However, given the wide variety of foods on the market, there may be situations where the conditions of use are being complied with as specified in the authorisation but where the resulting intake could still be challenged as insignificant.

This is clearly the case for many nutrition claims made for food supplements. Given that food supplements are concentrated sources of nutrients or other substances, the quantity ingested per day (expressed as weight) is only a few grams. For most nutrients the conditions of use specify 15% of the Nutrient Reference Value (NRV) as a sufficient quantity per 100 g or 100 ml. 15% of the NRV per 100 g for a food supplement could result in insignificant quantities ingested per day. This would literally be in conformity with the conditions of use of the claim, but not with Art 5.1.b. and 5.1.d which impose that the substance is contained in the final product in a significant quantity and that the quantity of the product that can reasonably be expected to be consumed provides a significant quantity of the substance that will produce the nutritional or physiological effect claimed.

It is therefore recommended practice for food supplements to consider the minimum quantity per portion of the product as recommended for daily consumption in the labelling rather than per 100 g or 100 ml.

In some cases the food operator is presented with a choice, either expressed per 100 g or 100 ml or 100 kcal. It falls upon the food operator to choose the most appropriate value and justify this for the product under consideration.

In the case of beverages, the significant quantity has been reduced to 7.5% of NRV by virtue of the new Food Information to Consumer Legislation. [Annex XII Part A.2 of Reg 1169/2011] This value seems now acceptable to define a significant quantity for the purpose of applying conditions of use for nutrition and health claims. It should however be noted that also in this case 7.5% should result in a significant quantity. This is likely to be the case for beverages that are taken in substantial quantities, like milk, juice or drinks. This is less likely for other products that are presented in liquid form but of which only limited quantities are used as a portion, such as drink yoghurt, oil or dressing or food supplements supplied in a liquid form.

It is noted that beverages containing more than 1,2 % by volume of alcohol are not allowed to bear any health claim and can only make nutrition claims referring to low alcohol levels or to the reduction of the alcohol or energy content. [Art 4.3] In this context, food supplements presented in a liquid form and containing more than 1,2 % by volume of alcohol are not considered as beverages under the NHCR. [Recital 13]

It is possible that a target group differs from the general population in terms of its nutritional needs (e.g. children, pregnant women, lactating women, groups with particular nutritional requirements, etc). In such cases the use of the conditions of use may result in inappropriate values that are either above the recommended levels or insufficiently significant. Also in those cases the choice of the significant quantity falls upon the food operator and would need to be justified by generally accepted scientific evidence.

For PARNUTS foods such deviations from the conditions of use can be justified on the basis of the basic principle that the NHCR applies without prejudice to PARNUT legislation. [Art 1.5] This would justify that the values included in the NHCR for the normal adult population are overruled by the specific ones of the PARNUT legislation. In addition, for nutrition and health claims, not only the conditions of use of the approved claims apply but also the general requirements of the NHCR. [Art 5] This means that the presence, absence or reduced content in a food or category of food of a nutrient or other substance in respect of which the claim is made has been shown to have a beneficial nutritional or physiological effect, as established by generally accepted scientific evidence and that the nutrient or other substance for which the claim is made is contained in the final product in a significant quantity as defined in Community legislation or, where such rules do not exist, in a quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence. These articles could justify the use of the specific NRV's for children and other groups of people with particular nutritional needs.

In the case of '*contains*' nutrition claims for nutrients, the same condition of use as for '*source* of' nutrition claim applies. However, for many other substances no daily recommended intake levels are established. In such cases the definition of a significant quantity falls upon the responsibility of the food operator that will need to define such a quantity on the basis of scientific knowledge and likely intake in the daily diet from other sources. The beneficial effect that is required for such a claim to be acceptable may determine what is a significant quantity. Justification should be at hand for enforcement authorities.

4.2.4. Availability

Principe 4: where applicable, the nutrient or other substance for which the claim is made must be in a form that is available to be used by the body. [Art 5.1.c]

This refers to the fact that intake of the nutrient or other substance is indeed capable of resulting in the claimed nutritional or physiological effect. Such availability may refer to bioavailability, meaning digestion and absorption. It may also refer to availability for the claimed effect in case the substances would not be digested or absorbed (e.g. substances that act in the gastro-intestinal tract).

Such availability is not only related to the nature of the substance (e.g. chemical form of a nutrient), but can also be affected by the matrix of the food it is used in and the processing or treatment of the food by food procession, storage or preparation by food operators or at home. A claim valid for a substance in a food would obviously lose its effect if processing destroys the substance.

The NHCR does not require the systematic verification of bioavailability. For nutrients that are included in permitted lists for use in foods [Annex II of Reg 1925/2006], food supplements [Annex II of Dir 2002/46] or dietetic foods [Reg 953/2009], it can generally be assumed that bioavailability has already been assessed as sufficient. When using such substances, food operators would not generally be expected to carry out additional tests unless they have reasons to believe that the product matrix or its processing would affect bioavailability.

For substances that are not subject to such lists, availability should be ascertained on the basis of available knowledge. Depending on the nature of information available, food operators should carry out case by case further testing if they have reasons to suspect that that the product matrix or its processing may indeed affect the availability of the substance and therefore the claimed effect.

It may be helpful to consult the relevant EFSA opinions to see how the food or food component was characterised and if factors have been highlighted that might affect the claimed effect. In principle for accepted claims used for the substance as characterised bioavailability can be assumed on the basis of the positive EFSA opinion unless there is knowledge that the specific formulation or processing of the food is likely to affect availability of the substances.

4.2.5. Quantity that can reasonably be ingested

Principle 5: the quantity of the product that can reasonably be expected to be consumed must provide a significant quantity of the nutrient or other substance to which the claim relates, as defined in Community legislation or, where such rules do not exist, a significant quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence. [Art 5.1.d]

This principle complements principle 2 above and covers situations where a certain (daily) intake of a nutrient or other substance is required for the beneficial effect.

In cases where the conditions of use for a claim specify the minimum quantity of the nutrient or substance in the food, it should be assessed if this is sufficient to satisfy this requirement. The quantity must indeed be significant in relation to the claimed effect (See section 4.2.3. on significant quantity).

In addition, food operators will need to consider if the claimed effect as communicated is valid within the diet of the consumer. If the food contains only part of what is needed, but it is reasonable to assume that consumers will obtain sufficient intake also through other sources in the diet, as such or by specific selection of particular foodstuffs, this would sufficiently cover the requirement of significant amount. However, if the food can be considered to be the only source of the nutrient or substance, the full amount needed for the claimed effect would need to be present. This is an assessment that needs to be performed case by case by the food operator and in as far as not specified in the conditions of use of the claim, sufficient justification should be available.

If the full amount for the claimed effect to be valid needs to be contained in a product, the number of servings required to be consumed must be reasonable and realistic.

4.3. Mandatory and additional labelling requirements

When making nutrition or health claims, food operators need to apply also a number of relevant additional labelling requirements.

4.3.1. Full nutrition labelling

Full nutrition labeling is required in all cases where a nutrition and health claim is made. It must be complemented with an indication of the quantity of the nutrients or other substances for which the claim is being made.

Nutrition labelling needs to be in conformity, for all foods except food supplements with the requirements of nutrition labelling as specified in the Food Information Regulation [Art 29-35 of Reg 1169/2011] or until the end of the transition period (13 December 2016) with the older rules specified in Directive 90/496/EEC.[33]

For food supplements the requirements of Directive 2002/46 apply. [Art 8.2 of Dir 2002/46]

4.3.2. Mandatory additional labelling

The following information must be presented in the labelling, and in case no labelling exists in the presentation and advertising of the food, including food supplements [In accordance with the 2013 Commission guidelines on the implementation of Article 10]:

- *A statement indicating the importance of a varied and balanced diet and a healthy lifestyle.* [Art 10.2.a]

  It is noted that for food supplements, it is obligatory also to indicate that food supplements should not be used as a substitute for a varied diet. [Art 6.3.d of Dir 2002/46] Both statements are not equivalent but can be combined into one statement.

- *The quantity of the food and pattern of consumption required to obtain the claimed beneficial effect.* [Art 10.2.b]

  The EC guidance specifies that food operators should provide the necessary information, based on the composition of the food, to ensure it can deliver the claimed effect. This should include information on how much of a food is required and how this should be eaten over the day, even in cases where such information is not explicitly required by the conditions of use of the claim. If not obvious from the context in which foods are used, information should be provided on whether the claimed effect can be achieved by one serving of the food, or if several portions need to be consumed over the course of the day. The quantity of the food needed to achieve the claimed effect must be reasonable and not encourage or condone excess consumption. [Art 3.c and 5.d]

  In the case of Food Supplements, the indication of the amounts of the nutrients or other substances declared and the portion of the product as recommended for daily consumption in the labelling is already mandatory. This would in principle be sufficient as information provided no additional labelling requirements are specified in the conditions of use of the claim under consideration.

- *Where appropriate, a statement addressed to persons who should avoid using the food.* [Art 10.2.c]

[33] Council Directive 90/496/EEC of 24 September 1990 on Nutrition labelling for foodstuffs. Official Journal of the European Union: L276/40 6 October 1990

- *An appropriate warning for products that are likely to present a health risk if consumed to excess.* [Art 10.2.d]
- *For reduction of disease risk claims: a statement indicating that the disease to which the claim is referring has multiple risk factors and that altering one of these risk factors may or may not have a beneficial effect.* [Art 14.2]

Nutrition labelling and the above labelling requirements only need to be presented in the labelling of the product, not in the presentation or advertising, unless no labelling exists.

4.3.3. General labelling requirements

The general prohibitions contained in food information to consumers legislation, remain applicable to foods making nutrition and health claims, including food supplements: [Art 7.1 of Reg 1169/2011]

- Food information shall not be misleading, particularly:
  - As to the characteristics of the food and, in particular, as to its nature, identity, properties, composition, quantity, durability, country of origin or place of provenance, method of manufacture or production.
  - By attributing to the food effects or properties which it does not possess.
  - By suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics, in particular by specifically emphasising the presence or absence of certain ingredients and/or nutrients.
  - By suggesting, by means of the appearance, the description or pictorial representations, the presence of a particular food or an ingredient, while in reality a component naturally present or an ingredient normally used in that food has been substituted with a different component or a different ingredient.
- Food information shall not attribute to any food the property of preventing, treating or curing a human disease, nor refer to such properties. [Art 7.3 of Reg 1169/2011]

  It is noted however that the possibility to use approved reduction of disease risk claims is permitted as a derogation to this general provision. [Art 14.1]

In addition, the NHCR also specifies that the use of nutrition and health claims shall not:

- Be false, ambiguous or misleading. [Art 3.a]
- Give rise to doubt about the safety and/or the nutritional adequacy of other foods. [Art 3.b]
- Encourage or condone excess consumption of a food. [Art 3.c]
- State, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general. [Art 3.d]

  In this context it would not be acceptable to refer to deficiency states or to nutrients for which sufficient quantities cannot be provided by a balanced and varied diet. Such statements would

be acceptable only when specifically authorised. Reference to official dietary guidelines and recommendations by government bodies would however be permissible.

- Refer to changes in bodily functions, which could give rise to or exploit fear in the consumer, either textually or through pictorial, graphic or symbolic representations. [Art 3.e]

Enforcement authorities are seen to apply the above principles in a rather restrictive way. The wording of claims should therefore be checked against these principles to ascertain they are in conformity with the intention of this provision.

4.4. Consumer understanding

The NHCR puts emphasis on the requirements that nutrition and health claims should be understood by consumers. It is specified that in the context of Directive 84/450/EEC 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, the NHCR takes as a benchmark the average consumer, who is reasonably well-informed and reasonably 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. [Recital 16]

Whether specific wordings of nutrition and health claims would be understood correctly by the average consumer is an assessment that needs to be part of the elements to be considered when making nutrition and health claims. If the approved wording of a claim is used, this requirement is likely to be covered. When deviating from this wording, consumer understanding will need to be considered case by case. Improving consumer understanding may also require more information on a specific nutrition or health claim to be presented. In such cases this explanation must be considered in the context of the claim and not go beyond the meaning of the wording that was approved.

Consumer testing conducted by food operators appear to be useful tools to collect consumer understanding, to help clarify some claim wording. However this is not a systematic requirement. If the claim is used as proposed in the approval and keeps the same meaning, consumer understanding can be assumed to be fulfilled.

Annexes

A.1. Overview of texts of relevance to the Nutrition and Health Claims Regulation

A.1.1. European Commission Register of Claims

- EU Register of Nutrition and Health Claims Made on Foods.
  http://ec.europa.eu/nuhclaims/

A.1.2. Legal texts

- Corrigendum to Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. Official Journal of the European Union: L12/3, 18 January 2007
- Regulation (EC) no 107/2008 of the European Parliament and of the Council of 15 January 2008 amending Regulation (EC) No 1924/2006 on nutrition and health claims made on foods as regards the implementing powers conferred on the Commission. Official Journal of the European Union: L39/8, 13 February 2008
- Regulation (EC) no 109/2008 of the European Parliament and of the Council of 15 January 2008 amending Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. Official Journal of the European Union: L39/14, 13 February 2008.
- Commission Regulation (EU) No 116/2010 of 9 February 2010 amending Regulation (EC) No 1924/2006 of the European Parliament and of the Council with regard to the list of nutrition claims. Official Journal of the European Union: L37/16, 10 February 2010
- Commission Regulation (EU) No 1047/2012 of 8 November 2012 amending Regulation (EC) No 1924/2006 with regard to the list of nutrition claims. Official Journal of the European Union: L310/36, 9 November 2012
- Commission Regulation (EC) No 353/2008 of 18 April 2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council. Official Journal of the European Union L109/11 19 April 2008
- Commission Regulation (EC) No 1169/2009 of 30 November 2009 amending Regulation (EC) No 353/2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council. Official Journal of the European Union L314/34, 1 December 2009.
- Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health. Official Journal of the European Community L136/1, 25 May 2012
- Commission Implementing Decision of 24 January 2013 adopting guidelines for the implementation of specific conditions for health claims laid down in Article 10 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council. Official Journal of the European Union: L22/25, 25 January 2013.
- Commission Regulation (EU) No 536/2013 of 11 June 2013 amending Regulation (EU) No 432/2012 establishing a list of permitted health claims made on foods other than those referring to the reduction of disease risk and to children's development and health. Official Journal of the European Community L160/4, 12 June 2013

A.1.3. Court Judgments

- Judgment of the Court (Third Chamber) of 6 September 2012. Case C-544/10. Deutsches Weintor eG v Land Rheinland-Pfalz,

A.1.4. Guidance documents

- Guidance on the implementation of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. Conclusions of the Standing Committee on the food chain and animal health. 14 December 2007.
  http://ec.europa.eu/food/food/labellingnutrition/claims/guidance_claim_14-12-07.pdf
- UK Department of Health. Nutrition and health claims: Guidance to compliance with Regulation (EC) 1924/2006 on nutrition and health claims made on foods. Version 2, November 2011.
  http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_131531.pdf
- UK Department of Health. Quick start guide to guidance on compliance with Regulation (EC) No. 1924/2006 on nutrition and health claims made on foods.
  http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_131237.pdf
- Swedish Food Administration. Näringspåståenden och hälsopåståenden om livsmedel Förordning (EG) nr 1924/2006 5 November 2009.
  http://www.slv.se/upload/dokument/livsmedelsforetag/vagledningar/vagledning_narings-_och_halsopastaenden.pdf
- EVIRA (Finnish Food Safety Authority). Nutrition and Health Claim Guide for food supervisors and food business operators. EVIRA Guideline 17052/1/en
  http://www.evira.fi/files/products/1336454639046_evira_guideline_17052_1_en.pdf
- Belgian Authorities (Food Safety Agency/Federal Public Service Health/Federal Public Service Economy). Lignes directrices concernant la flexibilité du libellé des allégations de Santé. Version Octobre 2012.
  http://www.health.belgium.be/filestore/19081203_FR/Guidelines%20wording%20flexibility%20claims%202012-10%20-%20FR.pdf
- General Principles on Flexibility of Wording for Health Claims. Non-official guidance resulting from an informal meeting in Brussels on 19 June 2012 with experts from 17 Member States to discuss a common approach to advising food business operators about flexibility of wording for health claims.
  https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/156287/health-claims-flexibility-of-wording-principles-UK-19-Dec-2012.pdf.pdf
- Guidance document for competent authorities for the control of compliance with EU legislation on Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 and Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling of foodstuffs and Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements with regard to the setting of tolerances for nutrient values declared on a label.
  http://ec.europa.eu/food/food/labellingnutrition/supplements/documents/guidance_tolerances_1212_en.pdf

A.1.5. Guidance documents from EFSA

- EFSA. Frequently Asked Questions (FAQ) related to the assessment of Article 14 and 13.5 health claims applications on request of EFSA. EFSA Journal 2009;7(9):1339. http://www.efsa.europa.eu/en/efsajournal/doc/1339.pdf
- EFSA. Pre-submission Guidance for applicants intending to submit applications for authorisation of health claims made on foods. 14 March 2007. Last updated (Rev.): 21 December 2007. http://www.efsa.europa.eu/en/ndaguidance/docs/ndapresubmissionguidance.pdf
- EFSA. Scientific and technical guidance for the preparation and presentation of the application for authorisation of a health claim (Revision 1). Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies. Adopted on 6 July 2007. Revision on request from EFSA, Question No EFSA-Q-2011-00215, adopted on 13 May 2011. EFSA Journal 2011;9(5):2170. http://www.efsa.europa.eu/en/efsajournal/doc/2170.pdf
- EFSA. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. EFSA Journal 2011;9(4):2135. http://www.efsa.europa.eu/en/efsajournal/doc/2135.pdf
- EFSA. Templates for claims submissions downloadable from http://www.efsa.europa.eu/en/nda/ndaguidelines.htm
- EFSA. Briefing document for Member States and European Commission on the evaluation of Article 13.1 health claims. Technical report. EFSA Journal 2009; 7(11):1386. http://www.efsa.europa.eu/en/efsajournal/doc/1386.pdf
- Article 13 Terms of Reference. European Commission request to the European Food Safety Authority for scientific advice on: the Community list of permitted health claims pursuant Article 13 of Regulation 1924/2006 on nutrition and health claims made on foods. http://www.efsa.europa.eu/en/ndaclaims13/docs/ndaart13tor.pdf
- Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies. The setting of nutrient profiles for foods bearing nutrition and health claims pursuant to Article 4 of the Regulation (EC) No 1924/2006. The EFSA Journal (2008) 644, 1-44. http://www.efsa.europa.eu/fr/scdocs/doc/644.pdf
- EFSA. Criteria for the initial screening of Article 13 (3) health claims of Regulation (EC) No 1924/2006 agreed by the NDA panel on 7 October 2008. 2 October 2008. http://www.efsa.europa.eu/en/ndaclaims13/docs/ndaart13torax01.pdf
- EFSA. Summary report: EFSA Conference on Nutrition and Health Claims, 8-10 November 2006, Bologna, Italy. http://www.efsa.europa.eu/en/supporting/doc/nutritionhealthclaims.pdf
- EFSA. Guidance on the scientific requirements for health claims related to gut and immune function. EFSA Journal 2011;9(4):1984. http://www.efsa.europa.eu/en/efsajournal/doc/1984.pdf
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- EFSA. Guidance on the scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations. EFSA Journal 2012;10(3):2604. http://www.efsa.europa.eu/en/efsajournal/doc/2604.pdf

- EFSA. Guidance on the scientific requirements for health claims related to bone, joints, skin and oral health. EFSA Journal 2012;10(5):2702. http://www.efsa.europa.eu/en/efsajournal/doc/2702.pdf
- EFSA. Guidance on the scientific requirements for health claims related to physical performance. EFSA Journal 2012;10(7):2817. http://www.efsa.europa.eu/en/efsajournal/doc/2817.pdf
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A.1.6. Scientific documents of relevance

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A.2. Overview of the minimum quantities of vitamins and minerals to make source of and rich in claims

Nutrient	Nutrient Reference Values	Source of (15 %)	High in (30%)
Vitamin A (µg)	800	120	240
Vitamin D (µg)	5	0.75	1.5
Vitamin E (mg)	12	1.8	3.6
Vitamin K (µg)	75	11.25	22.5
Vitamin C (mg)	80	12	24
Thiamine (mg)	1.1	0.165	0.33
Riboflavin (mg)	1.4	0.21	0.42
Niacin (mg)	16	2.4	4.8
Vitamin B6 (mg)	1.4	0.21	0.42
Folic acid (µg)	200	30	60
Vitamin B12 (µg)	2.5	0.375	0.75
Biotin (µg)	50	7.5	15
Pantothenic acid (mg)	6	0.9	1.8
Potassium (mg)	2000	300	600
Chloride (mg)	800	120	240
Calcium (mg)	800	120	240
Phosphorous (mg)	700	105	210
Magnesium (mg)	375	56.25	112.5
Iron (mg)	14	2.1	4.2
Zinc (mg)	10	1.5	3
Copper (mg)	1	0.15	0.3
Manganese (mg)	2	0.3	0.6
Fluoride (mg)	3.5	0.525	1.05
Selenium (µg)	55	8.25	16.5
Chromium (µg)	40	6	12
Molybdenum (µg)	50	7.5	15
Iodine (µg)	150	22.5	45

The above values are applicable by virtue of Regulation 1169/2011 on food information to consumers and apply to **all foods, except beverages and food supplements**.

- For **beverages** the values accepted for ‘source of’ and ‘rich in’ claims are 7,5 % and 15 % of the nutrient reference values specified.
- For **food supplements**, the values as expressed per 100 g or 100 ml could result in insignificant quantities. In order to be in conformity with Article 5 of the NHCR, it is recommended to apply these values per portion of the product as recommended for daily consumption in the labelling.

For **products that are intended for population groups with a particular nutritional need** (e.g. children), it may be justifiable to use nutrient reference values that are more appropriate for the target population in order to meet the requirements of a significant quantity under Article 5 of the NHCR.

The European food supplement sector brings together many of the most innovative and dynamic companies in the food area, making a substantial contribution to Europe's public health goals.

Food Supplements Europe combines the unique expertise of associations and companies committed to building partnership with regulatory, scientific and consumer bodies to help shape the future regulatory and policy framework in this area and to ensure that consumers can benefit from safe and high quality products.

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