food supplements europe

Guidelines for the Substantiation of Beauty Claims for Food Supplements

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Background and context

These guidelines are intended to assist food operators in the proper use of beauty claims that do not fall under the scope of the Nutrition and Health Claims Regulation (NHCR - Regulation 1924/2006). They cover specifically the way to generate data to support the use of such claims for food supplements.

This guidance should be used in conjunction with the various documents that are available from the European Commission, Members States and EFSA.

Since the publication of the NHCR the legal requirements of so-called beauty claims have been unclear and subject to controversies. At the date of implementation of the NHCR, there had been a tacit agreement in the majority of Member States that beauty statements are outside the scope of the NHCR. This is the reason why few applications had been submitted for evaluation under the article 13 procedure of the NHCR.

In early 2013, the Members States expressed a different view on this subject. They considered that beauty claims fall under the scope of the NHCR but that a physiological or psychological effect needs to be demonstrated to justify them. However, it can be argued that other statements that relate to beauty but do not refer to a function of the body do not fall under any of the categories of health claims included in the NHCR. As a consequence, their use could be justified to fall outside the scope of the NHCR. However a valid justification should be available and these statements need to comply with the EU Food Information Regulation 1169/2011 (FIC) which specifies that information provided to consumers should be true and not misleading.

Today, the acceptance of such beauty claims depends on national practice, on a case-by-case basis without the existence of a common framework. Food operators should consider carefully the wording and context of these statements so as not to state or imply that the claimed effect falls under the NHCR.

In addition, it is the responsibility of food operators to ensure that such statements are scientifically justified, in accordance with national provisions and opinions where applicable.

The purpose of this document is to give guidance to food operators to help them to substantiate such beauty claims in a responsible and correct way. It also provides guidance on how to communicate messages relating to beauty that fall outside the scope of the NHCR.

The justification of beauty claims

Beauty claims are substantiated by food operators with the use of bibliographical evidence, published research and/or by generating new efficacy data with active ingredients or a final product formulation.

Various methodologies can be used and it should be considered that new techniques are continuously evolving. Validated evaluation methodologies are an effective tool to assess product efficacy and facilitate innovation. It is the responsibility of food operators to evaluate which studies are necessary to justify the beauty claims they are using.

1. Main methodological approaches in relation to clinical trials

Clinical trials to evaluate beauty claims should be performed on a population that is representative of the target population, defined by clear and precise inclusion and exclusion criteria. Inclusion and exclusion criteria may include factors such as age, gender, the stage of beauty concern (e.g. wrinkles score, low level of skin hydration), use of topical products, nutrition during the trial, ..., and the presence or absence of other medical, psychosocial, or emotional conditions.

Moreover, another important issue regarding clinical study design is the choice of the size of the population. Underestimation of sample size may result in data turning out to be statistically non-significant even though clinical significance exists, while in a too large population small differences may become statistically significant even if these differences are not clinically meaningful. Thus, whenever possible, the size of the target population should be determined using sample size calculation. Sample size calculation is conducted through a pre-study power analysis. The purpose is to select an appropriate sample size in achieving a desired power for correct detection of a pre-specified clinical meaningful difference at a given level of significance.

Clinical trials could be in compliance with guidelines of Good Clinical Practices and should respect ethical rules.

- **Main objective**

  The main objective of the study has to be precisely defined in relation to the aim of the test.

  Where possible, reproducible and validated methods should be used.

- **Design**

  Depending on the study objectives, several designs can be used.

  The study protocol can be designed as an observational study in real conditions of use, as an interventional study versus a control group without intervention, or as a double blind randomized placebo controlled study.

- ## Methodologies

  Depending on the study objective, it is possible but not mandatory to combine several complementary approaches:

  - Instrumental approach
  - Evaluation by professional experts
  - Auto-evaluation

The **instrumental approach** consists in measuring precisely given parameters in accordance with a defined protocol. These tests are performed by a trained technician on subjects in controlled laboratory conditions/environment.

Below are examples of methodologies. These are examples and should not be considered as an exhaustive list.

Skin wrinkles

Measuring skin wrinkles size and depth can be achieved using skin replica on tested skin sites (e.g., wrinkles of the crow's feet).

The replication of the wrinkle is performed using a silicon rubber. These negative replicas can be analysed using an image processing system [see Corcuff et al, 1983; Hatzis, 2004].

Optical topometry with fringe projection also allows measuring topography of both real skin as well as replicas, and thus skin wrinkling. This technique is based on triangulation using temporal phase shifting techniques [see Stout KJ et al, 1994].

Limitations of such method are possible inhomogeneities, bubbles or artefacts of the replicas, possible interactions between the skin surface and the replicas and long drying times [Grove GL, Grove MJ, 1989; Fischer TW *et al*, 1999; Schreiner V *et al*, 1997].

Non-contact optical methods for direct in *vivo* measurements, such as the surface evaluation of living skin (SELS) developed by Tronnier *et al* in the 90s, are regarded as advantageous because the measurement process is quicker and the skin topography remains undisturbed [Tronnier H *et al*, 1999].

Another alternative is represented by the analysis of the skin surface by the phase shift rapid *in vivo* measurement of skin (PRIMOS). SELS and PRIMOS techniques were recently compared in a clinical study showing that both approaches provide a reliable measurement of skin topography [Kottner J *et al*, 2013].

Skin elasticity

Skin biomechanical properties such as elasticity are influenced by the hypodermis, dermis and epidermis. Skin elasticity is influenced by skin hydration, elastin, collagen and glycosaminoglycans contents and interactions. Many different non-invasive methods are available to measure mechanical properties of the skin based on tensile, torsional, indentation or suction skin deformation [see Agache P, 1995; Barel AO et al, 1995; Gniedecka M et al, 1995; Hargens CW, 1981; Murray BC et al, 1997, Piérard GE, 1993].

The measures of skin elasticity are greatly influenced by external conditions (room temperature and hygrometry) as well as by subjects that have to be at rest for 15 to 20 min before measurement to acclimate to room conditions.

Different devices such as Reviscometer, Cutometer or Frictiometer can be used. These three devices were compared in a recent publication [Neto P et al, 2013]. This study showed that Frictiometer and Reviscometer measurement were not correlated. Some Frictiometer and Cutometer parameters were significantly correlated. Moreover, the authors concluded that among the parameters, skin elasticity can be accurately evaluated by selecting two parameters selected from Uf (total deformation), Ua (viscoelasticity/plastic recovery) and Ue (elastic deformation) groups and from Ur (immediate retraction), Uv (viscoelasticity) and Ur/Uf (firmness parameter) groups.

Skin hydration

Skin hydration can be evaluated using the widely used and conventional corneometry. The Corneometer© determines the level of moisture in the outer skin layers of the stratum corneum. It measures electrical capacitance with a condenser-type sensor. The capacitance of the measurement probe in contact with the skin varies in proportion to the skin moisture content and measures are expressed in arbitrary units ranging from 0 (no water at all) to 120 (on water) [see Lévêque Jl et al, 1983; Rogiers V et al, 1990; Van Nesté D, 1990].

The principal drawbacks of this method are that room temperature as well as humidity and other substances than water can influence the measure.

Trans Epidermal Water Loss (TEWL) is also frequently used to monitor change in skin barrier function in relation to skin hydration. Numerous variables should be taken into consideration when assessing skin TEWL including anatomical variations, age, sex, race, sweat gland activity, circadian rhythm, relative humidity, temperature of the measurement probe and environmental variables [Rosado *et al*, 2005]. Moreover, generation of conflicting data is relatively frequent due to protocol variations.

Over the last years, Confocal Raman (CFR) spectroscopy emerges as a new interesting technique to measure water in the *stratum corneum* [Wu J, 2008]. One of the disadvantages to CFR is that it is relatively insensitive and requires the molecule of interest be present at a sufficient concentration and exhibit spectral features of sufficient intensity, to permit its differentiation from those of the skin. The output of a Confocal Raman experiment is, indeed, a relative concentration rather than an absolute quantification of the molecule [Rosado *et al*, 2005].

Hair Strength and Resistance

Hair strength/resistance can be evaluated using the Distron-MTT680. The MTT680 is an automated tensile tester based on a circular sample cassette. Before testing, the fibre samples are mounted using the crimp system for hair and placed in the 100 fibre sample cassette. One end of the sample is held in the cassette whilst the outer mount overhangs the cassette edge. The module is configured so that the load cell is driven in and out on the moving bridge of the tensile tester. Assembled on the load cell is the pneumatically operated sample gripper and, when in position, the gripper closes on the outer sample mount ready for testing (see www.diastron.com).

Instrumental measurement can be associated with an **evaluation by professional experts** (medical doctors, dermatologists, beauticians or hairdressers) to evaluate the perception of efficacy of a product.

These evaluations can be visual or tactile and based on scoring or questionnaires.

In addition, it is of outmost importance to register the perception of efficacy of the study subjects to anticipate consumer's expectations and to be sure that communication about beauty claims will match up with consumer's perceived efficacy.

One way to assess perceived efficacy is to test the product in **real condition of use**, i.e. in dermatologists facilities/laboratories.

• Validation of methods

Validation of study results depends on the use of an appropriate statistical method that should be defined at the beginning of the study design either in the study protocol or as part of a separate document and be referred to as the **statistical analysis plan**.

Usually a level of significance of 5% is considered appropriate. In addition to statistical relevance, study results should also be validated from a perception point of view and the relevance of the results should be precisely described in the study protocol.

2. In vitro data

In vitro experiments can be based on cell culture (keratinocytes, fibroblasts…) or on more complex models such as reconstructed skin integrating one or several skin cell types reproducing certain physiological functions of the epidermis and/or the dermis, the two main skin layers. Skin explants as well as human hair grown in vitro are also useful tools in elucidating some aspects of ingredients or finished products efficacy.

In the course of food supplement development, such models may be used as screening tools and for mechanistic studies but should be carefully correlated to clinical efficacy. Indeed, these models are only indicative, as they do not always take into account the metabolism of the ingredients after ingestion.

Communication best practices

1. Notion of Beauty

The notion of beauty is essentially a subjective notion, linked to appearance and mainly related to skin, hair and nails.

In communicating about beauty, care should be taken to ensure that the statements or claims remain out of the scope of the NHCR.

To help food operators to identify borderlines cases, examples of beauty statements have been compiled below.

These examples are based on the guidance and/or opinions published by EFSA.

Where possible, the overview also contains examples of claims that are clearly health claims, falling under the scope of the NHCR and therefore subject to approval before they can be used.

2. Examples

- **Hair**

Example of correct beauty claims	Rationale for these claims to fall outside the scope of the NHCR
• improve/maintain/increase* the **appearance or structure** of hair (resistance, volume and thickness, glossy/shiny hair, silky hair) * depending on clinical trial results	Appearance linked to beauty AND it is not a claim that states, suggests or implies that a relationship exists between a food category, a food or its constituents and health (Art 2.2.5). *EFSA Journal 2011;9(6):2228, pages 2/3 and 16: "The Panel considers that the following claimed effects do not refer to a function of the body as required by Regulation (EC) No 1924/2006: maintenance of normal structure and appearance of hair and nails structure."*

Examples of health claims that **fall under the scope of the NHCR** and require authorisation before use	Rationale for these claims to fall in the scope of the NHCR
• Reduction of excessive hair loss	This claim was submitted as an Art 13.5 claim. EFSA considered that maintenance of normal hair growth is a beneficial physiological effect. The claim was refused by EFSA as "cause-effect relationship not established between the intake of iron and maintenance of normal hair growth." (EFSA journal 2012,10(3):2602).

- **Skin**

Examples of correct beauty claims	Rationale for these claims to fall outside the scope of the NHCR
• improve/maintain/increase* the **appearance** of wrinkles (decrease in wrinkles) • Helps to improve **skin elasticity, skin surface structure** • Helps to improve **skin tonicity, skin firmness** * depending on clinical trial results	Appearance linked to beauty AND it is not a claim that states, suggests or implies that a relationship exists between a food category, a food or its constituents and health (Art 2.2.5) *See EFSA guidelines, 2012: Guidance on the scientific requirements for health claims related to bone, joints, skin, and oral health", NDA Panel, EFSA Journal 2012, 10(5): 2702, (page 11):* *"Health claims on the maintenance of normal structure, hydration, elasticity or appearance of the skin do not necessarily refer to a particular physiological function of the skin as required by Regulation (EC) No 1924/2006."* *EFSA Journal 2011;9 (4):2059:* *Maintenance of normal structure, elasticity and appearance of the skin.* *"The claimed effects are "helps to maintain elasticity, tenderness and health of skin, structure and function of skin and mucous membrane", and "membranes cell structure". The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the maintenance of the normal structure, elasticity and appearance of the skin. The Panel considers that the claims do not refer to a function of the body as required by Regulation (EC) No 1924/2006."* *EFSA Journal 2011;9(7):2264:* *Maintenance of normal skin tonicity* *"The claimed effect is "menopause/skin and hair health during menopause/cholesterol management". The target population is assumed to be post-menopausal women. In the context of the proposed wordings and the clarifications provided by Member States, the Panel assumes that the claimed effect refers to the maintenance of normal skin tonicity. No evidence has been provided on how skin tonicity could be related to skin function. The Panel considers that the claim does not refer to a function of the body as required by Regulation (EC) No 1924/2006."*

Examples of health claims that **fall under the scope of the NHCR** and require authorisation before use	Rationale for these claims to fall in the scope of the NHCR
• Maintenance (i.e. reduced loss) of the barrier functions of the skin • Maintenance (i.e. reduced loss) of the permeability barrier function of the skin protects the skin against dehydration • Protection of the skin (cells and molecules such as DNA, proteins and lipids) from oxidative damage, including photo-oxidative (UV-induced) damage • Decreasing DNA damage after UV radiation exposure • Increasing net collagen formation, or reducing net collagen breakdown, leading to maintenance (i.e. reduced loss) of tissue function(s) (e.g. bones, cartilage, gums, skin, tendons and blood vessels)	These claimed effects refer to a function of the body as required by Regulation (EC) No 1924/2006.

- **Nails:**

Examples of correct beauty claims	Rationale for these claims to fall outside the scope of the NHCR
• improve/maintenance/increase* the **appearance or structure** of nails (resistance, thickness, glossy/shiny nails) *depending on clinical trial results	Appearance linked to beauty AND is not a claim that states, suggests or implies that a relationship exists between a food category, a food or its constituents and health (Art 2.2.5) *EFSA Journal 2011;9(6):2228, pages 2/3 and 16: "The Panel considers that the following claimed effects do not refer to a function of the body as required by Regulation (EC) No 1924/2006: maintenance of normal structure and appearance of hair and nails structure."*

3. Basic principles for communication

• General principles

Any communication should comply with the basic principles of the “fair information practices” (Art 7 of the FIC regulation).

Communication shall not be misleading.

It shall be clear, precise, relevant and understandable by the consumer.

Claims shall be supported by adequate and verifiable evidence regardless of the types of evidential support used to substantiate them.

• Labeling, presentation and advertising

Food Supplements Europe advises operators to prepare a specific document summarising the data used to support the claims that are being used.

The evidence described in this document can be used in case of control by Authorities in addition to the clinical study report and /or scientific published literature.

Using published information is acceptable to substantiate a claim if it is relevant to the food product or food constituent. More weight is given to peer reviewed articles.

Communication on **consumer perception tests**: the claim must be directly substantiated by the results related to the relevant question without any questionable interpretation.

Bibliography

Agache P. Twistometry measurement of skin elasticity. In: Serup J, Jemec GBE, eds. Handbook of non-invasive methods and the skin (Chapter 14.1). Boca Raton: CRC Press, 1995,

Barel AO, Courage W, Clarys P. Suction method for measurement of skin mechanical properties; the Cutometer. In: Serup J, Jemec GBE, eds. Handbook of noninvasive methods and the skin. Boca Raton: CRC Press, 1995: 335–340.

Corcuff P, de Rigal J, and Leveque JL. Skin relief and aging. J. Soc Cosmet Chem 1983; 3, 4, 177-190

European Food Safety Authority documents are available at www.efsa.europa.eu.

European Union. 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

European Union. 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

Fischer TW, Wigger-Alberti W, Elsner P. Direct and non-direct measurement techniques for analysis of skin surface topography. Skin Pharmacol Appl Skin Physiol 1999; 12: 1–11.

Gniadecka M, Serup J. The suction chamber method for measurement of skin mechanical properties: the Dermaflexs. In: Serup J, Jemec GBE, eds. Handbook of non-invasive methods and the skin. Boca Raton: CRC Press, 1995: 329–335.

Grove GL, Grove MJ. Objective methods for assessing skin surface topography noninvasively. In: Leveque JL, ed. Cutaneous investigation in health and disease. Marcel Dekker: New York; 1989: 1–32

Haller D, Bode C, Hammes WP. Non-pathogenic bacteria elicit a differential cytokine response by intestinal epithelial cell/leucocyte cocultures. Gut 2000; 47: 79-87

Hargens CW. The gas-bearing electrodynamometer (GBE) applied to measuring mechanical changes in skin and other tissues. In: Marks R, Payne PA, eds. Bioengineering and the skin. New York: MTP Press, 1981, Chapter 14.

Hatzis J. The wrinkle and its measurement: A skin surface Profilometric method. Micron 2004; Volume 35, Issue 3, 201–219

Kottner J, Schario M, Garcia Bartels N, Pantchechnikova E, Hillmann K, Blume-Peytavi U. Comparison of two in vivo measurements for skin surface topography. Skin Res Technol. 2013 May; 19(2):84-90

Lévêque JL, De Rigal J. Impedance methods for studying moisturisation. J Soc Chem 1983; 34: 419–428

Murray BC, Wickett RR. Correlations between DermalTorque Meter, Cutometer, and Dermal Phase Meter measurements of human skin. Skin Res Technol 1997; 3: 101–106.

Neto P, Ferreira M, Bahia F and Costa P. Improvement of the methods for skin mechanical properties evaluation through correlation between diffrenet techniques and factor analysis. Skin Res Technol 2013; 19: 405-416.

Pierard GE. Mechanical properties of aged skin: indentation and elevation experiments. In: Lévêque JL, Agache P, eds. Aging skin. New York, Basel: Marcel Dekker Inc, 1993, Chapter 5.

Rogiers V, Derde MP, Verleye G, Roseeuw D. Standardized conditions needed for skin surface hydration measurements. Cosmet Toiletr 1990; 105: 73–82

Rosado, C., Pinto, P. and Rodrigues, L.M. Comparative assessment of the performance of two generations of Tewameter: TM210 and TM300. Int J Cosmet Sci, 2005, 27, 237–241

Schreiner V, Sauermann G, Hoppe U. Characterization of the skin surface by ISO-parameters for microtopography. In: Wilhelm KP, Elsner P, Berardesca E and Maibach H, eds. Bioengineering of the skin: skin surface imaging and analysis. Boca Raton: CRC Press, 1997, 129–143

Stout K J and Blunt L. Nanometers to Microns 3D Surface Measurement in Bio-Engineering, Proc. 2nd Int. Conf. on Surface Eng. Adelaide Australia March (1994)

Tronnier H, Wiebusch M, Heinrich U, Stute R. Surface evaluation of living skin. Adv Exp Med Biol 1999; 455: 507–516

Van Neste D. Comparative study of normal and rough human skin hydration in vivo. Evaluation with four different instruments. J Dermatol Sci 1991; 2: 119–124

Wu, J. and Polefka, T.G. Confocal Raman microspectroscopy of stratum corneum: a pre-clinical validation study. Int J Cosmet Sci 2008, 30, 47–56

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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International Non-Profit Organisation

Rue de l'Association 50
1000 Brussels

Tel: +32 2 209 11 51
Fax: +32 2 219 73 42
secretariat@foodsupplementseurope.org
www.foodsupplementseurope.org