The EU Health Claims Regulation

- Background
- Implementation and enforcement
- Practical examples

Dr. Gert Krabichler, FSE Board Member & Treasurer
Recital 3
This Regulation [...] lay down specific provisions concerning the use of nutrition and health claims concerning foods to be delivered as such to the consumer

Recital 4
This Regulation 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
This Regulation should also apply to trade marks and other brand names which may be construed as nutrition or health claims.
The Nutrition & Health Claims Regulation
What is allowed?

1. Only health claims included in the EU Register of authorised health claims, or claims submitted for authorisation and awaiting a decision, can be made on food.

2. Health claims referring to general, nonspecific benefits of the nutrient to overall good health, such as ‘good for you” must be accompanied by an authorised health claim (Article 10).

3. Health claims must be accompanied by additional labelling requirements, such as a statement indicating the importance of a varied and balanced diet and a healthy lifestyle.

4. Trademarks and brand names in use before January 2005 are allowed up to June 2022. Otherwise, all trademarks and brands which could be construed as claims must be accompanied by an authorised health or nutrition claim.
About on-hold claims

Health claims still on hold can be made until a decision is taken as long as they comply with the Nutrition & Health claims regulation and national provisions.

Remarks

1. Some of proposed claim wordings may not be acceptable under the general provisions of Regulation (EC) 1924/2006 or general food labelling rules.

2. Some of the proposed health relationships and claim wordings may be construed as medicinal claims and must not be made on foods.

3. Some of the substances listed may be unauthorised novel substances.
Claims on hold

The only generic health claims permitted now are those listed as ‘authorised’ in the EU Register of claims; and those put ‘on hold’ by the European Commission.

Claims on hold can continue to be used on the market under the responsibility of the food business operator provided they comply with the claims Regulation and existing national provisions applicable to them.

A list of all the ‘on hold’ claim ID numbers can be found on the EC website.

http://ec.europa.eu/nuhclaims/resources/docs/claims_pending.pdf
Claims on hold, remarks

• Botanical are only considered to be an ‘on hold’ claim if it relates to the same plant part(s), to the same health relationship and, if applicable, to the same proposed conditions of use (e.g. the dose). Information can be found in the EFSA Access database.

• Many of the proposed claim wordings may not be acceptable under the NHCR or general food labelling rules (e.g. Prevention of disease)

• Some substances for which a claim is on hold may not be authorised in food supplement.

• Some of these substances can also be non-authorised novel ingredients
Claimed effects should be linked to the substance (not product) for which claims have been authorised

Authorised health claim:

“X contributes to the normal function of the immune system”.

In relation to product Y containing the relevant amount of nutrient X it is acceptable to say:

“X contributes to the normal function of the immune system” or “Y contains X which contributes to the normal function of the immune system”

But not:

Y contributes to the normal function of the immune system. Y contains X”
The Nutrition & Health Claims Regulation

What is allowed?

Flexibility of wordings

Due to linguistic or cultural differences, flexibility is permitted provided that those adjusted claims have the same meaning for consumers as that of the permitted claims. Final judgment on consumer understanding is made by enforcement authorities.

EU Register of Nutrition & Health Claims

IMPORTANT!
PLEASE READ BEFORE GOING ANY FURTHER

» Any food business operator can use authorised health claims if the conditions of use and any applicable restrictions are respected.
» Non-authorised health claims should not be used.
» National authorities control the use of claims.
» Health claims should only be made for the nutrient, substance, food or food category for which they have been authorised, and not for the food product that contains them.
» 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 variations and the target population. Adapted wording must have the same meaning for the consumer as the authorised claim in the EU Register.

I have read this and wish to proceed I do not want to proceed
Due to linguistic or cultural differences, flexibility is permitted provided that those adjusted claims have the same meaning for consumers as that of the permitted claims.

Final judgment on consumer understanding is made by enforcement authorities.
General principles on flexibility of wording for health claims

EU member states have informally agreed some recommendations on the general principles to be taken into account by businesses if they adapt the wording of an authorised health claim.

January 2013
Adapted wording must mean same to consumers as authorised claims

X contributes to the normal function of

- Plays a role in the normal function of the immune system” or
- “X supports the normal function of the immune system” or
- “X contributes to maintaining
- The product Y contains X which ...

- Austria, Belgium, Denmark, Finland, France, Germany, Estonia, Hungary, Ireland, Lithuania, Luxembourg, Netherlands, Norway, Poland, Portugal, Sweden, United Kingdom
Adapted wording must mean same to consumers as authorised claims

- Stimulates the normal function of or
- “X optimises…"
- The product Y contributes to normal function

Difference between „substance“ and „product“!
Presentation of general, non-specific health claims
Art. 10(3)

When reference is made to general, non-specific benefits of a nutrient or food for overall good health or health-related well-being such claims are permitted but must be accompanied by a specific, authorised Article 13 or Article 14 health claim.

• If a claim were made for ‘GOOD FOR YOUR SKIN’ on the front of a product pack (product ‘Y’ which contains a substance ‘X’) it would be acceptable to present this as:

  • ‘GOOD FOR YOUR SKIN’ - X contributes to the maintenance of normal skin’ or
  • ‘GOOD FOR YOUR SKIN’ - Y contains X which contributes to the maintenance of normal skin’
Outside the scope of the Nutrition & Health Claims Regulation

**Recital 4**

Claims which are made in non-commercial communications, such as

- Dietary guidelines and advice issued by public health authorities and bodies (e.g. folate and neural tube defect, Lutein in relation to AMD)

- Non-commercial communications

- Information in the press and in scientific publications. E.g. combined with advert?
The Nutrition & Health Claims Regulation

What is not allowed:

Cannot be made:

1. Health claims which suggest that health could be affected by not consuming the food

2. Health claims which make reference to the rate or amount of weight loss

3. Health claims which make reference to recommendations of individual doctors or health professionals
Commercial communication/ non commercial communication?
(UK FSA guidelines, 2009)

1. What is the primary object of the claim and its context?
   
   *If the primary object is to induce the final consumer to eat a specific product, to the benefit of the manufacturer or retailer (either directly financial or indirectly, e.g. reputation), it is commercial.*

2. If a third party makes the claim, have they been paid to make the claim (commercial) or are they doing it to provide “information” (not commercial)?

3. If the third party has not been paid, is the claim within the information they give likely to lead to some intangible future benefit (indirectly commercial, in the sense that the inducement may call into question the independence of the information)

Download Nutrition and health claims - Guidance to compliance with Regulation (EC) 1924/2006 on nutrition and health claims made on foods
Examples:
Example:
Joint Health

Joint Plus

Vitamin C - Zinc – Devil’s Claw
Joint – Bone
Plus Antioxidants

Only 1x daily
With Vit C for Joints
Supports a Healthy Cartilage function
### Abtei Joint Plus - selected vitamins and trace elements for your health

#### Meaningful Nutrient Combination for Joints

- **Vit C** contributes to collagen formation and supports therefore a normal cartilage and bone function.
- **Zinc** supports the activity of specific cells, which are responsible for bone formation.
- The antioxidants **Selenium and Vit E** contributes to protect cells and their components against anti-oxidative stress.

Additionally, **Abtei Joint Plus** contains the extract from **Devil’s Claw** as well as **Glucosamine- and Chondroitin sulfate**.

#### Abtei Joint Plus – selected Vitamins and trace elements for your health

<table>
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<th>Nährstoffe</th>
<th>pro Tablette</th>
<th>% der Tageszufuhr pro Tablette*</th>
<th>Nährstoffe</th>
<th>pro Tablette</th>
<th>% der Tageszufuhr pro Tablette*</th>
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<td>**</td>
<td>Vitamin B₆</td>
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<td>100 %</td>
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<tr>
<td>Chondroitinsulfat</td>
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<td>**</td>
<td>Vitamin E</td>
<td>12 mg α-TE</td>
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**Referenzmenge nach EU-Lebensmittelinformationsverordnung**

**keine Referenzmenge vorhanden.**

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**Gelenk Plus**

Sinnvolle Nährstoffkombination für die Gelenke


**Abtei Gelenk Plus** enthält ausgewählte Mikronährstoffe:

- **Vitamin C** trägt zu einer normalen Kollagenbildung bei und unterstützt so eine normale Knorpel- und Knochenfunktion.
- **Zink** unterstützt die Aktivität spezifischer Zellen, die für die Knochenbildung verantwortlich sind.
- **Die Antioxidantien Selen und Vitamin E** tragen dazu bei, Zellen und deren Bestandteile vor oxidativem Stress zu schützen.

Zusätzlich enthält **Abtei Gelenk Plus** den Extrakt aus der Teufelskralle sowie Glucosamin- und Chondroitinsulfat.

**Abtei Gelenk Plus – ausgewählte Vitamine und Spurenelemente für die Gesundheit.**

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**ABTEI OP Pharma GmbH, Abtei 1, D-37696 Marienmünster**
Example:
Male Active

Male Active
Complex-Capsules

B-Vits support the energy metabolism and contribute to the reduction of tiredness
Zinc supports normal fertility
Vit B1 contributes to normal heart function

For active men’s health
Male Active Capsules contribute to the supply of Vits and Mins as well as further high value ingredients specifically adapted for male requirements.

- **Vits B6, B12 and C** contribute to a normal energy metabolism and a reduction of tiredness and fatigue.
- **Vit B1** supports the heart function.
- **Vit B6** contributes to the regulation of hormone activity.
- **Vit C, Selenium and Zinc** contribute to a normal function of the immune system and help to protect body cells against oxidative stress.
- **Zinc** is proven to support the maintenance of normal skin.
- **Zinc** is proven to support a normal testosterone level.
- Not only women, but also men have influence on the topic “fertility” as **Zinc** contributes to normal fertility and normal reproduction and **Selenium** supports sperm formation.

Additional high quality ingredients like **pumpkinseed oil, L-carnitin** and **astaxanthin** as a strong antioxidans complement this innovative formulation.
Example:
Meno Active

Meno Active for Balance and Vitality during and after Menopause

+ B-Vitamin B6
+ Calcium and Vitamin D
+ Soy Isoflavones
In the age between 40 and 50 years the hormonal alteration of the female organism begins. The production of Estrogen will be reduced, which frequently leads to unpleasant symptoms like hot flashes, tiredness, and loss of bone minerals.

Das gesunde Plus Meno Aktiv contains Vitamin B6, which supports the regulation of the balance and contributes to the reduction of tiredness and fatigue. Calcium is required for the maintenance of normal bones. Vitamin D supports the Calcium uptake and action. Vitamin E contributes to protect cells against oxidative stress. Biotin supports the maintenance of normal skin and hair and of the nervous system. Folic acid has a function in the division of cells. The product contains soy isoflavones as well, which are also called plant hormones or phyto-estrogens.
Example:

**New product based on new claim for Cocoa flavonoids**

Conservative version
Example:

New product based on new claim for Cocoa flavonoids

Conservative version
Clinically trialled and tested

Alpha-linolenic acid (ALA) has undergone numerous clinical trials demonstrating its efficacy at helping to maintain normal cholesterol levels, and the ability of this particular omega 3 (ALA) to support health has been validated by the European Food Safety Authority (EFSA). Our high quality ALA is sourced from cold pressed virgin flax seed oil.

The very specific live cultures in this supplement (‘AB-Life’ Lactobacillus plantarum CECT 7527, Lactobacillus plantarum CECT 7528, Lactobacillus plantarum CECT 7529) have undergone a randomised, double blind, placebo controlled clinical trial which was been published in the British Journal of Nutrition in May 2013. What’s more these strains from OptiBac Probiotics have been tested and shown to survive environmental stressors and gastric acidity, to survive to reach the gut alive.

More about ‘For your cholesterol’

This combined live cultures and omega 3 supplement supports blood cholesterol levels by utilising 6 different mechanisms of action – acting on both the liver’s natural production of cholesterol as well as absorption of dietary cholesterol in the gastro-intestinal tract.

Take OptiBac Probiotics ‘For your cholesterol’ every day to naturally help maintain healthy cholesterol levels.

Please see the links below for some of the frequently asked questions about ‘For your cholesterol’.
Enforcement Examples:

1. France
2. UK
3. Germany
Law Enforcement in France: Implementation of the NHCR

1. Organisation
   - National Level: DGCCRF
     - Set up and vote French & EU regulations
     - No power of control but train local inspectors
   - Local Level: DDPP
     - Under regional prefect authority
     - In charge of controls (local judgment)

2. Inspection
   - Regular local inspection according to a control plan (1-5y)
   - Local inspection due to « denunciation » (competitors, inspectors from other regions, ...)
   - National inspection on a specific / hot topic

3. Sanctions
   - Educational
     - Discussion + modification
     - Regulatory reminder letter
   - Preventive/corrective
     - Administrative injunction to comply.
     - Payments in case of delay: € 3,000 for the Natural Person and € 15,000 for the Legal Entity
   - Repressive
     - Ticket: fine to up to € 450 (NP) and € 2250 (LE) by offense (eg x20,000 for 20,000 packaging)
     - Statements with regard of deception: fine to up to 300K € (NP), € 1,500k € (LE) or 10% based on the annual turnover and up to 2 years imprisonment
Law enforcement in UK: Implementation of the NHCR

1. Organisation
   - National Level:
     Advertising Standards Authority (ASA)
     - Self Regulation Body
     Trading Standards (TS)
     - Government
   - Local Level:
     - Food inspection
     - In charge of controls

2. Complaint generation and handling
   - General principle: self-regulation first
   - Complaints may be issued by
     - Local inspections
     - Competitors
     - Consumers
   - Complaints are issued to ASA
   - Some complaints to ASA are a result from referrals from Trading Standards
   - There can also be times where if a company refuses to comply with ASA’s rulings, the ASA can refer them to Trading Standards where action will be taken including via the courts.
UK Self Regulation by Advertising Standards Agency

Examples:

   - **Website:** “This carefully created formula contains a special combination of vitamins, including B6, B12 and C, which contributes to the reduction of tiredness and fatigue. Perfect for anyone who is interested in metabolism

2. [https://www.asa.org.uk/Rulings/Adjudications/2015/5/Water-for-Health-Ltd/SHP_ADJ_292311.aspx#.VxPQk4f2bVI](https://www.asa.org.uk/Rulings/Adjudications/2015/5/Water-for-Health-Ltd/SHP_ADJ_292311.aspx#.VxPQk4f2bVI)
   - **Website:** "Clean Chlorella" stated "Chlorella ... Detoxifies and helps purify the body"

   - **Advertisement:** made a health claim that referred to the recommendation of an individual health professional

   - **Website:** The ASA considered that in the context of a website for a food supplement the claim "with particular relevance to people with diabetes"

   - **Product Info?:** Northamptonshire Trading Standards challenged whether the following 9 health and nutrition claims listed were authorised on the EU Register

6. [https://www.asa.org.uk/Rulings/Adjudications/2016/1/PharmaCare-(Europe)-Ltd/SHP_ADJ_297561.aspx#.VxPTeYf2bVI](https://www.asa.org.uk/Rulings/Adjudications/2016/1/PharmaCare-(Europe)-Ltd/SHP_ADJ_297561.aspx#.VxPTeYf2bVI)
   - **A national press ad and a website:** for Promensil MENOPAUSE

   - **A TV ad:** for Centrum multivitamins, included a voice-over that stated "What do you want from a multivitamin? She'd like help with energy release, ...
Law enforcement in Germany: Implementation of the NHCR

1. Organisation
   - National Level: BMEL & BVL
     - BMEL: Ministry, official participant in EU StCom
     - BVL: Notification of FS, training or supervision of local/regional agencies
   - Regional Level: inspection coordination by RP / LUA office
     - LUAs coordinate partly on national level
     - Training of county inspectors
     - In charge of controls: county offices

2. Inspection
   - Regular local inspection according to a control plan (1-5y)
     Target: Legal Entity, warehouse, etc.
     Done by agency responsible for location
   - Local inspection of product, anywhere, based on location of complaint, but no company site control:
     due to « denunciation » (competitors, lawyers of “warning society”, food inspectors, ...)
   - National inspection on a specific / hot topic

3. Decision:
   1. Either: Agreement between parties involved
   2. Or: By Court Case
Thank you for your attention!
Back-up slides
Brand names - Recital 3

3. 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 may be used without undergoing the authorisation procedures provided for in this Regulation, provided that it is accompanied by a related nutrition or health claim in that labelling, presentation or advertising which complies with the provisions of this Regulation.

But Article 28(2)

2. Products bearing trade marks or brand names existing before 1 January 2005 which do not comply with this Regulation may continue to be marketed until 19 January 2022 after which time the provisions of this Regulation shall apply.

Transition measure apply to brand registered or used prior to 1 January 2005.
Reference to excerpts from EFSA opinions possible but should be done with caution

E.g. from the Belgian Authorities. It will be possible to reword those claims as follows:

- Regulation: Magnesium contributes to normal function of the nervous system
- EFSA: Magnesium contributes to normal nerve transmission
- Reworded claims: Magnesium contributes to normal nerve transmission

- Regulation: Folate contributes to maternal tissue growth during pregnancy
- EFSA: During pregnancy, folate is needed to increase the mass of red blood cells of the mother, for the formation of the placenta and the growing fetus, uterus, breasts and other maternal tissues
- Reworded claims: Folates contribute to placenta formation and growth of the uterus during pregnancy
Commercial communication/ non-commercial communication?

Preliminary ruling from the Court of Munich to the European Court of Justice on the interpretation of Article 1(2) of Regulation 1924/2006: nutrition and health claims made in commercial communications from businesses to health care professionals (HCPs).

Advocate General of the view that Article 1(2) of Regulation 1924/2006 should include commercial communications when those are exclusively intended to professionals but which have the objective to indirectly reach the consumers through those professionals.

March 2016