

# The impact of the health claims regulation on the food industry and future innovation potential

April 7, 2016

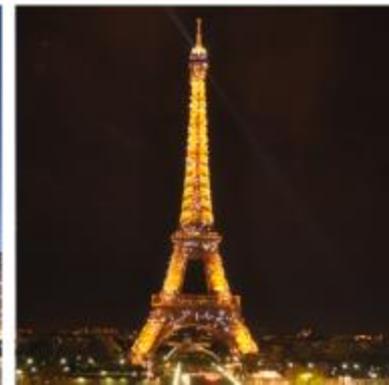
**Katia Merten-Lentz, Partner**

Keller and Heckman LLP

Brussels Office

+32 (0) 2.645.5073

[mertenlentz@khlaw.com](mailto:mertenlentz@khlaw.com)



- Nutrition and Health Claims Regulation
  - Experiences
  - Fundamentals
  - Pitfalls
  - REFIT evaluation
- Opportunities
  - Innovation Potential
  - Key to success
    - Legal viability
    - Claims as a marketing tool
- Conclusion

**Regulation (EC) No 1924/2006** of the European Parliament and the Council of 20 December 2006 on **nutrition and health claims** made on foods

## ➤ Experience of 10 years

- Protection of substantiated claims
- Unauthorized claims
- Absence of nutrient profiles
- Re-evaluation on its way (REFIT)
- Opportunities

# NHCR - definitions

---



‘**claim**’ means 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;

‘**nutrition claim**’ means any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to the energy (calorific value) the nutrients or other substances

‘**health claim**’ means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health;

- Nutrition claims listed in **Annex**
- Health claims

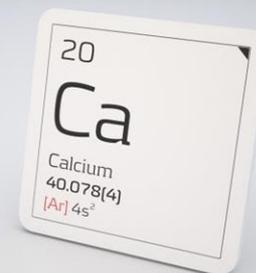
➤ **Art. 13 (1) health claims:**

- ‘generally accepted evidence’
- Regulation 432/2012

➤ **Art. 13 (5) health claims:**

- ‘recently generated scientific evidence’

High in fibre  
High in Vitamin C  
Light  
Low energy  
Source of Omega-3



*Calcium is needed for the maintenance of normal teeth*

*Sugar beet fibre contributes to an increase in faecal bulk*

## ➤ Art. 14 claims

- “reduction of disease health claims”
- Focus on risk factor

*Plant sterols and plant sterol esters have been shown to lower blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease.*

- “children’s development and health”
  - Data should relate to children

*Iron contributes to normal cognitive development of children*



# NHCR – authorization procedure



## Relevant institutions

Risk Managers

- **Member State authority**
- **Commission**

Authorisation; wording and conditions of use

Based on EFSA assessment, consumer understanding or other legitimate factors

Risk Assessor

- **EFSA – NDA Panel**

Scientific assessment to the ‘highest possible standard’

## ■ Article 3: the use of claims shall not:

- be false, ambiguous or misleading
- give rise to doubt on safety/ nutritional adequacy with other foods
- Encourage/condone excess consumption of a food
- Suggest a balanced and varied diet cannot provide adequate quantities of nutrients
- Refer to changes in bodily functions which could give rise to or exploit fear in the consumers

## ■ Article 5: general conditions

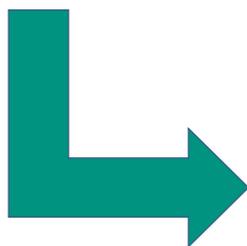
- Proven beneficial effect
- Present in significant quantity – reduced quantity that will produce claimed effect
- In readily available form
- Product quantity provides significant quantity of the compound
- The **average consumer** can be expected to understand the beneficial effect as expressed

WORDING

PRODUCT

WORDING

- **Article 4:** “...*nutrient profiles and the conditions, including exemptions, which **shall be respected** for the use of nutrition and health claims on foods and/or categories of foods.*”
  - Fundamental restriction on the use of claims
  - But currently no NPs in place
  - Uncertainty about introduction, application, consequences for new-existing claims



Creating legal uncertainty for innovative food producers

## ■ Article 6: scientific substantiation

1. Nutrition and health claims shall be based on and substantiated by generally accepted scientific data
2. A food business operator making a nutrition or health claim shall justify the use of the claim
3. The competent authorities of the Member States may request a food business operator or a person placing a product on the market to produce all relevant elements and data establishing compliance with this Regulation

- Elements of scientific assessment
  - A. Characterization of the food/constituent
  - B. Claimed beneficial effect can be measured (or is based on nutrient essentiality)
  - C. Establishing cause-effect relationship between A and B
- Required evidence

*Totality of the **available scientific evidence** in order to establish the cause-effect relationship for the chosen target population under the proposed conditions of use*

- **Element B: ‘beneficial physiological effect’**
  - **Essentiality of nutrient**
    - Exempted from randomized controlled trials
    - E.g.: *Effect of Vitamin C on the immune system*
  - **Other claims:**
    - Claimed effect refers to a specific body function, has a beneficial physiological effect for the target population for which the claim is intended, and can be assessed in vivo
    - **Pertinent Human studies** absolute requirement

- Complications in scientific substantiation

- *highest possible standard* (Recital 23); including pertinent human studies
- Previous lack of guidance



- Pending or insufficient applications and non-authorizations
- Disparity between claims on botanical foods and (herbal) medicinal products

**Legal burden** for innovative food producers

- Application of general principles
  - *Not false, ambiguous or misleading*
  - *Average consumer expected to understand*
- Proposed wording **applicant**
  - Consider legal and scientific correctness and consumer understanding
  - R&D, marketing and legal
- Consideration by **NDA Panel (EFSA)**
  - Reflecting the scientific evidence
- Authorized wording **EC**
  - Taking account of other legitimate factors

- Protection of scientific data and other information in the application (art. 20)
  - Conditions:
    - Requested by applicant
    - Data owned by the applicant
    - Essential for substantiation of claim
  - Cannot be used by for the benefit of subsequent applications
- **Proprietary health claim**
  - **Restricted use of 5 years** for applicant



## ■ Pitfalls of the NHCR

- Absence of Nutrient Profiles
- High standard of proof for health claims
  - *Necessity of human studies*
  - *No acceptance of traditional use as proof*
- Scope:
  - *Wide definition of claim*
  - *Only beneficial claims*
- Complexity, costs and length of procedure
- No remedies against negative EFSA opinion

## REFIT

### Regulatory Fitness and Performance Programme



- Questioning the fitness of the NHCR considering the objectives of the Regulation:
  - » Consumer protection and facilitate **healthy choices**
  - » Protection of fair competition; **promote and protect innovation**
  - » Improve free movement of foods with claims by **increasing legal certainty**

## ➤ Extent of REFIT- evaluation

- **Nutrient profiles**
- **Plants and their preparations used in foods**
  - 1500 applications on hold
  - Assessment of safety and health effect

*Need for pertinent human studies v. proof of traditional use*

## ➤ Other pitfalls?

*'...an evaluation of the Regulation in its entirety would be **premature** at this stage given that the list of authorised health claims only came into application in December 2012.'*

## ➤ Expected outcome of REFIT- evaluation

- End date REFIT evaluation: June 2017
- Consideration on Nutrient profiles
  - Need, effectiveness, alternatives, costs and benefits, ..
- Consideration on plants used in foods
  - Legal deficits, alternatives, costs and benefits, ..

 **Solutions to pitfalls not yet in sight**

## ■ Innovation potential under NHCR?

- **Scientific substantiation**
  - Protection of well-founded claims messages – fair competition
  - EFSA guidances (2011, 2015) available
  - Examples available
  - Data protection
  
- **Limitations on wording**
  - Protection of meaningful claims understood by consumers
  - Increases consumer trust

## ■ Key to success

- Application procedure takes between 5-10 years
- Speed up application by **integrating R&D and legal and marketing strategy** early in the process
  - Consider scientific substantiation;
  - with marketing strategy, and
  - legal viability
- Facilitates authorization procedure
- Time and cost reducing
- Increases effectiveness of claim



- Consider innovations in the light of legal constraints
  - NHCR, food supplement and/or novel food?
  - Consider complex aspects of authorization procedure
  - Cope with the legal uncertainties (nutrient profiles, high standard of proof, ...)
  - Examine the experiences and examples of earlier claims
  - Correspond scientific and effective wording to legal requirements

## Why do producers use claims?

- Product differentiation

- Competitive advantage

- Proprietary health claim!

- Marketing of food products

- From sensory aspects to health functionality

- Focus on target group

- ...



# Claims as a marketing tool

---



- Consider innovation in the light of marketing potential
- Identify consumer understanding process
  - A. Assess needs of consumers
  - B. Acceptance of the functional food product
  - C. Branding effects
  - D. Trust regarding branded product



**Need**



- Identify what consumers are looking for:
  - something different from other products
  - something that cannot, or not easily, be attained by balance and healthy diet

## Acceptance



- How to introduce new products with consumers?
  - Analyze dietary habits
  - Avoid changes in taste or convenience
  - Only minor changes for the sake of healthiness

## Branding



- Well known and trusted brands generally generate higher confidence towards functionality
- Front of pack indication – facilitate the reading of claims

## Understanding

- Short, easy to read messages
- Clear wording and explanation
- Balance between substantive explanation and understandable message



# Claims as a marketing tool

---



- Importance of legislation; high protection of consumers will lead to higher confidence in messages
- Importance of only well-substantiated claims

- 10 years of NHCR: pitfalls creating legal uncertainty
- Opportunities for innovative food producers
  - Protection of product innovation
  - Product differentiation
  - Ways to facilitate authorization

Combine R&D, legal and marketing strategy  
to generate bigger impact



# THANK YOU

**Katia Merten-Lentz, Partner**  
**Keller and Heckman LLP**

Brussels Office  
+32 (0) 2.645.5073  
[mertenlentz@khlaw.com](mailto:mertenlentz@khlaw.com)

Washington, DC • Brussels • San Francisco • Shanghai • Paris