

How to Make Health Claims with Legal Certainty

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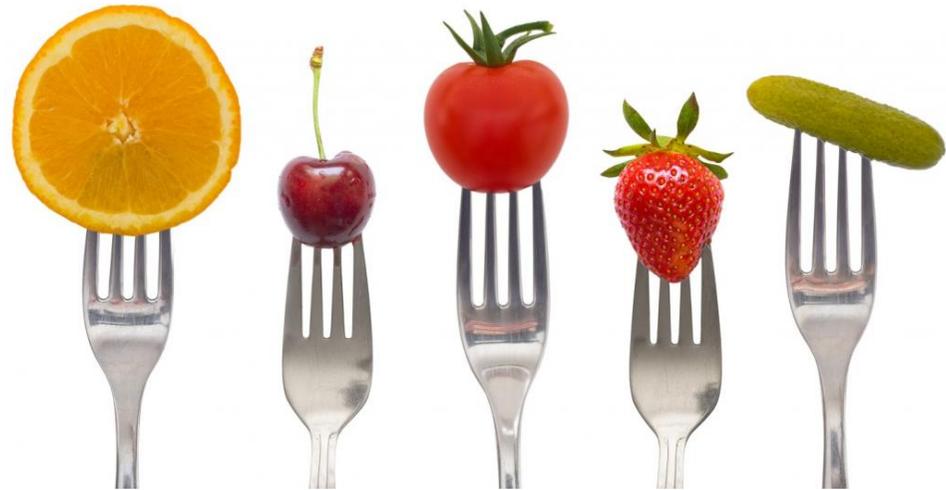
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Overview

- Introduction
- Approach to Legal Certainty
- Formal & Informal Approval
- Useful Guidance
- Conclusion



Introduction

- Regulation (EC) No 1924/2006 on nutrition and health claims made on foods has been around for nearly 10 years, the Union list established under Commission Regulation (EU) No 432/2012 for nearly 4 years.

- Many issues still remain, for example:
 - Availability of health claims
 - Exaggeration of health claims
 - Medicinal health claims
 - Consumer understanding
 - Translation of health claims
 - No formal progress on nutrient profiles



Approach to Legal Certainty

Health Claims = claims which refer to a relationship between a food or ingredient and health.

Key considerations and requirements when making a health claim:



EVIDENCE

RELEVANCE

PRESENTATION

Approach to Legal Certainty: Evidence

General Requirements

- Health claims can only be made if listed as authorised on the [EU Register](#).
- Exception: on-hold claims.
- If not listed on the EU Register and not an on-hold claim, then needs to submit evidence to EFSA for evaluation.
- Needs to hold evidence that the product meets the requirements for use, such as the required amount of the nutrient/ingredient.

Approach to Legal Certainty: Evidence

On-hold claims

- Cross check against non-authorized claims in EU Register
- Stick to same plant part, wording(s), health relationship and any proposed conditions of use (e.g. the amount)
- Some foods/ claims may be medicinal
- Check novel status



Non-specific health claims

- References to general, non-specific benefits of the nutrient or food may only be made if accompanied by a specific authorised health claims.

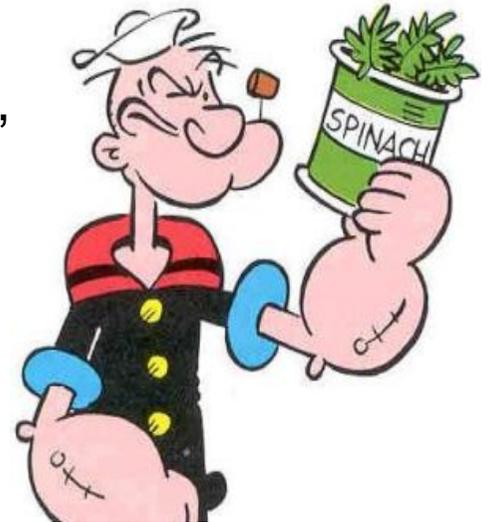
Approach to Legal Certainty: Relevance

- Needs to refer to the relevant nutrient/ingredient, for which the claim has been authorised.
 - e.g. cannot refer to the product instead of the nutrient/ingredient
- Context is important.
- Needs to be clear which nutrient/ingredient provides which benefit.
 - e.g. cannot combine claims for more than 1 nutrient, unless all nutrients are responsible for the same claimed effect



Approach to Legal Certainty: Presentation

- Recommended to stick to the authorised wording of health claims as closely as possible.
- Changes to wording possible only to aid consumers' understanding:
 - Must not make the claim more appealing.
 - Must not exaggerate the claim.
 - Must not change its meaning.
 - Meaning for consumer must remain the same as the authorised wording of the claim.



Approach to Legal Certainty: Presentation

- Not just explicit claims, claims which suggest or imply a relationship between health and food are also health claims.
- Visual claims may be classified as implied health claims, for example before and after photos showing weight loss.
- The size and font of the entire health claim should be the same and not emphasising any particular parts.



Approach to Legal Certainty: Presentation

Medicinal Claims

- Medicinal claims are prohibited for foods, their use on food supplements may render the product a medicine.
- Regulation 1924/2006 allows disease risk reduction claims with prior authorisation.



Approach to Legal Certainty: Presentation



Language and translation considerations

- T-296/12 - *Health Food Manufacturers' Association and Others v Commission*
 - UK on-hold list: initial approach – claims could not be translated, this has then changed.
 - If the term ‘normal’ appears in the approved wording in the English version, it must not be removed or changed in the amended wording.
 - There are differences between languages, some languages translate ‘normal’ as ‘healthy’ or ‘pure’.
 - Safest approach when translating health claims: avoid translating an already adapted version of the claim.

Approach to Legal Certainty: Presentation

Additional Considerations:

- Certain claims have specific conditions of use attached to them.
- When specific conditions of use apply, this must be made clear on the label.
- Consumers also need to be informed as to how much product they need to consume to achieve the relevant effect.
- For some claims, specific warning statements must also be included.



Formal & Informal Approval

Informal Approval:

- Approaching and engaging with regulators directly
- Email/postal correspondence with regulators
- Positive endorsement
- No objection



Formal & Informal Approval

Formal Approval Mechanisms:

- Declaratory Relief
- Judicial Review
- Write to Trading Standards (UK) / Relevant EU MS Authority, then review of their response by a court
- Assured Advice by Primary Authority (UK)



Guidance

- **EFSA Guidance for Applicants for Health Claims**

- Scientific and technical guidance for the preparation and presentation of an application
- General guidance covering the principles applied by the NDA Panel

Additional guidance on scientific requirements for health claims related to:

- Bone, joints and oral health (16 May 2012)
- Physical performance (17 July 2012)
- Neurological and psychological functions (17 July 2012)
- Gut and immune function (26 April 2011)
- Antioxidants, oxidative damage and cardiovascular health (*9 December 2011*)
- Appetite ratings, weight management and blood glucose concentrations (21 March 2012)

Approved!



Guidance

- [General Principles on Flexibility of Wording for Health Claims](#) (EU)
- [ASA Advice on Health Claims](#) (UK)
- [UK Department of Health Guidance](#) (UK)
- [Nutrition and Health Claim Guide for food supervisors and food business operators](#) (Finland)

Conclusion

- Safest approach: Stick to the authorised wording of the health claim.
- Make changes only if necessary for consumers understanding. Have evidence to justify this.
- When translating claims into other languages, avoid translating the amended health claims. Amend the authorised wording in the relevant language if necessary for consumers understanding.
- Be prepared to justify the use of the claim.
- Avoid misleading claims.
- Seek informal/formal approval from relevant MS authorities.
- Consult Guidance documents available.



Questions?

