

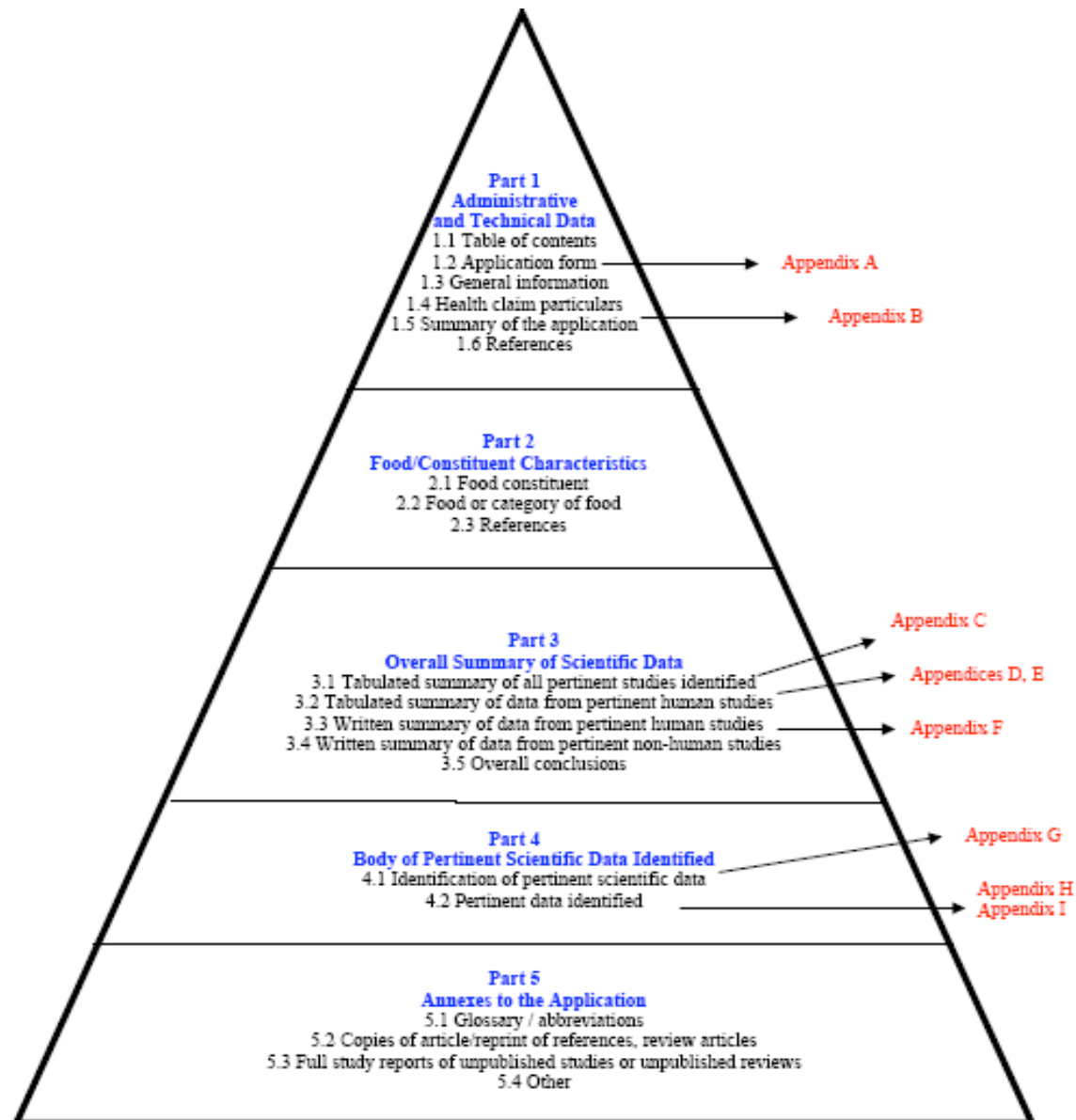
NHCLAIMS 2007

How to make an application
for a health claim in practice?

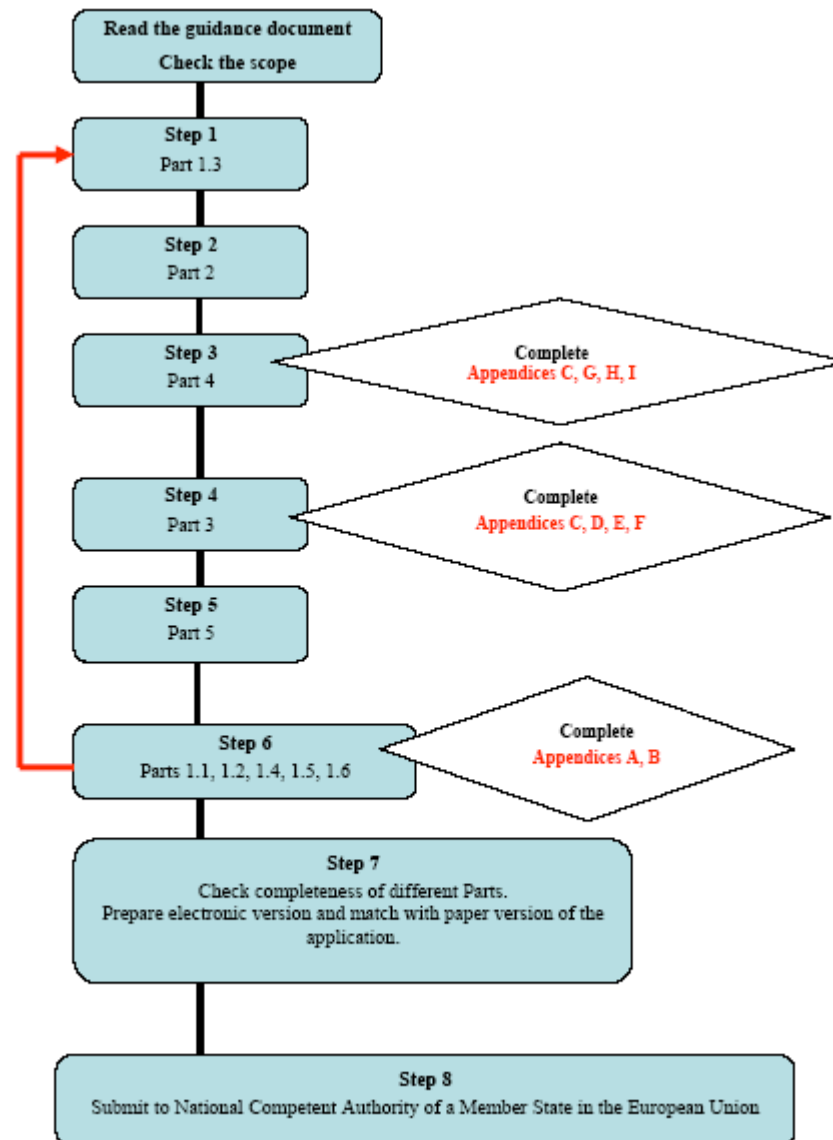
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- How to make an application for a health claim?
 - in theory
(Guidelines of EFSA, Health Canada, US FDA, Passclaim, etc.)
 - in practice
- Questions, thoughts, consequences

Organisation of the dossier



Preparation of the dossier



Quality of intervention studies

	Yes	Partially	No	Unknown	N/A ¹
1. Power calculations performed					
2. Baseline characteristics of subjects reported					
3. Subjects inclusion and exclusion criteria specified					
2. Information on background dietary habits provided					
3. Information on physical activity provided					
4. Information on smoking/alcohol drinking provided					
5. Information on medication use provided					
6. Information on other risk factors provided					
7. Randomisation					
a. Random sequence generation					
b. Treatment allocation concealed					
8. Control and intervention(s) group(s) comparable at baseline for relevant risk factors/outcome variables.					
9. Blinding of subjects					
10. Blinding of care givers ²					
11. Blinding of outcome assessors ³					
12. Compliance of subjects with the intervention reported					
13. Duration of intervention(s) adequate to test the hypothesis					
14. Point estimates and variability of main outcome variable reported.					
15. Surrogate markers of the claimed effect validated analytically					
16. Surrogate markers of the claimed effect validated biologically					
17. Analyses include an intention to treat analysis					
18. Adjustment for potential confounders performed					

¹ N/A=Not applicable

² Appropriate placebo available

³ Investigators in charge of assigning laboratory values and of evaluating complementary exams (ECG, ultrasounds, etc.) blinded to subjects' allocation arm.

Synopsis of intervention studies

Variable 1	Pre-test	Post-test	Mean difference	P-1*	P-2**	Follow up	Mean difference	P-1*	P-2**
Controls									
Intervention 1									
Intervention 2									
Intervention n									
Variable 2	Pre-test	Post-test	Mean difference	P-1*	P-2**		Mean difference	P-1*	P-2**
Controls									
Intervention 1									
Intervention 2									
Intervention n									

This table is only an example and could be adapted to accommodate different types of study design.

Values are expressed as: (state means/medians \pm SD/SEM/interquartile ranges/95%CIs, as appropriate)

* P-1= Significance for changes in the variable considered during each treatment.

**P-2 = Significance for changes in the variable considered during each treatment as compared to the control group.

Mandatory elements of the dossier

According to Article 15 of the Regulation:

- Administrative and technical data
- Summary (for public display)
- Definition of the health relationship
- Copy of all relevant study reports, etc.
- Proposed claim with conditions of use

Mandatory elements of the dossier

According to EFSA Guideline:

- Application must contain all pertinent scientific data (published and unpublished, in favor or not in favor). This must be confirmed by signature in the application form.

Definition of the health relationship

There must be a causal relationship between the consumption of the food / food ingredient and the claimed effect, characterized with regard to the:

- magnitude of effect
- minimum effective dose
- physiological relevance
- target population
- conditions under which effect occurs
- sustainability over time
- biological plausibility

High Level Health Claims (FSANZ)

- Biomarker claim

Biomarker = measurable parameter
predictive of a serious disease

e.g., enhanced bone mineral density

- Risk-reduction claim

e.g., reduces the risk of osteoporotic
fracture

Opinion of the SCMPMD on the "anticariogenic properties of xylitol" (1999)

"no clear data that xylitol possesses
specific effects in vivo..."

based on "reports provided by DGXXI
(reviews) and its knowledge of the
literature relating to dental caries."

Opinion of the SCMPMD on the "anticariogenic properties of xylitol" (2002)

"no scientific evidence to justify a revision of the Committee's opinion" based on an expert review provided by the applicant, 36 papers published since Jan. 1999 (31 papers without new data) and 5 new study reports that were critically evaluated.

Opinion of the SCF on the benefits of phytosterols by lowering LDL-cholesterol (October 2002)

"The benefits of phytosterol-enriched foods for helping hypercholesteremic individuals reduce their LDL-cholesterol are well supported by the available literature"

"Increased blood cholesterol is a well-known risk factor for CHD"

Assesment by an Expert group
under the Dutch Code of Practice
(April 2007)

"Spread or yoghurt (drink) with added Reducol, providing 1.8 - 2.2g phytosterol, induces up to 10% reduction of serum LDL-cholesterol"

Questions arising from EFSA's Guidance for article 14 claims

- What additions are required to cover Article 13(5) claims?
- How will "generally accepted scientific evidence" as basis of Article 13(1) claims be determined, if not by applying the same principles as for Article 14 claims?

Questions arising from EFSA's Guidance for article 14 claims

- How will "totality of evidence" be ensured, if not only by a call for data or own investigations?
- Is the fact that a claim is not disputed sufficient to accept its scientific substantiation?