

***ehpm* Discussion Paper on Botanical Health Claims**

Jonathan Griffith
(Chairperson Botanicals Working Group)

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The Presenting Problem

1. Analysis of the EU Nutrition & Health Claim Register ('12 years in'):

- 90% of existing claims are not approved
- Of the 10% approved, 70% are for generally recognised benefits of nutrients
- Less than 1% are for new claims based on innovative research
- Very few 'botanicals' are authorised and over 2000 were put on hold.

2. Implications

- Industry is not engaging in the process;
- Research and development is being inhibited.
- ❖ Consumers are not being provided at point of sale with the information they are accustomed to receive on the health benefits of foods;
- Consumers are therefore turning to uncontrolled sources for information and, in the case of food supplements, products – increasing the likelihood of being misled, distorting the market and undermining legitimate business in the EU.

The Cause of the Problem

1. NHCR Objectives are unacceptably limited:

- ✓ The Regulator's aspirations to protect Consumers and harmonise the Internal Market
- ❖ Consumer aspirations for information on the health benefits of foods
- ❖ Business's aspirations to authentically address these Consumer needs

2. The Scientific Focus is impractically restrictive

- ✓ The needs of scientists in establishing consensus of proof
- ❖ The nature of food and its effects on health;
 - ❖ The challenges which this poses to scientific inquiry

Three Graded Claims

Grade A - 'Scientifically Established Health Claims'

- e.g. Red yeast rice contributes to the maintenance of healthy cholesterol levels
- Based on convincing science similar to that currently used by EFSA.

Grade B - 'Well-Supported Health Claims'

- e.g. *"Red clover isoflavones can contribute to lowering LDL-cholesterol in postmenopausal women, which helps reduce the risk of cardiovascular disease", at a daily dose of 50 to 80 mg. (ID2496)*
- Based on significant science confirming a body of converging evidence

Grade C - 'Traditional Use Claims'

- Based (a) On the existence of a tradition;
(b) And on demonstration of plausibility.

e.g. Nettle root is traditionally used to support the health of the prostate gland.

Scientific Evaluation of Botanical Health Claims

Quality of Control & Evidence

Grade A
Scientifically Established Claims
'a contributes to b'

Conclusive Scientific Evidence

- Convergent scientific evidence
- Confirmatory human studies

Grade B
Well-Supported Claims
'a can contribute to b'

Significant Scientific Evidence,

- Pertinent Human Studies;
- Convergent scientific evidence
- Observational Studies (supportive);
- Biological Plausibility (supportive);

Grade C
Traditional Use Claims
'a is traditionally used for b'

Significant History of Use + Scientific Plausibility

- 25 years significant use, as applied in the modern era.
- Scientific Plausibility based on:
 - Authoritative Publications;
 - Comprehensive review of the scientific literature.



Quantity of Evidence

Note on Monographs and Meta-Analyses

These are comprehensive reviews of data, which when officially recognised, remove the need to independently gather and evaluate evidence.

Levels of Evidence & Their Evaluation

The Levels of Evidence Applied

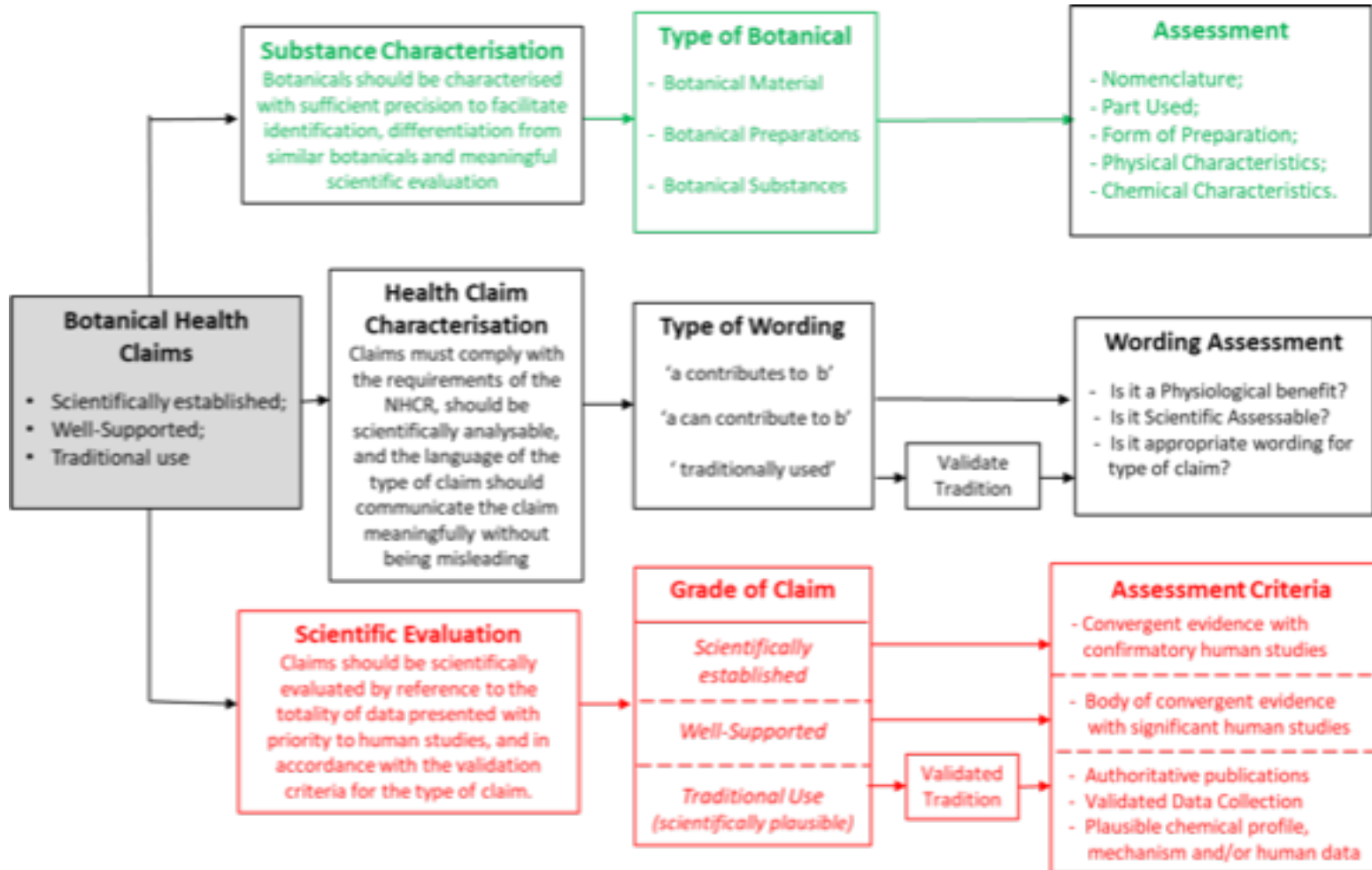
In order to be more precisely assessed the different grade of claim needs to be evaluated by reference to the types of predominantly human evidence available.

Grade	Type of Evidence according to GRADE Group 2004
Ia	Evidence from a meta-analysis of randomised controlled trials
Ib	Evidence from at least one randomised controlled trial
IIa	Evidence from at least one controlled study without randomisation
IIb	Evidence from at least one other type of quasi-experimental study
III	Evidence from observational studies
IV	Evidence from expert committee reports or experts

Grade	Other Type of Evidence available on Botanicals
Supportive	Biological or Mechanistic studies
Prerequisite	Chemical Profiling (for identity and substances of interest)
Supportive	History of use data

Level (**)	Type of Evidence	Type of Study	Grade A Claims Scientifically established	Grade B Claim Well supported (can contribute)	Grade C Claim Traditional
1b IIa	Human Experimental	RCT (fully randomized)	2 convergent studies with at least 1 RCT on the preparation	Convergent body of evidence, including at least 1 x clinical controlled study or quasi-experimental study	Should be identified and reviewed as part of the overall evidence mix, in the absence of, or complementary to published meta-analyses or monographs
		Significant experimental studies with varied randomization and control			
IIb	Human Quasi-Experimental	e.g. Observational studies with intervention + variable randomization/control	Non-randomised trials, and/or observational studies, and/or mechanistic studies Also reviewed as part of the evidence mix	Also reviewed as part of the overall evidence mix	
III	Human Observational	e.g. Cohort, Case Control, Cross-Sectional,			
		Other (e.g. case history, consumer satisfaction)			
IV	Experts Consensus	Experts opinions			
	Mechanistic (Human, animal or in vitro)	Mode of Action	As required	as required	Generally not required
		Bioavailability			
	Chemical Profiling	Precise Characterisation, including markers or actives	Required	Required	Required
	History of Use	Authoritative Publications		Supportive	Preferred
		Professional Writings			Required as mix of evidence of use
		Industry Sales Data			
		General Bibliography			

Adaptation of the EFSA Approach



What do we do with the Document?

Step 1: Consult with Industry

- ✓ Ehpm member Associations
 - ✓ Their member companies
 - ✓ Other significant parties in the industry
- ✓ Other elements of the industry not represented:
 - ✓ E.g. FSE, Food & Drink Federation
 - ✓ Industry in not-represented Member States

Step 2: Consult with National Regulators and Legislators

- *Ehpm can co-ordinate this, but only national associations and their local businesses can persuade MEPs to what we want*

Step 3: Consult with European Commission and **MEPs**

- *Ehpm can co-ordinate this, but only national associations and their local businesses can persuade MEPs to what we want*

Concluding Observations

Ehpm members need to be aware that this Discussion Paper reflects the considerable work in particular of SYNADIET (France) and FEDERSALUS (Italy). For Example:

The **SYNADIET** working Group, represented by Helene Kergosien:

- Have analysed and sorted the On-Hold claims ;
- Continue to analyse claims, using the outcomes to inform the *ehpm* model;
- Engaged leading scientific experts in developing the GRADE approach in general and the Grade B Approach in particular.

FEDERSALUS:

- Have managed to achieve in Italy a large market for botanical food supplements with a large list of recognised botanicals with associated claims.;
- Under the co-ordination of Stefania Mariani, they are currently collating data on this list that can be used as evidence for plausible traditions of use in support of Grade C claims.

End of Presentation.
Thank you for your Attention

The Legislative Options

1. New Implementing Regulations
 - Unlikely because of current interpretation of 'generally accepted science';
2. Amend the NHCR to allow for New Implementing Regulations
3. Parallel Legislation under Food Law*
 - a. All botanicals
 - b. Botanical Food Supplements only

** Of you were to do this it would make sense to do it for other substances as well*

The NHCR Problem & Solution

Aspirations of NHCR <i>(Preamble)</i>	Current Situation	Solution
Facilitate Informed Consumer Choice	✘	✓
Protect Consumers from being misled	✓	✓
Assist Harmonisation of Internal Market	✓	✓
Encourage research and business (also for SMEs)	✘	✓
Scientific Assessment under the NHCR		
High Quality Scientific Assessment	✓	✓
Generally Recognised Science (prioritise human evidence)	✓	✓
Only certainty claims established by scientific consensus of proof	✓	✘
Reflect the nature of food and its effects on health;	✘	✓
Recognise the challenges food poses to scientific health research	✘	✓