

Substantiation of claims

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Chairman EHPM**

Legal requirements

- Many countries in the world have some form of legislation for claims – health or nutritional.
- Europe works on harmonisation: “**Regulation for Nutrition and Health Claims made on foods**”
- Key question: What level of evidence is required for which type of claim??

EU Claims Regulation

- ➡ Nutrition and health claims shall be based on and substantiated by **generally accepted scientific data** (*knowledge – evidence*)
- ➡ A food business operator making a nutrition or health claim shall justify the use of the claim.
- ➡ Claims to be evaluated before market access

EU: CLAIMS RELEVANT TO FOOD AND FOOD COMPONENTS

◆ WHAT THE PRODUCT CONTAINS

- e.g. **nutrient content claim** (e.g. low fat, fat free, high in vitamins) or comparative claim (e.g. increased, reduced, light).
- ‘**Other substance**’ claim (e.g. polyphenols, omega-3, glucosamine, probiotic)

◆ WHAT THE PRODUCT DOES

- well-established nutrient function claim; enhanced function claim (ARTICLE 13)
- reduction of disease risk claim (ARTICLE 14)

ARTICLE 13 Generic claims **- positive list -**

- **Based on generally accepted scientific data**
(knowledge – evidence)
- **Well understood by the average consumer**
- **Generic list to be submitted by Member States - with reference to scientific justification and conditions of use**
- **Evaluated by EFSA and adopted**
- **→ no authorisation required for use of these claims**

**EFSA TO DEVELOP RULES AND GUIDANCE
on SCIENTIFIC DATA (*evidence*)**

HOW WILL THE SCIENCE BE ASSESSED?

HOW MUCH SCIENCE DO YOU NEED?

Prior activities

- WCRF (1997)
- US FDA CFSAN (1999)
- WHO Report on Diet and Health (2004)
 - All three above used grading of evidence -
- ILSI Europe PASSCLAIM (2001-2005)
 - Criteria for scientific substantiation – project involved many independent scientists
- UK Joint Health Claims Initiative
- Netherlands Model Paper Dec 2004
 - Drew on earlier work to propose approach



Process for the Assessment of Scientific Support for Claims on Foods

PASSCLAIM

A European Commission (EC) Concerted Action
organised by International Life Science Institute -
ILSI Europe

SOURCES OF SCIENTIFIC SUPPORT

- ✓ National/international expert consensus reports, including authoritative statements
- ✓ Human intervention studies, including use of biomarkers
- ✓ Human observational/epidemiological studies
- ✓ Animal and *in vitro* studies
- ✓ Traditional knowledge and experience of use

Insufficient Possible Probable Convincing →

In vitro or animal studies only

Small uncontrolled human studies

Epidemiological data with contradictory results

Single large human study
 + contradictory epidemiological data + supportive epidemiological data

Multiple small human studies
 + consistent results with flawed designs + consistent results with good designs

Meta-analysis

Single small human study
 + supportive laboratory data

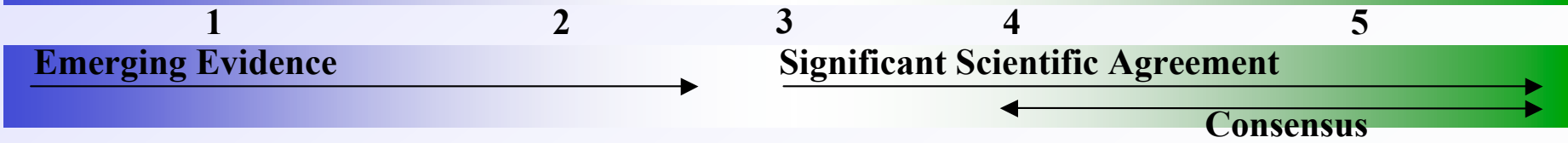
Critical reviews by experts

Epidemiological data with consistent results
 + Difficulty measuring + contradictory lab data + biological plausibility and consistent lab data

Evidence accepted by scientific bodies or independent expert bodies

- e.g. Judgements by government-related organisations (EFSA, FDA, AFSSA, ...)
- e.g. Judgements by expert organisations (WHO, SACN, NAS, ...)
- e.g. Judgements by scientific organisations (ESPGHAN, ...)
- e.g. Recent acknowledged text books
- e.g. Monographs (ESCOP, ...)

History of use



**ISSUE: COPING WITH CONSENSUS AND
EMERGING EVIDENCE.**

**Weight of scientific evidence is
sufficient to permit a conclusion that
a change in dietary intake of the
food or food component will result in
a health benefit**

TOTALITY OF AVAILABLE DATA AND WEIGHT OF EVIDENCE

Factors to be considered include:

- **Persuasiveness of each relevant study**
- **Consistency of results across different studies**
- **Consistency among various populations and within them**
- **Magnitude of the effect**
- **Strength of the association**
- **Dose–response relationships**
- **Temporal relationships**
- **Biological plausibility**
- **Specificity of the effect**
- **Statistical validity**

NUTRIENT FUNCTION CLAIMS

Calcium	Bone health	Convincing
Vitamin D	Bone health	Convincing
Folate	Normal development of neural tube	Convincing
	Heart health	Probable
	Cognitive function in elderly	Possible

PROPOSED TABULATION FORMAT OF CLAIMS FOR ARTICLE 13 (CIAA/EHPM/ERNA initiative)

Food or food component	Diet & health relationship	Any conditions for claim to be valid	Source & nature of evidence	References	Example of Claims Wording

Substance

GLUCOSAMINE

Diet & health relationship

Joint health

Conditions

1.5 g/day glucosamine sulphate

Source/nature of evidence

Systematic review

References

Towheed *et al.* (2005) Cochrane Database Syst. Review (2): CD002946

Register JY *et al.* (2001) *Lancet* 357, 251–256; Jordan *et al.* (2003) *Ann. Rheum. Dis.* 63, 1145

Example of claims wording

**May help to maintain healthy joints;
Improves mobility; Helps to keep
your joints supple and flexible**

Conclusions



Consumer confidence in claims is critical from the consumer, government and industry points of view.



Industry should take the lead and start to prepare lists.



EHPM/ERNA/CIAA have taken the initiative



Questions :



What initiatives are going on in your area?



How can we enlist your help and that of your member companies (specific ingredient manufacturers) to make this into a success?