



Compiling your dossier - what the EFSA guidance doesn't tell you

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Overview

- Guidance Physical Performance
- Case for caffeine & performance
- Peer-review vs. EFSA evaluation - GAP!?
- Scientific criteria evaluation art. 13(1) vs. art. 13(5)/14 claims
- Implications

Guidance

- Increase in physical performance during short-term high-intensity exercise
- Increase in endurance performance
- Increase in endurance capacity
- Reduction in the rated perceived exertion/effort during exercise

Guidance

- Increase in physical performance during short-term high-intensity exercise
 - increase in physical performance during short-term high-intensity (>80 % maximum O₂ consumption) exercise.
 - Performance relates to the ability of completing a certain task (e.g. running a certain distance) as fast as possible.
 - E.g. sprint

Guidance

- Increase in endurance performance
 - increase in endurance performance (i.e. during longer-term exercise generally at intensity <80 % maximum O₂ consumption).
 - Performance relates to the ability of completing a certain task (e.g. running a certain distance) as fast as possible.
 - E.g. Time-trial (TT)

Guidance

- Increase in endurance capacity
 - Endurance capacity refers to the exercise time to self-reported fatigue when exercising at a constant workload or speed, generally at intensity <80 % maximum O₂ consumption.
 - Time-to-exhaustion (TTE)

Guidance

- Reduction in the rated perceived exertion/effort during exercise
 - Reduction in the rated perceived exertion/effort during exercise.
 - E.g. RPE-questionnaire

Caffeine & Performance

EFSA opinion

- Meta-analysis by Doherty and Smith (2004)
- 40 laboratory-based, double-blind, fully randomised (and mostly cross-over), placebo-controlled intervention studies on adult subjects
- 76 different outcome measures!!
- 414 subjects (mean sample size 9.3 ± 2.5 subjects)
- *published in peer-reviewed Journals in English after 1975*

(Isolated) soy protein

Meta-analyses may wrong-foot you!

Soy protein and lowering of LDL-cholesterol

Regular consumption of 1 to 2 servings of soy protein daily (15 to 30 g) has a significant favorable impact on serum lipoprotein risk factors for CHD.

Anderson & Bush. J Am Coll Nutr. 2011 Apr;30(2):79-91.

(Isolated) soy protein

EFSA opinions:

(Isolated) Soy protein and lowering of LDL-cholesterol

Cause and effect relationship not established

EFSA J. 2010;8(7):1688

EFSA J. 2012;10(2):2555

Caffeine & Performance

- published in peer-reviewed Journals in English after 1975

GAP?



- Peer-reviewed studies

Pertinent studies HC

Criteria peer-review

Prof. Albert Flynn (chair NDA-Panel):

“scientific criteria peer review and criteria for scientific evaluation HC applications are the same”

Only: the objectives are different!

*KNAW Health Claims symposium
Amsterdam 26 March 2012*

Objectives peer-review?

To establish:

- Significant advance in an experimental method, clinical practice, or fundamental scientific knowledge
- Originality and quality of research

Objectives EFSA evaluation?

To establish:

- Cause and effect relationship
- Food constituent defined and characterized
- Claimed effect physiologically beneficial

*KNAW Health Claims symposium
Amsterdam 26 March 2012*



Scientific Criteria

peer-review vs EFSA

Prof. Albert Flynn (chair NDA-Panel):

“**scientific criteria** peer review and criteria for scientific evaluation HC applications are the **same**”

Only: the objective is different!

*KNAW Health Claims symposium
Amsterdam 26 March 2012*

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[Int J Sport Nutr Exerc Metab.](#) 2011 Feb;21(1):55-64.

Daily probiotic's (*Lactobacillus casei* Shirota) reduction of infection incidence in athletes.

[Gleeson M](#), [Bishop NC](#), [Oliveira M](#), [Tauler P](#).

School of Sport, Exercise and Health Sciences, Loughborough University, Loughborough, UK.

Abstract

The purpose of this study was to examine the effects of a probiotic supplement during 4 mo of winter training in men and women engaged in endurance-based physical activities on incidence of upper respiratory-tract infections (URTIs) and immune markers. Eighty-four highly active individuals were randomized to probiotic (n = 42) or placebo (n = 42) groups and, under double-blind procedures, received probiotic (PRO: *Lactobacillus casei* Shirota [LcS]) or placebo (PLA) daily for 16 wk. Resting blood and saliva samples were collected at baseline and after 8 and 16 wk. Weekly training and illness logs were kept. Fifty-eight subjects completed the study (n = 32 PRO, n = 26 PLA). The proportion of subjects on PLA who experienced 1 or more weeks with URTI symptoms was 36% higher than those on PRO (PLA 0.90, PRO 0.66; p = .021). The number of URTI episodes was significantly higher (p < .01) in the PLA group (2.1 ± 1.2) than in the PRO group (1.2 ± 1.0). Severity and duration of symptoms were not significantly different between treatments. Saliva IgA concentration was higher on PRO than PLA, significant treatment effect F(1, 54) = 5.1, p = .03; this difference was not evident at baseline but was significant after 8 and 16 wk of supplementation. Regular ingestion of LcS appears to be beneficial in reducing the frequency of URTI in an athletic cohort, which may be related to better maintenance of saliva IgA levels during a winter period of training and competition.

PMID: 21411836 [PubMed - indexed for MEDLINE]

[+](#) Publication Types, MeSH Terms, Substances

[+](#) LinkOut - more resources

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[Review Biological effects of impact does l \[Int J Immunol](#)

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Scientific criteria

Art. 13(1) vs. art 13(5)/14

- Clarification specific issues paper (clock stop)
- Not addressed in article 13(1) opinion!

Walnuts & endothelium-dependent vasodilation

- One pertinent study in healthy human hypercholesterolemic volunteers (Ros et al., 2004)
- One supportive study in medicated type 2 diabetes patients (Ma et al., 2010)
- One supportive acute study (Cortès et al., 2006)

Acceptable for art. 13.5/14 claim?

Caffeine & Performance

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Peer-review & EFSA

Indeed,
scientific criteria acceptance peer-reviewed journal
apparently differ from
scientific criteria for health claim substantiation!

Scientific criteria claims

Apparently
scientific criteria evaluation art. 13(1) claims
may differ from
scientific criteria art. 13(5)/14 claims

Implications

Redoing peer-review!!

Peer-reviewed should be meticulously screened for potential flaws in study methodology/statistics before paper can be included as pertinent -

EFSA mindset!!

Newly designed studies should be targeted at HC substantiation

- ‘proof’ vs. ‘significant advance’

- ‘Established’ methodologies
- ‘Validated’ techniques

- Be mindful of the ‘peer-review mindset’ when collaborating with CRO/academic group

A vibrant landscape featuring a large field of tulips in various colors (red, orange, yellow, pink, purple) stretching towards a traditional Dutch windmill. The sky is bright blue with scattered white clouds. The text "Thank you!" is overlaid in a large, orange, italicized font across the middle of the image.

Thank you!

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