



EFSA assessment of health claims

Procedural aspects

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- Article 14 and 13.5 applications
 - Communications between applicants and EFSA
- Procedural aspects of Article 13 claims evaluation

EFSA health claims evaluation status (30 April 2010)

Claim type	Received	Withdrawn	Adopted	In progress
Children (Art. 14)	219	32	48 opinions covering 55 applications	2*
Disease risk reduction (Art. 14)	48	7	15	7**
New science/ proprietary (Art. 13.5)	36	8	22	5***
Total - applications	303	47	85 covering 92 applications	19
Art 13 list of health claims	4637	298	1080 (937 published)	3259

* 1 in clock stop
 ** 5 in clock stop
 *** 0 in clock stop

Reduction of disease risk/development and health of children

- Application submitted through Member State to EFSA
 - EFSA check completeness, not legal scope
 - EFSA informs other MS, EC, publish summary on web
- EFSA evaluation
 - adopt opinion (5 months + 2 months if additional information needed)
 - opinion published, sent to EC
 - 30 days for public to comment to EC
- EC takes decision through regulatory procedure with scrutiny
 - Decision is notified to applicant and published in OJ
- Article 13.5 claims mainly similar

Communication between EFSA and applicants on individual applications



Contact point is NDA staff in charge of the application

In principle 5 stages

1. Indirectly via admissibility check with Member States
2. Before EFSA considers an application complete (applicant is also informed when the clock starts)
3. During evaluation - EFSA request for supplementary information ('stop the clock' procedure)
4. Before publication of adopted opinion
5. Indirectly after publication of opinion via EFSA response to Commission in relation to scientific comments raised during public comment period

NDA staff

Administrative completeness checking including

- ✓ Clear identification of food/constituent for which the claim is made (consistency throughout application)
- ✓ Clear definition of claimed effect: a defined claimed effect including identification of (surrogate) endpoint(s) and methods of measurements, identification of a risk factor(s) for disease risk reduction claims
- ✓ Conditions of use

Selection of food/constituent and claimed effect are key decision points for the evaluation

‘Stop the clock’ procedure

NDA Experts - case-by-case judgement

- Independent discretionary decision of NDA experts based on scientific consideration
- Clarification of aspects of data provided/not provided in the application
- Questions related to the definition of the claim - proposed food/constituent, claimed effect, risk factors, target population, conditions of use
- 2 clock stops in 2008, 11 in 2009, 14 in 2010 (June)

Before publication

EFSA sends to applicants a copy of the adopted opinion in advance of publication

- For information
- For applicant to indicate any mistake in the opinion
- To check that no confidential data are disclosed
- But not for re-opening the evaluation

- Public has opportunity to provide comments to the Commission on published EFSA opinions (within 30 days)
- EFSA is asked by the Commission to provide input on comments of scientific nature
- As appropriate EFSA is asked by the Commission for additional advice, e.g.
 - Quantification of the cholesterol lowering effect of plant sterols/stanols taking into account possible matrix effects
 - Labelling reference intake values for n-3 and n-6 PUFAs
 - Risk factors for caries
 - Conditions of use for DHA/ALA claims
 - Clarification on satiety claim

- Update of EFSA briefing document on claims as additional issues are identified
- Plan to provide additional guidance in selected areas including stakeholder consultation on
 - which claimed effects are beneficial physiological effects
 - studies/outcome measures acceptable for substantiation
- First stakeholder consultation envisaged in autumn 2010.
Possible topic: gut and immune function claims

General function claims (Art. 13.1)

- A list of 4,185 claims submitted by EC to EFSA (Jul/Nov/Dec 08)
- EFSA screening (Jan 09)
 - Approx. 2,000 required further clarification by EC/MS
- Additional clarification on product/comparative claims (June 09)
- Feedback from COM/MS on claims sent back (Nov 09, Mar 10)
 - Comparative claims to be evaluated (60 claims)
 - Product specific claims: out of 260 claims - 180 claims withdrawn
 - In total around 300 claims withdrawn (including product specific claims)
 - For ca 620 claims no clarification provided
- Addendum received in March 2010: 452 claims (mainly botanicals)

Status of list on general function claims

4,637 claims received in total

1,080 claims evaluated (937 claims published)

297 claims withdrawn

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- Σ 3,260 claims still to be evaluated by EFSA
 - EFSA will continue to adopt and publish claims opinions in series to ensure transparency and to keep the workload manageable
 - EFSA is trying to be as efficient as possible in combining claims into series of opinions to be published
 - Next publication of claims opinions: Sept 2010

Finalisation of Article 13 claims

- Envisaged deadline to complete all claims evaluation:
December 2011
- Overall timeframe may need to be reconsidered in case new priorities emerge, in particular in the context of a possible resubmission under Article 13.5 of those Article 13 claims for which the Panel already issued an opinion and which are on the Commission “grey list”

Article 13 Access database

- 9 (revised) Access databases received between July and Dec 2008
- One combined database published in Jan 2009
- Since publication, a number of changes made to the list, e.g. reallocating misplaced claims, adding missing claims, clarification on vague claims, addendum
- Updated Access database published in April 2010
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_article13.htm
- Contains 4637 main entry claims and ca 10,500 similar health claims clustered with this main entry claims

Health relationship: Intestinal health

- too unspecific

Proposed wordings:

C 0: "Support gastrointestinal health" / "Supports better bowel performance" / "Supports regular **bowel movements**" / "For a regular bowel motion" / "Supports **bowel transit**" /

C 3: Helps to support the digestion; contributes to the function of intestinal tract

- Only if it was very obvious from the list provided that food/constituent was not characterised, claims were sent back for more clarification on the characterisation, e.g. dairy products', 'soups'
- Out of over 4000 claims only 94 claims sent back for clarification on characterisation

NDA Panel considered during **scientific evaluation** whether the information provided was sufficient to characterise the food/constituent in relation to the claimed effect

Literature provided

- Compilation of references for around 2200 claims covering around 40,000 individual references already finalised and published

<http://www.efsa.europa.eu/panels/nda/claims/article13.htm>.

- EFSA continues with compilation of references for remaining claims
- Quality of literature far from optimal (e.g. incomplete citations, relevance of literature provided)
- Difficulties with translations of references provided in other languages than English
- Accessibility to some references

Examples of references provided

Ezekiel 27.17. The Old Testament In: The Holy Bible. (For “*Panax ginseng*” and “*Cognitive performance*”)

(Full text: Judah and Israel gave you their finest wheat, fancy figs, honey, olive oil, and spices in exchange for your merchandise.)

Tea association, 2003. Classical drink as trend: tea consumption stable at a high level. German tea industry satisfied with financial year. Press Release.

Caffeine. 2000. In: The American Heritage Dictionary of the English Language.

British Royal Air Force, 1966. Report der British Royal Air Force.

Beck, L, The complete idiot's guide to total nutrition for Canadians.

Wikipedia, Tribulus, <http://en.wikipedia.org/wiki/Tribulus>

Examples of clarification provided

Food original:	clarification	Health relationship original	Clarification
Breakfast	breakfast which include ready-to eat breakfast	mental performance and wellbeing in the morning	same
Fish (fresh and frozen)	same	heart health	promotes heart health through adequate levels of blood pressure, cholesterol, platelet aggregation, inflammatory response, TG. Promotes growth and development and function of the brain, through the content of omega 3, iodine and vitamin D

Communication on Article 13 claims

- EFSA's contact point for any issues related to Article 13 list is the European Commission/ Member States
- Information on each claim including evaluation status and or deadline is available through
 - EFSA Register of Question
<http://registerofquestions.efsa.europa.eu/roqFrontend/login>
 - Claims Access Database
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_article13.htm
- At least 48 hours before publication of next series of Article 13 opinions, EFSA will provide stakeholders with a list of claims concerned

THANK YOU FOR YOUR KIND ATTENTION

