



# **Update on EFSA's evaluation on health claims**

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- Latest update Article 13
- Latest update Article 14
- Default approach by EFSA
- Technical meeting with stakeholders on health claims

## Regulation (EC) 1924/2006 (Recital 23)

- Health claims should only be authorized for use in the Community after a **scientific assessment of the highest possible standard**
- In order to ensure harmonized scientific assessment of these claims, the **European Food Safety Authority** should carry out such assessments

**EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) adopts scientific opinions**

- 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  - Product specific claims: out of 260 claims - 180 claims withdrawn
  - In total around 300 claims withdrawn (including product specific claims)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

993 claims evaluated (937 claims published)

297 claims withdrawn

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- $\Sigma$  3,347 claims still to be evaluated by EFSA
- Next publication of claims opinions: Sept 2010
- Envisaged deadline to complete all claims evaluation: December 2011, but may need to be reconsidered if new priorities emerge

# Article 13 Access database

- 9 (revised) access databases received from MS/COM between July and Dec 2008
- One combined database published in Jan 2009
- Since publication, a number of changes made to the list, e.g. re-allocating misplaced claims, adding missing claims, clarification on vague claims
- Updated access database will be published in the coming weeks

[http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_article13.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_article13.htm)

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### Consolidated list of Article 13 health claims

For Conditions of use, Nature of evidence and Scientific references see similar health relationships submitted by Member States

**Criteria for the initial screening of Article 13 (3) health claims**

**Disclaimer for the Article 13 list of health claims**

Food	Health relationship	Example of wording	Stakeholder Coding	EFSA Comments	EFSA Deadline
Vitamins, in general	Development, growth, body maintenance, body metabolism and equilibrium	-vitamin(s) help to maintain a strong body;-vitamin(s) are needed/important for your body;-vitamin(s) are needed for body metabolism.	1	3	to be negotiated
<input type="text" value="1"/> <b>Similar health relationships submitted by Member States</b>		Quantity <input type="text" value="15"/>	Addition / New similar <input checked="" type="checkbox"/> Other changes <input type="checkbox"/>		
Clarification Food	Clarification Health relationship	Clarification wording	Comments from Member States		
Vitamins, in general	Normal healthy growth and maintenance of the physiological process in the body because vitamins are essential compounds required by every living cell for all metabolic.	-vitamin(s) help to maintain a strong body; -vitamin(s) are needed/important for your body; -vitamin(s) are needed for your body metabolism.			
Changes to Food <input type="checkbox"/>	Changes to HR <input checked="" type="checkbox"/>	Changes to Wording <input type="checkbox"/>			
All vitamins	Reproduction	XX contributes to normal reproduction. I XX is needed for reproduction. II		0	31 July 2009
<input type="text" value="2"/> <b>Similar health relationships submitted by Member States</b>		Quantity <input type="text" value="1"/>	Addition / New similar <input type="checkbox"/> Other changes <input type="checkbox"/>		
Clarification Food	Clarification Health relationship	Clarification wording	Comments from Member States		
Changes to Food <input type="checkbox"/>	Changes to HR <input type="checkbox"/>	Changes to Wording <input type="checkbox"/>			
All vitamins	Conception	XX contributes to normal conception. IXX is needed for conception. II		0	31 July 2009
<input type="text" value="3"/> <b>Similar health relationships submitted by Member States</b>		Quantity <input type="text" value="1"/>	Addition / New similar <input type="checkbox"/> Other changes <input type="checkbox"/>		

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# EFSA Publication of Art. 13 opinions in series

- Progressive adoption/publication of opinions in order to comply with requirements for transparency and to keep workload manageable
- EFSA is trying to be as efficient as possible in combining claims into series of opinions to be published
- At least 48 hours before publication of next series of Article 13 opinions, EFSA will provide stakeholders with a list of claims concerned

# Commission 'Grey' list of claims already adopted by EFSA

1. Microorganisms not characterised (170 claims)
2. Evidence insufficient to establish cause and effect relationship (20 claims)
3. Claims based on “tradition of use”
4. Evidence in sick people

1 and 2: may be resubmitted to EFSA – impact on EFSA’s workload

3 and 4: ongoing discussion with MS and Commission

- EFSA is not rejecting reference textbooks and monographs – these were reviewed to see if they contain pertinent scientific data; if there are such data, it is taken into consideration.

In other words:

- All data available to EFSA from which scientific conclusions can be drawn (supportive/not supportive) are considered pertinent by EFSA and weighed for the evidence.

# Health claims application evaluation status (24 March 2010)

Claim type	Received	Withdrawn	Adopted	In progress
<b>Children (Art. 14)</b>	217	32	48 opinions covering 55 applications	1*
<b>Disease risk reduction (Art. 14)</b>	48	5	15	6**
<b>New science/ proprietary (Art. 13.5)</b>	34	6	15	12***
<b>Total - applications</b>	299	43	78 covering 85 applications	19

\* 1 in clock stop

\*\* 1 in clock stop

\*\*\* 1 in clock stop

# EFSA opinions on Art 13.5/14 claims (March 2010)

78 opinions adopted - within legal deadlines

[http://www.efsa.eu.int/EFSA/efsa\\_locale-1178620753812\\_1211902056325.htm](http://www.efsa.eu.int/EFSA/efsa_locale-1178620753812_1211902056325.htm)

- Opinions reflect varying quality of the evidence submitted
- Transparency of opinions & dialogue with applicants
- EFSA dialogue with Commission after opinions adopted (comments, wordings)
- EC + Member States - authorisation decisions ongoing
- First authorisations adopted into EU Law
  - list of permitted claims + list of rejected claims

- EFSA will seek additional advice from Commission and Member States on certain possible compliance/eligibility issues for health claims.
- Default approaches as outlined in the EFSA briefing document, e.g.
  - Comparative claims: EFSA will consider whether food/constituent has an independent role in the claimed effect or whether role is based on the inclusion or substitution of other substances
  - Target population: EFSA considers that where a health claim relates to a function that may be associated with a disease, subjects with the disease are not the target for that claim

- Frequently Asked Questions (FAQ) related to the EFSA assessment of Article 14 and 13.5 health claims applications (public consultation, meeting with applicants, revised version published in September 2009)

[http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1211902433897.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902433897.htm)

- Briefing document for Member States and European Commission on Article 13.1 health claims list (meeting with MS & Commission, revised version published 18 November 2009)

[http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1211903064774.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211903064774.htm)

- EFSA presentations at various meetings
- Clock the stop procedure (request for supplementary information related to health claims applications) frequently applied before publication of opinions related to health claims application

## Technical meeting with Stakeholders on Recent Developments Related to Health Claims

1 June 2010, Parma, Italy

Registration open up to 3 May 2010

<https://services.aimgroup.it/ASPClient/home.asp?EventoID=2617>

The objective of the meeting is to provide an update on EFSA's health claims evaluations and to have an exchange of views between experts from food industry/applicants, Member States, European Commission, NDA Panel members and EFSA staff.

Member State experts, officials from the European Commission and experts from food industry will be invited to contribute to the meeting.