

EFSA's Modus Operandi for Article 13 (3) Health Claims of Regulation (EC) No 1924/2006

PUBLISHED LIST

The consolidated list of Article 13 health claims published on the EFSA website in the form of an Access database contains 4,637 health claims (main entries) with corresponding conditions of use and literature for about 10,500 similar claims/health relationships.¹

Each claim (main entry) includes an identification number provided by the European Commission, the name of the food, the proposed health relationship, examples of wordings and a stakeholder coding, if available, which is based on a previous food industry claims list (CIAA/ERNA/EHPM list, October 2007). Many main entry claims have associated with them a number of similar health claims (health relationships) which were identified by the European Commission from the lists of health claims provided by Member States. These contain an identification of the country that submitted the claim, a Commission identification number, the name of the food, the proposed health relationship, the conditions applying to them, the references for the scientific substantiation, example of wordings, and a stakeholder coding, if available.

EFSA is asked to evaluate the main entry claims only, but taking into account the conditions of use and references provided in the similar health relationships.

¹Lists of Article 13 health claims received by EFSA from the Commission:

July 2008: draft list with 2,870 main entries and about 7,000 similar health relationships in 9 separate Access files including 885 botanicals). This was a consolidated list of Article 13 claims submitted by Member States to the European Commission (about 44,000 claims in total, accompanied by the conditions of use and by references for the scientific substantiation).

November 2008: list with 3,138 main entries and over 8,000 similar health relationships in 8 separate Access files (the Access file for health claims for botanicals was not included). This was a revision of the draft list received in July 2008.

December 2008: list of health claims (mainly for botanicals) with 4,185 main entries and about 10,000 similar health relationships in 9 separate Access files. This was a revision of the draft list received in July 2008.

March 2010: addendum to the list with 452 main entry claims (single entries with no additional similar health relationships). This was an addition to the list received in July, November and December 2008.

Upon request of the European Commission and Member States EFSA re-allocated after publication of the first version of the Access database on the EFSA website in January 2009 a number of similar health claims which had been accidentally placed under a wrong main health claim entry (misplaced claims). During this process some Member States also identified a number of missing similar health claims which still needed to be submitted to EFSA (“missing claims”). These similar claims were also added to the database under the appropriate main entry claim.

Detailed information on each claim, including evaluation status, question number and proposed deadline for completion of evaluation is also available through the [EFSA Register of Questions](#).

SCREENING OF CLAIMS

EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out. The outcome of this screening is indicated for each claim (main entry) on the list. Those claims for which more information or clarification was needed were classified in the list according to the six screening criteria (numbered 1-6).

Subsequently, the European Commission coordinated with Member States the provision of the information or clarification which was requested by EFSA and EFSA received this information in November 2009.

The clarifications which were received by EFSA through this process have been included in the Access database in separate fields underneath the information which had originally been provided. This additional information will serve as clarification to the originally provided information. Comments which have been provided by the Member States in this process and which are also made available in the Access database will be taken into account if related to the matter for which EFSA had requested clarification and which were not included in the other fields, i.e. additional information on the food/constituent, health relationship or conditions of use.

Screening criteria

1. Claims where clarification on legal scope is needed (e.g. claims referring to risk reduction or referring to children’s development and health, or medicinal claims)
2. General well-being claims where the health relationship is not clear, e.g. “Compound X supplementation to sustain vitality while aging”
3. Claims which are too vague (claimed effect not specified/measurable), e.g. Compound X and “energy and vitality”. Proposed wording: Compound X is “necessary to maintain energy and general vitality”
4. Foods which are not sufficiently characterised or conditions of use are not sufficiently specified
5. Combination constituents that are not sufficiently defined
6. Claims in languages other than English (to be returned for translation). If EFSA is asked to carry out the translations, EFSA will send translated claims back to Member States for validation of the translation.

TIMELINES FOR EVALUATION

EFSA envisages completing its work by 31 December 2011 on the evaluation of all health claims contained in the consolidated list of Article 13 health claims which have so far not been adopted by EFSA.

However, this timeframe may need to be reconsidered in case new priorities emerge for the evaluation of Article 13 health claims

REFERENCES

The consolidated list of Article 13 health claims as published in the form of the Access database does not include all references that EFSA uses to evaluate Article 13 health claims, as EFSA has received references from the Member States also via the Commission in separate files and directly from stakeholders.

The deadline for submitting scientific references to the Commission was 31 January 2008 at the latest, as outlined in Article 13(2) of the Regulation (EC) No 1924/2006. Following 31 January 2008, it was agreed that industry as well as Member States could submit those scientific references as full copies already submitted to the Commission in accordance with the deadline of 31 January 2008, directly to EFSA to facilitate its work. The deadline for this was December 2008 at the latest. In order to ensure an equal treatment for all claims EFSA did and does not accept any additional references submitted after this deadline.

EFSA wishes to acknowledge the full-text copies of relevant literature provided by stakeholders.

A [compilation of the references](#) for around 2,200 claims is already published on the EFSA website, which correspond to around 40,000 individual references. This compilation includes the references for main entry claims which have passed the EFSA pre-screening as well as the references for those main entry claims for which an opinion of the NDA Panel has been published after having received clarification from Member States via the European Commission in November 2009. EFSA is continuing to compile the references for the remaining claims and will update the documents containing the list of references.

DISCLAIMER

The list of Article 13 health claims published on the EFSA website constitutes an EFSA working document for internal use. This list is not, and cannot be interpreted as being, representative of the final Community list of permitted health claims to be adopted by the European Commission in accordance with Article 13 (3) of Regulation (EC) No 1924/2006.

The framework of the Health Claims Regulation (EC) No 1924/2006 does not foresee a safety evaluation of the food or one of its component nor a decision on whether the food or one of its components is or is not, classified as a foodstuff.

EFSA is not accountable for the content of the list as the content lies solely within the responsibility of the European Commission/Member States. Therefore questions related to this (updated) list should be directed to the respective National Competent Authority or the European Commission.
