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PRESS RELEASE

EFSA provides guidance to applicants on health claims
Final Guidance Document published

Following public consultation, the European Food Safety Authority (EFSA) has today published its final guidance to applicants on the submission of health claims for authorisation. During the consultation of the draft document useful comments were received from stakeholders and Member States and all of them were considered by the NDA Panel[1]. The guidance will help companies who want to submit health claims for authorisation. It addresses what they need to include in their application, in particular concerning the scientific data and evidence required to support claims.

EFSA has given the opportunity to Member States and stakeholders to comment on the draft guidance document on disease risk reduction claims and claims for children. A technical meeting with experts of the Stakeholder Consultative Platform[2] was held on 11 June in Parma, discussions with experts from Members States took place and in addition the draft Guidance Document was placed on the EFSA website for public consultation

Comments received during the consultation covered issues such as the type and level of evidence needed for substantiation of the claim; information on the characteristics of the product such as its composition and the manufacturing process; and consumer understanding of claims. Altogether some 300 comments were received. Whilst the overall principles and approach for substantiating claims initially put forward in the draft Guidance Document have not changed, all comments received were thoroughly considered by the Panel.

The consultation led to text changes resulting in a clearer, simpler and more user-friendly document. Examples have also been added to assist the applicants. Following questions raised during the consultation, clarifications have been made for instance regarding the type of information required for a claim concerning an ingredient or a food and the type of human studies to be considered.

The issue of consumer understanding was perceived as one of the key topics. In the event of a favourable opinion, the NDA Panel will evaluate the wording of the health claim proposed by the applicant. In doing so, the Panel will seek to ensure that it reflects the scientific evidence and is understandable in terms of its relevance for human health. Where required, the Panel may recommend changes based on their scientific assessment. The Panel will ensure that claims that are

[1] NDA Panel: Panel on dietetic products, nutrition and allergies
[2] Information about the Stakeholder Consultative Platform at
http://www.efsa.europa.eu/en/stakeholders_efsa/consultative_platform.html

considered from a scientific point of view to be vague, confusing or misleading will not receive a favourable opinion.

EFSA expects now to receive the first applications as regards disease reduction claims and claims referring to children's development and health (article 14 of the Regulation[3]). Following a completeness check and the formal acceptance of the validated dossiers the Panel will assess the health claim and provide a scientific opinion within 5 months.

The full Guidance Document can be found on the EFSA website at
http://www.efsa.europa.eu/en/science/nda/nda_opinions/claims/ej530_guidance_health_claims.html

Related information is available at
http://www.efsa.europa.eu/en/press_room/press_release/pr_nda_guidance_health_claims.html
http://www.efsa.europa.eu/en/in_focus/nutrition_health.html.

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[3] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_012/l_01220070118en00030018.pdf