Call to Action: Let's get EFSA to stop misleading the public about healthy foods and nutrients

Public consultation: "Draft guidance for the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health".

EFSA consultation page: https://www.efsa.europa.eu/en/consultations/call/170712

Closing date for consultation: 3 September 2017.

Comments can be made by any interested party, company or person that is based in the European Union.

Comments should be made on the electronic template.

Link to ANH feature on this consultation.

The big question is this: will EFSA's draft guidance improve the success rate?

We are not convinced it will – and that it will only benefit a few companies – especially those with deep pockets who can afford to play the new rules of the game - while ignoring decades of research that has until this point built the foundation of public health policy in the field of nutrition. It will further distort the science and in EFSA's attempt to be the scientific arbiter, public health in the EU will have been done a further major disservice.

Following are some important principles we think need to be communicated to EFSA in its consultation.

Comments should be given to particular sections. ANH-Intl will be making a comprehensive submission by the deadline of 3 September 2017. We wish to argue that a minor tweak to EFSA's guidance is unacceptable and a sea change in approach is required. The more consultation responses that support this view, the more impact it will have. We therefore outline below some key points relating to the sections on Generic Comments and Antioxidants that can be used in part or in full in your responses to EFSA that should be made using this link.

COMMENTARY ON SECTION 0. GENERIC COMMENTS:

Requirement for a global change to EFSA assessment approach

Article 6(1) of the Nutrition and Health Claims Regulation (1924/2006/EC requires that "…health claims shall be based on and substantiated by generally accepted scientific

evidence", while Article 13(1)(c)(ii) also requires that such claims are "well understood by the average consumer."

EFSA has evolved a highly reductionist approach, that relies almost entirely on the data that have been submitted by an applicant while ignoring the peripheral, existing evidence. This approach fails to meet the legal requirements and results in discretion, disproportionality and inequality in considering the overall evidence in relation to beneficial foods and nutrients.

For example, it is not scientifically rational that there is an authorised claim for 15% of the Nutrient Reference Value (150 mcg/dose) of copper (this amount being arbitrary and unrelated to the scientific evidence for the mineral in question) relating to "the protection of cells from oxidative stress", while there is no claim for any botanical substance for this same function. This is despite generally accepted evidence that plant-based diets are strongly associated with protection against oxidative stress and chronic disease risk, viz (including references therein): Hever J, Cronise RJ. Plant-based nutrition for healthcare professionals: implementing diet as a primary modality in the prevention and treatment of chronic disease. J Geriatr Cardiol. 2017; 14(5): 355–368.

EFSA should review the entirety of its approach, not simply tweak guidelines, a process that prevents the claims authorisation pathway being accessible to corporations other than the largest. The latter represent the only stakeholder group with the financial capacity to pay for the EFSA-specific trials that are effectively creating a new paradigm in nutritional science that is becoming ever-closer to the approach required for drug licensing.

Validate the new approach using model nutrient groups

The starting point for any such approach is ensuring that the methodology used by EFSA delivers a positive opinion for nutrients for which there is generally accepted scientific evidence of beneficial properties.

Given the complexity of nutritional science, the evidence is generally more robust for classes or groups of nutrients consumed as part of a food matrix than it is for individual, isolated compounds in foods.

Good examples that would be useful candidates allowing evaluation of the suitability of EFSA's assessment methodology would be polyphenols or flavonoids, as found in fruits and vegetables.

From causal evidence to evidence of association

One of the major stumbling blocks for EFSA is its decision to require causal evidence of a highly conclusive or unequivocal nature. Such a view requires that the totality of scientific evidence on which a claim is based is entirely free of any contradictions. This is very rarely the case with nutritional science, where the evidence continues to emerge and for which there are differences in individual response as result of differences in nutritional requirement, physiological stress, gene expression, epigenetic background, polymorphisms, xenobiotic exposure, etc.

The nature of nutritional research and public health policy that has evolved alongside it is that evidence of association has been sufficient to justify the vast majority of public health

advice, such as salt reduction, increased fruit and vegetable intake or decrease in certain categories of food (e.g. foods high in sugars, processed meats).

For the purpose of the Regulation and to ensure the public is both informed and not misled, EFSA should adapt its scientific approach so as to include evidence of association between the consumption of particular foods or nutrients and beneficial effects.

Such an approach would then allow health claims to be made for a wide range of foods with known beneficial properties such as polyphenol-rich berry fruits which have yet to receive authorised health claims.

Another indication of the failure of EFSA's assessment methodology is the rejection of health claims for any of the essential amino acids, without which humans cannot survive.

From conclusive to plausible evidence

Linked to the need by EFSA, in order to fulfil its role as a scientific assessor, is the degree of conclusivity of the evidence. It is well established that nutritional science is rarely black and white, and given it is an emerging science that relates to a highly complex and variable interaction between multiple population groups, is not appropriate that only highly conclusive evidence is accepted.

The notion of graded evidence has already been widely used in many branches of medical and nutritional science. It continues to be used effectively by the Therapeutic Research Center's Natural Medicines™ Professional Database (https://naturalmedicines.therapeuticresearch.com/), formerly Natural Standard™, where the available proposed evidence is broken into one of 6 categories depending on the strength or conclusivity of that evidence: https://naturalmedicines.therapeuticresearch.com/grading.aspx.

Given that establishing highly conclusive evidence, either for licensed pharmaceutical products and even more from foods and related substances, that are consumed alongside varying diets by highly variable population groups, provision of plausible evidence should be sufficient.

The dismissal of health claims based on all but highly conclusive evidence has resulted in hundreds of plausible or credible claims, such as the benefits associated with consumption of essential amino acids, being rejected and now being 'non-authorised' throughout the EU. Of relevance here is the US case, Alliance for Natural Health USA vs Sebelius (786 F.Supp.2d 1 (D.D.C. 2011), in which the Alliance for Natural Health USA successfully challenged the imposition of a ban on qualified health claims for the antioxidant status of vitamins C and E by the US Food & Drug Administration (FDA). The threshold required for making qualified health claims in the US is "significant scientific agreement" which is similar to the EU's "generally accepted scientific data" requirement established in the Regulation (1924/2006) on nutrition and health claims. In summary, the District Court of Columbia found that evidence is rarely conclusive or significantly agreed. A ban on the health claims was regarded as an infringement of a manufacturer or seller's First Amendment right to freedom of expression and the only legal requirement was that the evidence be credible scientifically. We raise this case because we suggest that plausible or credible evidence should be a sufficient threshold of evidence to allow a health claim to be made on the basis

that conditions relating to it, these being based on the scientific assessment of the food or substance in question, are met.

Adaptation of health claim wording to fit with current nutritional scientific knowledge

Another approach that should be taken by EFSA and the European Commission in the determination of authorised health claims is to allow food business operators to communicate the presence of a specific food or nutrient that is associated with a dietary regime for which there is generally accepted evidence of benefit, e.g. the Mediterranean diet.

By way of example, olive oil with the claim to promote heart health was issued with a negative opinion by EFSA in 2011 (http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2044/abstract).

However, the Cochrane Collaboration has found that there is "limited evidence to date [that] suggests some favourable effects on cardiovascular risk factors" from the Mediterranean diet (Rees et al. 'Mediterranean' dietary pattern for the primary prevention of cardiovascular disease. *Cochrane Database of Systematic Reviews* 2013; 8 (CD009825). DOI: 10.1002/14651858.CD009825.pub2; http://www.cochrane.org/CD009825/VASC_mediterranean-diet-for-the-prevention-of-cardiovascular-disease). More recently, the PREDIMED study has found that additional olive oil consumption as part of a Mediterranean diet improves HDL which is associated with reduced cardiovascular disease risk (Hernáez et al, Mediterranean Diet Improves High-Density Lipoprotein Function in High-Cardiovascular-Risk Individuals Clinical Perspective. *Circulation*, 2017; 135 (7): 633 DOI: 10.1161/CIRCULATIONAHA.116.023712).

Based on these kinds of evidence, EFSA should be able to flex any originally proposed wording to meet the current state of knowledge of the nutritional science. In the case of olive oil, the following proposed wording entirely meets the legal requirements of Article 13(1) of the Regulation, being substantiated by both Cochrane and PREDIMED (among other scientific studies/publications):

> "contains olive oil, daily consumption of 15-60g/day of which is associated with a reduced risk of heart disease"

COMMENTARY ON SECTION 3.1: FUNCTION CLAIMS RELATED TO ANTIOXIDANTS

Antioxidant is a property of a nutrient

It is accepted that the process by which homeostatic redox status is maintained in humans is highly complex, and one that varies in space and time, both between and within individuals. This homeostatic mechanism is ultimately down to a balance between exogenous and endogenous antioxidants and pro-oxidant load, this in turn being the result of
metabolic/physiological function and pro-oxidant exposure.

However, in an effort to help consumers make informed decisions about their diet, it is important that food business operators can communicate to consumers about those foods or substances that are rich sources of nutrients that are able to act as antioxidants.

Contrary to the opinion of EFSA, it is generally accepted scientifically that foods or nutrients that increase "overall antioxidant capacity of plasma", as demonstrated from *in vivo* human studies, are beneficial to humans. That is because they have the potential to combat pro-oxidant load. If the food contains significant amounts (e.g. >250mg) of polyphenols per portion, there are ample data to show these foods are beneficial.

This should allow general function claims for foods that meet specific conditions i.e. amounts of polyphenols (total or specific) per portion or dose, e.g. "[food x] contains polyphenols that are a dietary source of antioxidants."

Dietary antioxidants: hybrid nutrition and functional health claims

EFSA's reductionist approach separates out functional antioxidant effects from reduction of disease risk, yet the two are interconnected. This is well illustrated by the research on polyphenols, and is discussed by Roche et al. (Representative literature on the phytonutrients category: Phenolic acids. *Crit Rev Food Sci Nutr.* 2017; 57(6): 1089-1096; http://www.tandfonline.com/doi/abs/10.1080/10408398.2013.865589?journalCode=bfsn20) who state "research has emerged in strong support of the antioxidant capacity of polyphenols and their role in the prevention and/or treatment of certain cancers, diabetes, cardiovascular diseases, and inflammation."

Therefore, the significant presence of antioxidants such as catechins, ellagic acid, gallic acid, tannic acid and capsaicin should allow a nutritional claim for a functional category of nutrient, such as flavonoids. Such nutritional claims for functional substances, that could be referred to as 'hybrid nutritional and functional claims' should be authorised subject to conditions (notably concentration/daily intake of beneficial compounds in the functional group) without any need for further scientific substantiation.

Such an approach not only better fits the intent of the Nutrition and Health Claims Regulation, it also reduces the assessment burden on EFSA and the requirement for stakeholders to undertake new scientific research that aims simply to meet EFSA's guidelines for scientific substantiation.