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Nutrition Congress 2017: Food enrichment with omega-3: new oilseed sources and algal oils for microencapsulation and delivery of healthy lipids- Francois Andre Allaert- Cen Nutriment Dijon

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In the European Regulation 1924/2006 and especially its first recital; the evaluation of health claims (HC) by European Food Safety Agency (EFSA) was introduced so as "to ensure a high level of consumer protection, [and] give the consumer the necessary information to make choices in full knowledge of the facts…" Now, with 10 years of hindsight since the Regulation was adopted, it can be asked whether EFSA HC process of evaluation that led to a marginal number of accepted claims is consistent with this objective, not just for protecting consumers nonetheless for allowing them to decide freely and make informed choices. The aim of this paper is to demonstrate that the inclusion of a ranking of the weight of evidence in the assessment of EFSA's scientific substantiation of HC would allow consumers to benefit from the very high standard of scientific evaluation performed by EFSA. The definition of standards of proof is a generalized practice and rests on the principle that evaluations of health practices should be understood in terms of descriptions ranging from formal proof from high-power double-blind placebo-controlled studies to rankings based on the consensus views of experts or even agreement among professionals. Grading of weight of evidence – not of scientific expertise – is pervasive in all the recommendations or consensus meetings of health authorities or learned societies. This approach would stimulate research and product innovation as industrials would see a positive return on investment. The transition from an all-or-nothing system of health claims to a system graded by weight of evidence would be an alternative to the current system.

This approach would be more consistent with the rationale of European Regulation which aims both to provide consumers with the best possible information by giving them the opportunity to exercise their free will in full knowledge of the facts and to promote research that meets sound scientific and medical grounds providing a basis for such information. The true target population is often a population experiencing discomfort or with a risk factor of illness but not the entire population. The idea of healthy population must change a minimum of in what's meant by the term "healthy". However, in order to show the existence of a clinical benefit, some discomfort should actually be present and/or a biological parameter actually be disturbed either by short fall or surfeit. Everything then hangs on the definition and assessment that separates the physiological and the pathological states. Limits have been set for many metabolic risk factors such as the level of glycaemic or lipid parameters, but they are somewhat artificial and it is known that the progression of risk with biological factors is a continuum. However, to be able to show a difference in the effect of a product versus a placebo or an identical matrix without the added ingredient, it is necessary for sufficiently intense discomfort to be present or for a biological parameter to have available a large enough room for potential improvement. This is one of the great difficulties in demonstrating the effectiveness of dietary supplements or enhanced food stuffs. The margins for improvement are rather narrow, making improvement difficult to demonstrate and requiring very large numbers in each group. These selection criteria also raise the issue of the population under consideration and many claims are rejected on the grounds that the population in the trial does not correspond to the general population, particularly in the area of joint discomfort. Should it not be considered that by definition, the clinical trial is an experimental situation that does not correspond to a common life situation, particularly because of other inclusion and exclusion criteria that are used to limit risks or a void interference with the parameters under study, and therefore it is a model devised to demonstrate efficacy. It is often only in observational studies that the health benefit provided in everyday practice can be truly observed. One line of thought might be to accept the experimental proof and pair it with the issuing of a claim, possibly of grade "B", by matching it with the need to provide data in everyday practice in the context of a reappraisal of the claim. This situation is now commonplace in the domain of medical devices and medication where virtually any marketing authorization or any inclusion on the list of products refunded under the health insurance scheme involves an obligation to provide concrete evidence of the benefits. It might also be imagined that rather than the effect being demonstrated in at least two clinical studies, a clinical study and an observational study on a large population might be preferred. This position would probably not be as sound in purely statistical terms for the alpha risk but would allow a more concrete evaluation of the product by giving indications from the outset about dimensions that the clinical trial cannot assess because of its controlled character. These factors shall be expanded on in the following subsections.

The definition of standards of proof is a generalized practice and rests on the principle that evaluations of health practices should be understood in terms of descriptions ranging from formal proof from high-power double-blind placebo-controlled studies to rankings based on the consensus views of experts or even agreement among professionals. Grading of weight of evidence – not of scientific expertise – is pervasive altogether the recommendations or consensus meetings of health authorities or learned societies. This approach would stimulate

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