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1409 Lack of Toxicity of the Omega-3 Fatty Acids, EPA and DHA

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There is general consensus among authoritative and regulatory bodies that intake of the n-3 long-chain polyunsaturated fatty acids, Eicosapentaenoic Acid (EPA) and Docosahexaenoic Acid (DHA), is associated with potential health benefits. However, there is inconsistent or missing guidance on tolerable upper intake levels (ULs), which the Codex Alimentarius Guidelines on Nutrition Labelling indicates should be taken into account when establishing Nutrient Reference Values (NRVs) for the general population. Thus far, there is neither a no observed adverse effect level (NOAEL) nor a lowest observed adverse effect level (LOAEL) for EPA or DHA, alone or combined. Since the establishment of an UL is dependent upon the existence of a NOAEL or LOAEL, an UL has not been set. In fact, for the last 25 years, every known comprehensive safety evaluation has concluded that there is insufficient evidence to establish an UL for EPA and DHA, alone or combined. In 2005, a workshop convened by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) was held with the purpose of discussing a model for nutrient risk assessment. Of particular interest were nutrients without reported adverse health effects. For such nutrients, the highest observed intake (HOI) level was introduced as a strategy to provide guidance to risk managers. "The HOI is derived only when no adverse health effects have been identified. It is the highest level of intake observed or administered as reported within (a) study(ies) of acceptable quality." While there is a desire to establish a NRV for EPA+DHA, it will require an acceptance of utilizing HOI. Recent safety evaluations concluding an absence of sufficient evidence to establish an UL for EPA and DHA, alone or combined, provided levels at which there existed no safety concerns. The European Food Safety Authority (EFSA) and the Norwegian Scientific Committee for Food Safety (VKM) indicated 5 g/day and 6.9 g/day respectively – levels at least 20X higher than the FAO minimum recommended intake of 250 mg/day