Abstracts

Scientific Colloquium N°26 on Risk Benefit Assessment of combined exposure to Nutrients and Contaminants through food | On-line meeting, 15-16-17 February 2022

Overall Objectives of the Scientific Colloquium

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Risk-benefit assessment is a critical element in evaluating the safety of food. It requires that potential risks from consuming certain foods is weighed against its nutritional benefits. One prominent example is that of fish consumption. This is of relevance to risk managers and consumers alike. In 2021 EFSA received a draft mandate from the European Commission to prepare a risk-benefit assessment (RBA) of fish consumption in relation to the presence of dioxins (PCDD/Fs) and dioxin-like PCBs (DL-PCBs) and considering how the presence of other contaminants in fish, such as methylmercury, brominated flame retardants (BFRs) and perfluoroalkyl substances (PFAS), influence the outcome of the risk benefit assessment (RBA).

The need for an updated EFSA guidance to conduct the RBA requested by the EC was identified by the scoping taskforce, based on input from the EC and Member States who expressed the need for an RBA outcome that can be used to provide support for defining fish consumption advice at national level. The existing EFSA Guidance for conducting a human health RBA of foods, published in 2010, was reviewed and discussed. This Guidance aims at producing commonly used composite risk-benefit metrics, such as disability-adjusted life years (DALYs) and quality-adjusted life years (QALYs), which are useful comparative measures of risk-benefit among various exposures. However these parameters cannot be interpreted in terms that could support Member States in defining fish consumption advice. Therefore, the existing EFSA RBA guidance was considered insufficient to guide the development of a RBA as requested in the current mandate, it is evident that an updated guidance that takes into account the latest methodologies and addresses the needs of decision makers is needed. While not included in the ToR of the EC mandate, the EFSA SC is undertaking an update of the guidance by end 2023 as the basis for further work on the issue.

The purpose of this colloquium is to discuss current approaches to risk-benefit analysis, novel methodologies that provide practical information to decision-makers, data requirements and availability, and aspects of risk perception and communication. The outcome of the colloquium will be the starting point for the update of EFSA's Guidance on RBA.

Need for scientific advice on risks and benefits of consumption of food in relation to the presence of contaminants and nutrients

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The EU General food Law (Regulation (EC) 178/2002) and the EU legislation on contaminants (Regulation (EEC) No 315/93) provide that food can only be placed on the market, when it is safe. For contaminants, this means that a food containing a contaminant in an amount which is unacceptable from the public health viewpoint shall not be placed on the market. Furthermore, contaminant levels shall be kept as low as can reasonably be achieved by following good practices at all stages of the production chain (the so-called ALARA principle).

Maximum levels for several contaminants are set taking into account the outcome of the risk assessment performed by EFSA and at levels that are achievable by following good practices at stages of the production chain to ensure a high level of public protection. Compliance with the maximum levels ensure in most cases that the European citizen is exposed to a contaminant at a level below the Health Based Guidance Value (HBGV) or results in an Margin of Exposure (MOE) that is of no health concern.

However, the presence of not all contaminants in all foods can be minimized/prevented by applying good practices to levels that ensure a human exposure below the HBGV or result in an MOE that is of no health concern for all population groups in all exposure scenarios. This is because the presence of a contaminant in food is sometimes related to factors that cannot be managed by fishermen, farmers or food business operators because of unavoidable background environmental contamination, necessary processing steps, climate change, extreme weather conditions …

On the other hand, such foods can be an important source of nutrients of which the intake is necessary and consumption of these foods provide nutritional benefits for public health. It is therefore important that the nutritional benefits of these foods are weighed against the potential risks related to the presence of contaminants in these foods.

A risk-benefit assessment of consumption of such foods for different groups of the population in which the nutritional benefits are weighed against the potential risks

related to the presence of contaminants, is necessary in support of defining dietary consumption advice ensuring a high level of public health protection.

Current approaches to Risk-Benefit Assessment – Experience gained

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Risk-benefit assessment of food is the estimation and comparison of the overall health impacts of different intake scenarios, and has gained increased interest as including and combining both beneficial and adverse health effects, when providing dietary guidance, intuitively is perceived as the right thing to do.

Holistic health assessment of foods has been known for many years, but during the last decades, the development of risk-benefit assessment has been advanced through European research projects, guidance documents, and numbers of performed case studies. One of the fundamental thing differentiating former holistic assessment with today's risk-benefit assessment is the ability to quantify health effects and introduction of a common health metric, like the Disability-Adjusted Life Year (DALY). Despite the establishment of RBA as a scientific robust and useable methodology, it has only to a very minor extent being implemented in regulatory settings.

To date, almost 200 risk-benefit studies has been performed, most of them about fish and fish products. The remaining studies has focused on other specific food and nutrients, fortification, cooking preparation methods, whole diets, etc. Recently, substitution has been included as an important aspect of the risk-benefit assessment to make more realistic intake scenarios. Lack of data, especially dose-response data, are considered as a challenge in risk-benefit assessment and could lead to greater uncertainty. As in risk assessment, uncertainty and variability are challenges in risk-benefit assessments, and the suggested approach is to identify, characterize and quantify them, if possible.

The future aim within risk-benefit assessment will be to strengthen the methodology to improve transparency of risk-benefit management decisions and dietary recommendations, and thereby lead to enhanced public health outcomes. An interesting perspective will be to include parameters of sustainability and economy in the health-based risk-benefit assessment.

Risk-benefit assessment for the breastfed infant in relation to the presence of dioxin-like compounds as determined from the WHO and UNEP global human milk surveys

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Despite being banned in the 1980's, dioxin-like compounds (DLCs) are still omnipresent in human milk. This presentation describes a risk-benefit analysis based on the results of decades of WHO global human milk surveys and a critical review of multiple health-based guidance values (HBGVs) set by various regulatory agencies. Formally, these HBGVs for DLCs have been established to protect human health for a lifetime exposure but should not be used for the breastfed infant situation. However, much of the underlying experimental data of DLCs for these HBGVs addresses a relatively short early life-time exposure situation, including the lactational period. This should be considered the strongest scientific toxicological argument to use these HBGVs for DLCs also for the breastfed infant.

When using these various HBGVs for DLC levels in human milk as determined in the WHO surveys, it must be concluded that these are still exceeded by one order of magnitude or more in industrialized countries in the period 2000 to 2019. When e.g., HBGVs for the breastfed infant of 1 or 0.1 pg TEQs/kg/day are used to calculate future acceptable levels of DLCs in human milk, it can be expected that these levels may not be attained before 2030 or 2050. A similar approach is possible for non-dioxin like PCBs and brominated diphenylethers as again many of the underlying experimental studies also concern short term and early lifetime exposures.

For this risk-benefit analysis the subtle adverse health effects of DLCs in the breastfed infant that were reported during the 1990's has been compared with the confirmed health benefits of breastfeeding for the infant and mother. Based on the combined information, it is concluded that the benefits of breastfeeding grossly outweigh the potential adverse health effects of these DLCs. This conclusion is supported by many clinical epidemiological studies that focused on the health situation of the breastfed versus non-breastfed infant. Consequently, it must be concluded that the WHO has rightfully stimulated breastfeeding for the last decades.

Trends and developments in the assessment of nutritional health benefits of consumption of food

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The health risks and benefits of specific foods are of great interest to consumers but are not easily determined. In principle, these could be best studied by randomizing large numbers of people to consumption or not of a specific food and following them over their

lifetime. Not only is this not feasible, but even if this were possible for all commonly consumed foods, the results would depend on which foods were substituted isocalorically, the amount of the food consumed, the other foods in the diet, and the definition of the health outcomes. The result would be further complicated if these theoretical studies started at different times in life. Because the ideal studies are not possible, risks and benefits will usually need to be made by piecing together evidence from different types of studies that include analyses of the composition of foods, short term randomized trials with risk factors for disease as the outcomes, and long term epidemiologic studies with clinical outcomes or mortality. The balance of risks and benefits can probably be best considered as a spectrum from highest risk to highest benefit because this balance is most realistically expressed relative to specific alternative foods. Further, this spectrum is probably best considered within major food categories, such as major protein sources, carbohydrate sources, and fat sources. While current knowledge is far from complete, we have sufficient data to provide at least approximate ordering for many foods within these categories, and strong evidence that this ranking can predict health outcomes. In addition to direct effects on individual health, a full consideration of risk and benefits should also consider public health, which would include effects on climate change, antibiotic resistance, and pandemic risks.

The influence of trust and perception of risks and benefits of consumption of food: needs from a consumer point of view in relation to dietary advice

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Consumers' food choices and dietary behavior are markedly affected by information and personal attitudes. Whether provided information is processed by the target group – and thus becomes likely to be effective in terms of altering food-related attitudes and changing food consumption behaviour – depends on numerous factors including risk-benefit perceptions. A particular challenge in this respect pertains to the role of traditional versus new social media and balancing the risk versus the benefit component in future communication.

This contribution will present insights from a diversity of empirical food consumer studies. As a first example, insights will be shared from a study on consumer acceptance of an online tool with personalised risk-benefit communication about seafood consumption. Although in this case health benefits outweigh risks for the general population, caution may be needed for specific vulnerable consumer groups. It has been shown that in such a case an online tool informing consumers of the health risks and benefits linked to their consumption pattern is perceived as user-friendly and useful, and therefore promising in

specific situations. It has also been shown that consumers are not necessarily scared off by provided risk information but able to cope with balanced risk-benefit information.

This contribution will also address the role of communication and information provision as potential factors shaping consumer responses and public attitudes to emerging technologies used in food production and processing. Consumers may be quite sceptical about the application of new technologies in food production, especially in cases where the technology is unknown or unfamiliar, associated with possible and unclear risks, and perceived as offering no tangible or merely irrelevant benefits. As a second example, the case of cultured meat will be addressed where perceived barriers – including a lack of trust – emerged as being twice as powerful compared to motives in shaping consumers' willingness to eat this product.

The presentation will furthermore integrate findings from studies on consumer response to health risk-benefit and environmental sustainability information; it will address consumer confidence in food, food processing and the food industry; consumers' personal response strategies and expectations towards restoring consumer confidence following food safety incidents and related risk communication; and trust and credibility of information sources and their usage to obtain nutrition information. Finally, conclusions and recommendations for the provision of information about food products in relation to the presence of contaminants and nutrients will be presented.