BRAFO

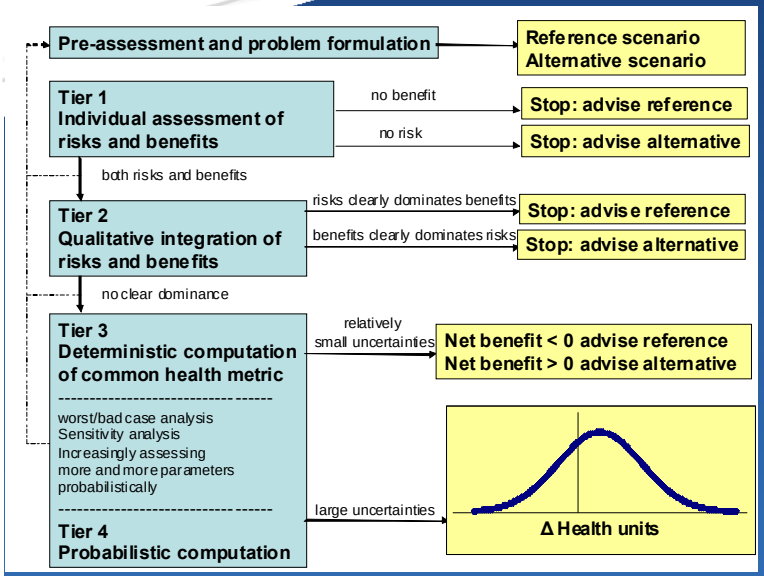
ILSI International Life Sciences INSTITUTE

Risk Benefit Analysis of Foods

The aim of BRAFO, a project funded by the European Commission and coordinated by ILSI Europe, is to develop a framework that allows quantitative comparison of human health risks and benefits of foods and food compounds based on a common scale of measurement. It is based on the evaluation of changes in the quality/duration of life using a system that allows weighting of data quality and severity of effect, with quantification by QALY or DALY-like methodology. The framework took into account how risks and benefits interrelate. It is intended that the methodology developed is sufficiently transparent to serve as a reference for the harmonisation of the evaluation methods used within the European Union and more widely in international evaluations. The European network (BRAFO) was set up in September 2007, which involves expertise in risk/benefit analysis and nutrition, with representatives from academia, regulatory agencies and the food industry. The BRAFO Consortium is made of the European branch of the International Life Sciences Institute (ILSI Europe, BE), Imperial College London (ICL, UK), the Rijksinstituut voor Volksgezondheid en Milieu (RIVM, NL), the Max Rubner Institute (MRI, DE) and Procter and Gamble (P&G, BE). Additionally more than 50 “external experts”, mostly from academia, are also involved in the different work packages.

A methodology group reviewed and assembled the methodologies available relevant to the evaluation of risks and benefits in food, producing a guidance document that describes a tiered ('stepwise') approach for performing a risk and benefit assessment. This process starts with a pre-assessment and problem formulation step to set the scope of the assessment. This includes defining two scenarios for comparison in the assessment: the reference scenario (e.g. current diet, or a zero intake scenario), and an alternative scenario (e.g. introducing a new food or food policy). The approach consists of 4 tiers. In many cases, a lower tier assessment using simple methods may be sufficient to show a clear difference between the health impacts of the two scenarios. In other cases, increasingly sophisticated methods are used at higher tiers until there is sufficient certainty for decision-making.

The tiered approach assesses the risks and benefits of changing from the reference scenario to an alternative, resulting in a statement about which scenario is preferred in terms of health effects.



In Tier 1, each risk and benefit is assessed independently. These assessments will often use standard screening methods, but it may be worth using more refined methods if this avoids the need to proceed to Tier 2. Tier 1 comprises a separate, but as comprehensive as needed risk assessment, and a separate benefit assessment.

In Tier 2, risks and benefits are compared in a qualitative way; no common metric is used yet. Although the assessment of each individual risk or benefit can be quantitative or even probabilistic

In Tier 3, risks and benefits are integrated quantitatively in a common metric, by a deterministic approach

In Tier 4, risks and benefits are integrated quantitatively in a common metric by a probabilistic approach

The steps needed to reach a conclusion in each tier follow largely the same steps as in the risk assessment paradigm. But after the first tier, comparison (tier 2) and integration (tier 3 and 4) of the risks and benefit follow.

The development of the risk-benefit framework was expedited by its use on a number of selected examples of foodstuffs and food components. In October 2008, the three case study groups commenced work on applying and adapting the methodological approach developed to undertake a risk assessment, a benefit assessment, and quantitative net health impact assessment on the selected cases. The three case studies are: Natural Foods, Dietary Interventions and Heat Processing.

Case study on natural foods

Oily fish is an exceptionally good example of consumer confusion and therefore has been selected as a case study. Both, qualitative and quantitative review on benefits and risks within BRAFO will link to the work developed in the EU funded project QALIBRA, in which fish in general is one of the case studies. Therefore, based on the present benefit calculations it is concluded that the consumption of 200 g/week of oily fish is more beneficial than no consumption at all as it resulted in a significant reduction of incidence of cardiovascular diseases. Although this scenario increased the intake of contaminants, for methyl-mercury as well as for dioxins the intake will still be lower than the toxicological endpoint. **Soy** has been selected as the second case study of a natural food because it is recognised as a healthy natural food delivering various essential nutrients. In addition, soy intake is associated with a reduced risk for cardiovascular disease. However, phytochemicals occurring naturally in soy such as the isoflavones can have both, beneficial as well as adverse effects as demonstrated in a number of animal studies. For this case study, it was not advised to go to Tier 3. Soy protein consumption would result in an overall benefit for the general adult population.

Case study on dietary interventions

The work of this group comprised examples of food fortification and macronutrient replacement/food substitution: **folic acid**, the isocaloric replacement of **saturated fatty acids with carbohydrates**, the replacement of **saturated fatty acids with monounsaturated fatty acids**, and the replacement of **sugar-sweetened beverages** containing mono- and disaccharides with low calorie sweeteners. The isocaloric replacement of saturated fatty acids described an overall health benefit in relation to cardiovascular disease, in the absence of health risks. Finally, an example of addition of specific ingredients to food: **chlorination of drinking water was addressed**. The respective examples illustrated how the BRAFO-tiered approach provides for various results, ranging from a quick stop as the result of non-genuine benefit-risk questions to continuation through the tiers into deterministic/probabilistic calculations.

Case study on heat processing

Building on existing information related to the benefits and risks associated with changes potentially formed during such processes, this work package focused on a variety of areas. This ranged from individual components (e.g. **acrylamide or benzo(a)pyrene**) as well as on microbiological issues and available data on health risks associated with them, to the collection of information on other substances/parameters associated with the presence of potential risks. This work package addressed also some changes, seen as (potentially) beneficial, including relevant components (e.g. nutrients in the **milk treatment** case study) coming from raw materials.

The results on the applicability of the BRAFO methodology on the case studies were presented and discussed at a second workshop in October 2009 in order to adapt the methodology according to the findings of the case studies.

Following this last workshop, the BRAFO Consensus work package started its work. The aim of this group is to knit together the work performed by the different expert groups. It will establish the extent to which the BRAFO methodology applied to the three case studies is broadly applicable across various risk/benefit categories by updating the framework document/methodology with experience obtained from adapting it to the case studies. Priority will also be given to the harmonisation of the approaches identified by applying the framework to the specific case studies. In addition, the consensus work package will also provide support to the dissemination work package by identifying key messages that need to be further communicated to stakeholders and risk managers.

The BRAFO methodology and its application to the group of case studies will be published in 2010 in *Food and Chemical Toxicology*.

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