Caffeine: Friend or Foe?

Concluding Panel Session:

Discussion on Benefit-Risk Analysis
Disclosure

I have been involved in caffeine and health issues since 1981, when I was employed for 10 years at General Foods and Kraft General Foods; and since 1991 I have consulted for many global companies, trade associations (NCA, SCAA, GMA, ABA) and other organizations (ILSI, IFIC) on caffeine/health issues.
BRAFO

Risk-Benefit Analysis of Foods

Over the past years the risk-benefit analysis in relation to foods and food ingredients gained much attention in Europe but also worldwide. The debate focused mainly on how and when to conduct such analysis.

BRAFO, short for Benefit-Risk Analysis of Foods, developed a framework quantitatively compare human health risks and benefits of foods and food compounds, using a common scale of measurement. Such scale was based on duration and quality of life years with weighting of data quality and severity of effect, with quantification by DALY or DALY-like methodology.

During the first year of the project (2007), the methodology group reviewed the existing methodologies available for risk-benefit analysis, and developed a new draft model. Such draft was applied during the second year of the project through three different case study groups on 1) natural foods like oil, fish and soy, 2) macronutrient replacement agents e.g. sweeteners, fat substitutes, and 3) the impact of heat processing on foods. In the final year the methodological findings of the different case studies were integrated in a final model, which can then be applied to a wide range of foods and food compounds.

The European Commission (DG Research under the Sixth Framework Programme, Priority 6, Food Quality and Safety) financially supported this project, ILSI Europe and its Risk Assessment of Chemicals in Food Task Force acted as Coordinator.

OUTCOMES

- To download the BRAFO Executive Project Summary click here
- To download the BRAFO Consensus paper click here
- To download the BRAFO publications click here

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Benefit-Risk Analysis for Foods (BRAFO)-
Executive Project Summary

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Critical appraisal of the assessment of benefits and risks for foods, ‘BRAFO Consensus Working Group’

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Pre-assessment and problem formulation

Tier 1
Individual assessment of risks and benefits
- no benefit
  - Reference scenario
  - Alternative scenario
- no risk
  - Stop: advise reference
  - Stop: advise alternative
- both risks and benefits

Tier 2
Qualitative integration of risks and benefits
- risks clearly dominates benefits
  - Stop: advise reference
  - Stop: advise alternative
- benefits clearly dominates risks
- no clear dominance

Tier 3
Deterministic computation of common health metric
- worst/bad case analysis
- Sensitivity analysis
- Increasingly assessing more and more parameters probabilistically

Tier 4
Probabilistic computation

Net benefit < 0 advise reference
Net benefit > 0 advise alternative
SCIENTIFIC OPINION

Guidance on human health risk-benefit assessment of foods

EFSA Scientific Committee

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The Scientific Committee of the European Food Safety Authority (EFSA) developed guidance for performing risk-benefit assessments of food. The document focuses on human health risks and human health benefits, and does not address social, economic and other considerations such as “cost-effectiveness” considerations. It is considered as essential that formulation of the problem precedes the risk-benefit assessment as such. Agreement between the risk-benefit assessor and the risk-benefit manager on the terms of reference should be reached in order to ensure that the outcome of the assessment is useful and relevant for the risk-benefit manager goals. A stepwise approach is recommended for the risk-benefit assessment, i.e. i) initial assessment, addressing the question whether the health risks clearly outweigh the health benefits or vice versa, ii) refined assessment, aiming at providing semi-quantitative or quantitative estimates of risks and benefits at relevant exposure by using common metrics, and iii) comparison of risks and benefits using a composite metric such as DALYs or QALYs to express the outcome of the risk-benefit assessment as a single net health impact value. The outcome of each step of the assessment should also include a narrative of the strengths and weaknesses of the evidence base and its associated uncertainties. After each step of the risk-benefit assessment, discussion should take place between the risk-benefit assessor and the risk-benefit manager on whether sufficient information has been provided or whether the terms of reference should be refined in order to proceed with the next step of the assessment. Two examples (selenium as an indispensable nutrient, and fish consumption) illustrate the proposed approach for risk-benefit assessment.
This is hard
Some Questions We Need to Address

1. Do we have too many disease endpoints to even consider trying to develop a benefit-risk analysis? Would it just be too complex?

2. Which risk and benefit endpoints could we evaluate/weigh?

3. Do we have some health benefits that are well-enough established (based on weight of the evidence) at this time?

4. Do we have the quantitative data necessary to accomplish a benefit-risk analysis?

5. How do we handle sensitive sub-population (pregnant women, children) intakes vs. intakes by healthy adults? Separately?

6. Would naturally occurring food/beverage sources of caffeine need to be evaluated separately from caffeine-added products?