A Specific Support Action under the FP6 coordinated by ILSI Europe
Background

FUFOSE 1995-1999
Benefit assessment

Passclaim 2001-2005
Benefit assessment

FOSIE 2000 – 2004
Risk assessment

BRAFO 2007 – 2010
Benefit risk assessment
Objectives

1. 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

2. To test the developed methodology on selected case studies

3. To adjust the model according to the outcomes of the case studies

4. To disseminate the results to as wide audience as possible
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<th>WP leaders</th>
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Pre-assessment and problem formulation

**Tier 1**
Identification and screening
Both risk and benefit expected?

**Tier 2**
Qualitative evaluation

**Tier 3**
Deterministic computation of common health metric
Worst-case assumptions

**Tier 4**
Probabilistic computation
Increasingly assessing more and more parameters probabilistically

Reference scenario
Alternative scenario

Stop
Perform either Risk or Benefit assessment

- Risks clearly dominates benefits
  - Stop: advise reference

- Benefits clearly dominates risks
  - Stop: advise alternative

Both risk and benefit expected?

Yes

- Risks clearly dominates benefits
  - Stop: advise reference

- Benefits clearly dominates risks
  - Stop: advise alternative

No

- No clear dominance
  - Clear net risk
    - Stop: advise reference
  - Clear net benefit
    - Stop: advise alternative

Probability of net benefit

Net health impact

Distribution for health units
The Case Studies

- Soy
- Fish
- Folic acid
- Macronutrient replacements
- Addition Chlorine to water
- Temperature (Acrylamide, BenzoApyrene, Milk)
Reference/alternative scenario
No intake of farmed salmon vs. increased intake of farmed salmon

Benefit-risk factor(s) under consideration
Natural food containing beneficial/adverse constituents

The population
Dutch population

Exposure
Background exposure to beneficial/adverse constituents including n-3 PUFA, Hg, and PCB
The Case Study - Fish

- Fish

Reference: No intake

Alternative: 200 g of farmed salmon (weekly intake)

Problem formulation → Tiers → Conclusions

- Benefits outweigh risks
- Stop after Tier 2
Key messages I

- Problem formulation is essential
- Tiers are useful
- One metric
- Bring together experts (tox., epi., nut.)
- In line with EFSA approach
Key messages II

- Data gaps (availability of disability weights)
- Extrapolation from animal data
- Risk driven
- Transparency of outputs
- BRAFO tiered approach for benefit-risk assessment of foods. Food and Chemical Toxicology (accepted)

- Application of the BRAFO-tiered approach for benefit-risk assessment to case studies on natural foods. Food and Chemical Toxicology (accepted)

- Application of the BRAFO tiered approach for benefit-risk assessment to case studies on dietary interventions. Food and Chemical Toxicology (accepted)

- Application of the BRAFO tiered approach for benefit-risk assessment to case studies on heat processing. Food and Chemical Toxicology (submitted)

- Critical appraisal of a novel methodology to assess benefits and risk for foods. ‘BRAFO Consensus Working Group’. Food and Chemical Toxicology (to be submitted)
New activity

BRAFO follow-up: Derivation of human health metrics from experimental animal data for use in benefit-risk analysis