

This Specific Support Action project is carried out with the financial support of the European Commission, DG Research under the Sixth Framework Programme (FP6), Priority 5, Food Quality and Safety, Contract Number: FOOD-CT-2007-031731

# Risk Benefit Analysis of Foods

As the burden of health costs within society increases due to a longer lifespan, overall balanced nutrition can play an important role in disease prevention. There is considerable disparity in the way benefits and risks are compared for compounds found in food, relying almost always on subjective judgement. This prevents adequate comparison of alternatives and renders resource prioritisation difficult. In addition, it is extremely difficult to provide comprehensible advice to consumers. It is therefore vital that an effective strategy be developed to enable a holistic analysis of the net health impact of chemicals in food to be assessed and quantified, in a manner analogous to the current assessment of risk.



The risk assessment of compounds in food is a mature process that follows a well-developed scientific approach; the strategy followed is the result of a substantial amount of thought and experience. Such a risk assessment has served society well to the extent that it has protected consumers from the potentially harmful effects of chemicals to which they might otherwise have been exposed through food consumption. For chemicals used to secure the integrity of food that require prior approval, such as pesticides or packaging materials, this works reasonably well, although it is difficult to weigh the indirect benefit against residual risk. For chemicals with putative direct health benefits such as vitamins or phyoestrogens, the situation is more complex. It is necessary to evaluate both risks, manifest as negative impacts on health, and those benefits that produce a positive impact on health.

The aim of the project 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 will be 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 will take 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.

A European network 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.

A methodology group reviewed and assembled the methodologies available. This group is now collaborating with three case study groups to integrate the methodological findings in their area and to develop a framework applicable to a wide range of foods and food compounds. The development of a risk-benefit framework will be expedited by its use on a number of selected examples of foodstuffs and food components. Three case studies will be conducted: Natural Foods, Dietary Intervention and Heat Processing. In October 2008, the case study groups have 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. Publications are planned after each of these steps: methodological review, three worked examples and the proposed framework.

**In order to obtain detailed information please visit and register on the BRAFO website at [www.brafo.org](http://www.brafo.org)**

## Objectives of the project

The primary aim of this specific support action (SSA) is to develop a framework that allows for the quantitative comparison of human health risks and benefits in relation to foods and food compounds by expressing these on a common scale, which takes account of quality of data and severity of effect.

The objectives of this project are to:

- Establish a common scale of measurement for comparing risk and benefits of food and food components present in the diet
- Provide a scientific framework to aid in the objective comparison of benefits and risks and in decision-making
- Improve harmonisation of the principles and practices in the risk/benefit analysis process
- Create a stronger scientific base for communication of risks and benefits to the consumer, including appropriate expression of uncertainty.

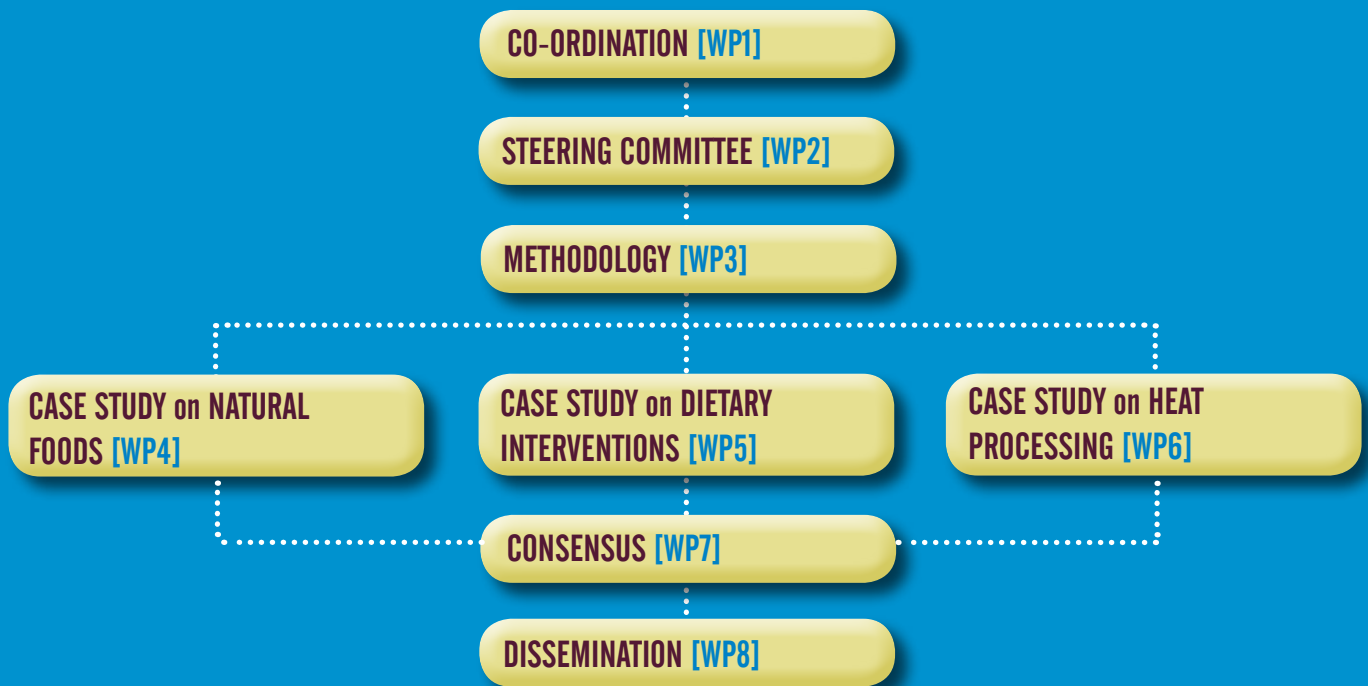
The principal outputs are:

- A website for dissemination of results from this and related projects and to provide an online educational resource for interested stakeholders
- A literature review on the risk-benefit evaluation of food
- A full description of beneficial and adverse effects of BRAFO's targeted food components in the population at large. These examples are organised in three categories: natural foods, foodstuffs used for dietary interventions, and heat processed compounds
- A comprehensive framework that can be used to compare the quantitative and qualitative values of human health risks and benefits of compounds based on the same scale of measurement.

These outputs will lead to the following benefits:

- Improved understanding of the qualitative and quantitative comparison of human health risks and benefits of compounds in foods
- A framework risk-benefit methodology that could be extended to take into consideration indirect health effects, economic, societal and environmental impacts
- The ability to directly compare the net health benefits and net risks of the selected examples
- Improved interaction between European researchers working in the risk and benefit areas, less duplication of effort.

# Structure of the project



## **Work Package 1:** **coordination**

Work Package (WP) 1 is related with project management and further development; it is therefore responsible for all the other work packages' progress and performance. WP1 is also responsible for developing the project's website, keeping the partners informed of the project's progress and their obligations, for satisfying the EC's reporting requirements and for ensuring the scientific quality of the results.

## **Work Package 2:** **steering committee**

WP2 is designed to guide the project's technical work. Its purpose is to provide scientific and strategic advice to the project, using this knowledge to enable the smooth and optimal progression of the project.

## **Work Package 3:** **methodology**

WP3 brings together methodologies from several disciplines relevant to the evaluation of risks and benefits in food. Much of the primary data required for this evaluation will exist in a form that may be only partially useful and these will require remodelling so as to derive better estimates of risks and benefits.

The reprocessing of available data to achieve a standard representation of inputs and outputs (costs and consequences) is required, which in turn necessitates the formulation of agreed guidelines that are common to all constituent elements of the project.

## **Work Package 4:** **case study natural foods**

The natural foods covered within WP4 are fish and soy. An inverse relationship of fish intake to coronary heart disease has been substantiated, but there is also some evidence of a healthy effect of fish intake by pregnant and lactating mothers on the neurological development of foetuses and infants. These beneficial effects are ascribed to the fish oil component: long chain  $\omega$ -3 polyunsaturated fatty acids ( $\omega$ -3 PUFA). As a result the public is advised to increase their fish consumption as in many countries people consume considerably less than optimal. On the other hand it should be noted that fish contains hazardous substances as well like dioxins, PCBs (especially found in oily fish) and methyl-mercury. The negative effects of these substances may for example relate to the development of cancer and developmental changes in the foetus. The assessment will also focus on soy foods (e.g. proteins, isoflavones).

Intake levels of soy have been linked to: reducing the risk of prostate cancer or osteoporosis and the increased risk of breast cancer; however the links between severity of effects, beneficial or adverse, in relation to intake levels, need to be established.

## **Work Package 5:** **case study on dietary interventions**

WP5 will involve assessment of benefits and risks associated with folic acid (as an example of food fortification) and macronutrient replacements (as an example of food substitution). The folic acid example brings together experts in nutrition and safety for folic acid. They will describe in detail the beneficial effects of intake of folic acid across dose levels in qualitative and quantitative aspects, taking into account sub groups perceiving the benefits or risks.

The focus of the macronutrient replacement example is on the quantification of any residual risks associated with the toxicity of these substances at intakes above the Accepted Daily Intake (ADI) or similar accepted levels, the potential for nutritional interferences, and the nutritional benefits associated with typical ranges of intake.

**Work Package 6:  
case study on heat processing**

Building on existing information related to the benefits and risks associated with the chemicals formed in such processes, WP6 will focus on a variety of areas. This will range from individual components (e.g. acrylamide, Benzo(a)pyrene and potentially heterocyclic aromatic amines (HAAs)) and the available data on health risks associated with them, to the collection of information on other substances/parameters associated with the presence of the potential risk substances. The positive/negative impacts of heat treatment versus no heat treatment on milk will also be analysed.

**Work Package 7:  
consensus**

The purpose of the consensus work package is to knit together the work performed by the previous work packages WP3-6. WP7 will establish the extent to which the methodology, as developed by WP3, and applied to WP4-6, 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 to its relation to WP3-6, the consensus work package will also provide support to the dissemination work package WP8 by identifying key messages that need to be further communicated to stakeholders and risk managers.

**Work Package 8:  
dissemination**

WP8 will lead the promotion, marketing and dissemination of the information, ideas and conclusions drawn from the project. This will be done through the publication of two newsflashes and the development of the project's website ([www.brafo.org](http://www.brafo.org)). Particular attention will be paid to ensure that SMEs are made aware of the latest developments in the field. Education of relevant stakeholders will also be an objective of this WP and as such the project website will also host an educational resource that will include an explanation of the project results and their implications, links to external sources of information and contact details for appropriate experts related to the project.



Start of the project: September 2007

Feb 08

INTRODUCTION MEETING

Sept 08

METHODOLOGY GROUP

METHODOLOGY WORKSHOP

1<sup>st</sup> PUBLICATION

Oct 09

CASE STUDIES GROUPS

CASE STUDIES WORKSHOP

2<sup>nd</sup> PUBLICATION

Dec 10

CONSENSUS GROUP

CONSENSUS WORKSHOP

3<sup>rd</sup> PUBLICATION

End of the project: December 2010

## Timeframe

The project started on 1 September 2007 and is intended to run for 40 months until December 2010. This is realistically the minimum timeframe for a project of this magnitude. The work plan has been designed so that most of the work can begin immediately, but some of the tasks require input from other work packages before they can begin their activities. The project management work package (WP1) runs throughout the project, as well as the steering committee (WP2) designated to provide scientific and management support.

Methodologies for the risk benefit assessment in food (WP3) began in September 2007, reached its first results (see below) and presented the outcome during a first workshop in September 2008 in Rome, Italy. This WP3 provided input to WP4-WP6 during their work to ensure that recommended methodology is correctly applied.

The case studies analysis of benefits and risks related to natural foods (WP4), dietary interventions (WP5) and heat processing (WP6) commenced in October 2008 and will continue for one year until October 2009. The results of these case studies will be presented in a workshop in October 2009.

The Consensus Group (WP7) will work from October 2008 to the end of the project in December 2010. The consensus on the outcome will be expected to be achieved during the third and last workshop in December 2010.

Specific measures will be addressed by WP8 and taken to ensure dissemination and provide education to stakeholders and other interested parties. Publications in scientific journals will take place every year after every workshop on the results obtained by 1) the methodology group, 2) the case studies and 3) the consensus.

The first peer-reviewed scientific publication will be produced to disseminate the deliberations and decisions from the work package on methodology. The next publication will serve to report back on the outcome of the case study work packages. The final scientific publication will be the work package on consensus that will focus on the important principles arising from the work packages.

# Partners

Partners	Country	Work Packages	Leaders
International Life Sciences Institute, European Branch (ILSI Europe)	BE	WP1, WP2, WP8	Dr. Stéphane Vidry Mr. Alessandro Chiodini
Max Rubner-Institut (MRI)	DE	WP4	Dr. Bernhard Watzl
National Institute for Public Health and the Environment (RIVM)	NL	WP3, WP5	Dr. Jeljer Hoekstra Dr. Hans Verhagen
Procter & Gamble Eurocor NV/SA (PG)	BE	WP6	Dr. Katrin Schütte
Imperial College London (ICL)	UK	WP7	Prof. Alan Boobis



The International Life Sciences Institute is a non-profit, worldwide foundation established in 1978 to advance the understanding of scientific issues relating to nutrition, food safety, toxicology, risk assessment, and the environment. By bringing together scientists from academia, government, industry, and the public sector, ILSI seeks a balanced approach to solving problems of common concern for the well being of the general public. ILSI Europe, the European branch of ILSI was established in 1986 to identify and evaluate scientific issues related to the above topics through symposia, workshops, expert groups, and resulting publications. The aim is to advance the understanding and resolution of scientific issues in these areas. ILSI Europe focuses on the specific needs defined by the Institute's European partners. <http://europe.ilsii.org/>



The Max Rubner-Institut is a research institution of the Federal Ministry of Food, Agriculture and Consumer Protection. The research focus of the MRI is health and consumer protection in the food sector. Important research fields are the determination and nutritional assessment of health relevant food ingredients, the investigation of careful and resource-preserving procedures of processing, the quality assurance of vegetable and animal food as well as the investigation of the motivation of nutritional behaviour, and the improvement of nutrition information. <http://www.mri.bund.de>



The National Institute for Public Health and the Environment (RIVM) is a recognised leading centre of expertise in the fields of health, nutrition and environmental protection. RIVM works mainly for the Dutch government. RIVM also shares its knowledge with governments and supranational bodies around the world. The results of research, monitoring, modelling and risk assessment are used to underpin policy on public health, food, safety and the environment. RIVM employs over 1500 employees, many of whom work in multidisciplinary fields. <http://www.rivm.nl/en/aboutrivm/>



Procter and Gamble is a worldwide operating consumer goods company. Products include a number of food brands (snacks, coffee, tea, hard candy, dietary supplements) as well as household detergents, cosmetic and personal care products, absorbent hygiene products, and pharmaceuticals. <http://www.eu.pg.com/>



Imperial College London is a world-renowned centre for research and reaching in medicine and science. The role of the Faculty of Medicine is to develop and advance new therapies for disease whilst helping in disease prevention. It draws upon the skills of basic scientists and clinicians with expertise in molecular biology, genetics, histopathology, toxicology, clinical investigation and risk assessment. <http://www3.imperial.ac.uk/>

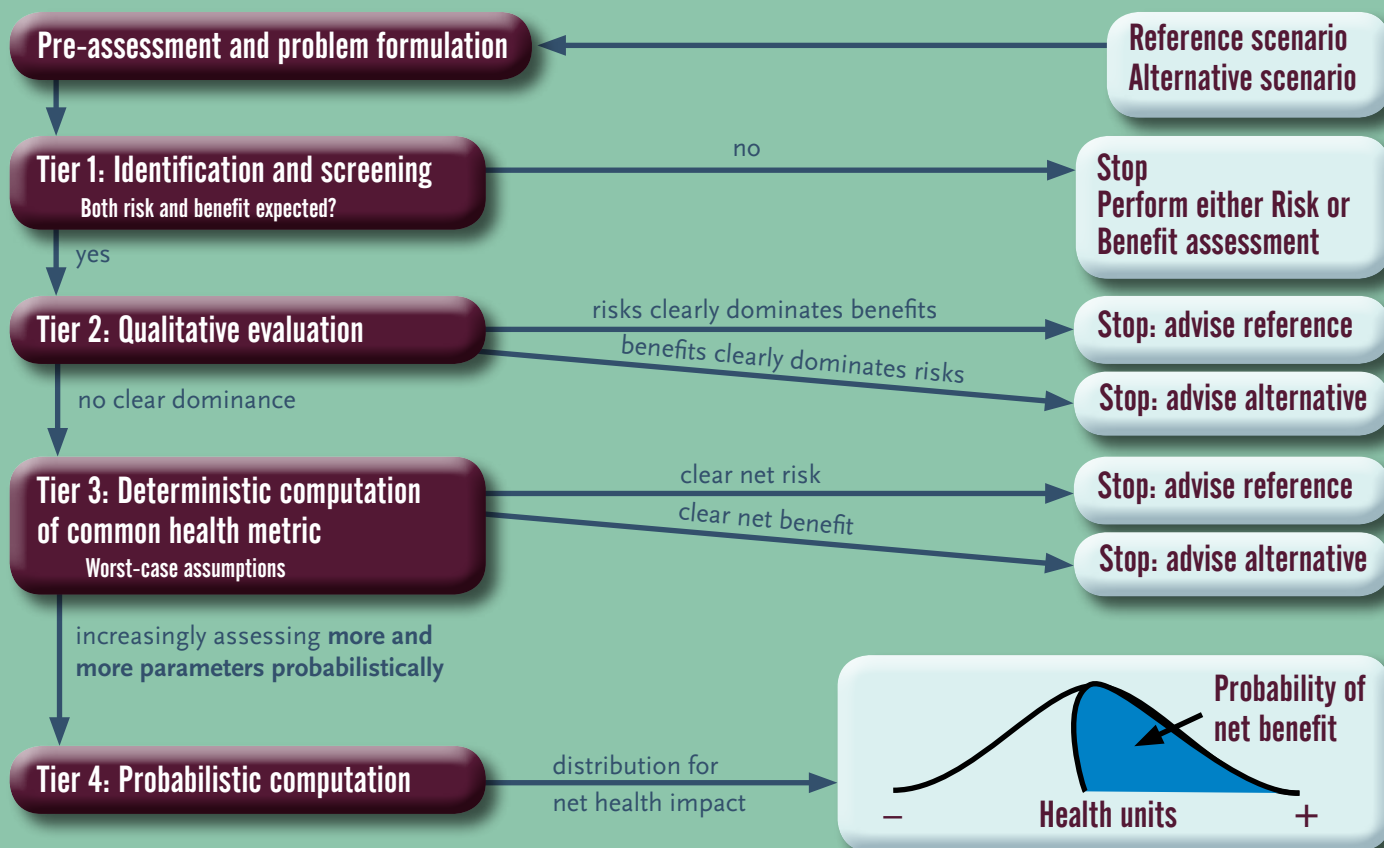
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# First results: Development of the methodological framework

The guidance document describes a tiered ('stepwise') approach for performing a risk and benefit assessment of foods and it was presented at the BRAFO workshop held on 25-26 September 2008, in Rome. 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 (see Figure 1). 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.

**Figure 1.** Flow chart of the BRAFO tiered approach for performing a risk and benefit assessment of foods



The currently ongoing research is focusing on the application of the methodology developed to three case studies on natural foods, dietary interventions and heat processing. This part of the project will last one year. The results will then be presented and discussed at the second workshop in October 2009 to adapt the methodology according to the findings of the case studies.

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