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# Food and Chemical Toxicology



## BEPRARIBEAN
## Best Practices for Risk-Benefit Analysis: experience from out of food into food

**Guest Editors**
**Brian G. Lake, Mariken J. Tijhuis and Hans Verhagen**

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Review

# State of the art in benefit–risk analysis: Introduction

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ABSTRACT

Risk-taking is normal in everyday life if there are associated (perceived) benefits. Benefit-Risk Analysis (BRA) compares the risk of a situation to its related benefits and addresses the acceptability of the risk. Over the past years BRA in relation to food and food ingredients has gained attention. Food, and even the same food ingredient, may confer both beneficial and adverse effects. Measures directed at food safety may lead to suboptimal or insufficient levels of ingredients from a benefit perspective. In BRA, benefits and risks of food (ingredients) are assessed in one go and may conditionally be expressed into one currency. This allows the comparison of adverse and beneficial effects to be qualitative and quantitative. A BRA should help policy-makers to make more informed and balanced benefit-risk management decisions. Not allowing food benefits to occur in order to guarantee food safety is a risk management decision much the same as accepting some risk in order to achieve more benefits. BRA in food and nutrition is making progress, but difficulties remain. The field may benefit from looking across its borders to learn from other research areas. The BEPRARIBEAN project (Best Practices for Risk-Benefit Analysis: experience from out of food into food; http://en.opasnet.org/w/Bepraribean) aims to do so, by working together with Medicines, Food Microbiology, Environmental Health, Economics & Marketing-Finance and Consumer Perception. All perspectives are reviewed and subsequently integrated to identify opportunities for further development of BRA for food and food ingredients. Interesting issues that emerge are the varying degrees of risk that are deemed acceptable within the areas and the trend towards more open and participatory BRA processes. A set of 6 'state of the art' papers covering the above areas and a paper integrating the separate (re)views are published in this volume.



**Contents**



*Abbreviations:* BEPRARIBEAN, Best practices in risk–benefit analysis.

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Review

# State of the art in benefit–risk analysis: Food and nutrition

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ABSTRACT

Benefit–risk assessment in food and nutrition is relatively new. It weighs the beneficial and adverse effects that a food (component) may have, in order to facilitate more informed management decisions regarding public health issues. It is rooted in the recognition that good food and nutrition can improve health and that some risk may be acceptable if benefit is expected to outweigh it. This paper presents an overview of current concepts and practices in benefit–risk analysis for food and nutrition. It aims to facilitate scientists and policy makers in performing, interpreting and evaluating benefit–risk assessments.

Historically, the assessments of risks and benefits have been separate processes. *Risk* assessment is mainly addressed by toxicology, as demanded by regulation. It traditionally assumes that a maximum safe dose can be determined from experimental studies (usually in animals) and that applying appropriate uncertainty factors then defines the 'safe' intake for human populations. There is a minor role for other research traditions in risk assessment, such as epidemiology, which quantifies associations between determinants and health effects in humans. These effects can be both adverse and beneficial. *Benefit* assessment is newly developing in regulatory terms, but has been the subject of research for a long time within nutrition and epidemiology. The exact scope is yet to be defined. Reductions in risk can be termed benefits, but also states rising above 'the average health' are explored as benefits. In nutrition, current interest is in 'optimal' intake; from a population perspective, but also from a more individualised perspective.

In current approaches to combine benefit and risk assessment, benefit assessment mirrors the traditional risk assessment paradigm of hazard identification, hazard characterization, exposure assessment and risk characterization. Benefit–risk comparison can be qualitative and quantitative. In a quantitative comparison, benefits and risks are expressed in a common currency, for which the input may be deterministic or (increasingly more) probabilistic. A tiered approach is advocated, as this allows for transpar-

*Abbreviations:* ADI, acceptable daily intake; AICR, Association for International Cancer Research; ALARA, as low as reasonably achievable; AR, Average Requirement; ATBC, alpha-tocopherol, beta carotene cancer prevention (trial); BCRR, Benefit Cancer Risk Ratio; BENERIS, benefit–risk assessment for food: an iterative value-of-information approach; BMD, benchmark dose; BMDL, lower one-sided confidence limit on the BMD; BNRR, Benefit Noncancer Risk Ratio; BRA, Benefit–risk analysis; BRAFO, benefit risk analysis of foods; CARET, beta-carotene and retinol efficacy trial; DALY, disability adjusted life years; EAR, Estimated Average Requirement; EFSA, European Food Safety Authority; FAO, [United Nations] Food and Agriculture Organization; FOSIE, food safety in Europe: risk assessment of chemicals in the food and diet; FUFOSE, Functional Food Science in Europe; ILSI, International Life Sciences Institute; JECFA, Joint FAO/WHO Expert Committee on Food Additives; LLAB, lower level of additional benefit; LOAEL, Lowest Observed Adverse Effect Level; MOE, margin of exposure; NOAEL, No Observed Adverse Effect Level; OECD, Organisation for Economic Co-operation and Development; PAR, population attributable risk; PASSCLAIM, process for the assessment of scientific support for claims on foods; POD, point of departure; PRI, population reference intake; RDA, recommended dietary allowance; RfD, Reference Dose; RIVM, [Dutch] National Institute for Public Health and the Environment; RR, relative risk; SCF, Scientific Committee on Food; (P)TDI/WI/MI, (provisional) tolerable daily/weekly/monthly intake; UL, tolerable upper intake level; ULAB, upper level of additional benefit; WHO, World Health Organization; QALIBRA, quality of life – integrated benefit and risk analysis; QALY, quality adjusted life years; WCRF, World Cancer Research Fund.

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Review

# State of the art in benefit–risk analysis: Medicines

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ABSTRACT

Benefit–risk assessment in medicine has been a valuable tool in the regulation of medicines since the 1960s. Benefit–risk assessment takes place in multiple stages during a medicine's life-cycle and can be conducted in a variety of ways, using methods ranging from qualitative to quantitative. Each benefit–risk assessment method is subject to its own specific strengths and limitations. Despite its widespread and long-time use, benefit–risk assessment in medicine is subject to debate and suffers from a number of limitations and is currently still under development.

This state of the art review paper will discuss the various aspects and approaches to benefit–risk assessment in medicine in a chronological pathway. The review will discuss all types of benefit–risk assessment a medicinal product will undergo during its lifecycle, from Phase I clinical trials to post-marketing surveillance and health technology assessment for inclusion in public formularies. The benefit–risk profile of a drug is dynamic and differs for different indications and patient groups. In the end of this review we conclude benefit–risk analysis in medicine is a developed practice that is subject to continuous improvement and modernisation. Improvement not only in methodology, but also in cooperation between organizations can improve benefit–risk assessment.



**Contents**



*Abbreviations:* ADR, adverse drug reaction; BR, benefit–risk; CHMP, Committee for Medicinal Products for Human use; EC, European Commission; EMA, European Medicines Agency; EU, European Union; EudraVigilance, European Union Drug Regulating Authorities Pharmacovigilance; FDA, Food and Drug Administration; MHRA, Medicines and Healthcare Products Regulatory Agency; NHS, National Health Service; NICE, National Institute for Clinical Excellence; PMS, post-marketing surveillance; PROTECT, Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium; QALY, quality-adjusted life year; TMF, trial master file; TURBO, Transparent Uniform Risk Benefit Overview; UK, United Kingdom; WHO, World Health Organization.

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# State of the art in benefit–risk analysis: Food microbiology

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ABSTRACT

Over the past years benefit–risk analysis (BRA) in relation to foods and food ingredients has gained much attention; in Europe and worldwide. BRA relating to food microbiology is however a relatively new field of research. Microbiological risk assessment is well defined but assessment of microbial benefits and the weighing of benefits and risk has not been systematically addressed. In this paper the state of the art in benefit–risk analysis in food microbiology is presented, with a brief overview of microbiological food safety practices.

The quality and safety of foods is commonly best preserved by delaying the growth of spoilage bacteria and contamination by bacterial pathogens. However, microorganisms in food can be both harmful and beneficial. Many microorganisms are integral to various food production processes e.g. the production of beer, wine and various dairy products. Moreover, the use of some microorganisms in the production of fermented foods are often claimed to have beneficial effects on food nutrition and consumer health. Furthermore, food safety interventions leading to reduced public exposure to foodborne pathogens can be regarded as benefits. The BRA approach integrates an independent assessment of both risks and benefits and weighs the two using a common currency.

Recently, a number of initiatives have been launched in the field of food and nutrition to address the formulation of the benefit–risk assessment approach. BRA has recently been advocated by EFSA for the public health management of food and food ingredients; as beneficial and adverse chemicals can often be found within the same foods and even the same ingredients. These recent developments in the scoping of BRA could be very relevant for food microbiological issues. BRA could become a valuable methodology to support evaluations and decision making regarding microbiological food safety and public health, supplementing other presently available policy making and administrative tools for microbiological food safety management.



*Abbreviations:* ALOP, Appropriate Level of Protection; BENERIS, Benefit–risk assessment for food: an iterative value-of-information approach – project; BRA, Benefit–risk analysis; BRAFO, Benefit–risk analysis of foods – project; CAC, codex alimetarius commission; DALY, disability-adjusted life year; EFSA, European Food Safety Authority; EU, European Union; FAO, Food and Agriculture Organization; FOSIE, Food Safety in Europe: Risk Assessment of Chemicals in the Food and Diet – Project; FSO, Food Safety Objective; GMP, good manufacturing practices; HACCP, Hazard Analysis Critical Control Point; HIC, health impact criteria; ILSI RF, International Life Science Institute Research Foundation; IPRA, Integrated Probabilistic Risk Assessment; LYL, Life-Years Lost; MID, minimum infectious dose; MRA, microbiological risk assessment; PHIA, Probabilistic Health Impact Assessment; PO, Performance Objective; QALY, Quality-adjusted Life Year; RIVM, [Dutch] National Institute for Public Health and the Environment; WHO, World Health Organization; QMRA, quantitative microbiological risk assessment; QALIBRA, quality of life-integrated benefit and risk analysis, Web-based tool for assessing food safety and health benefits – project.

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Review

# State of the art in benefit–risk analysis: Environmental health

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ABSTRACT

Environmental health assessment covers a broad area: virtually all systematic analysis to support decision making on issues relevant to environment and health. Consequently, various different approaches have been developed and applied for different needs within the broad field. In this paper we explore the plurality of approaches and attempt to reveal the state-of-the-art in environmental health assessment by characterizing and explicating the similarities and differences between them. A diverse, yet concise, set of approaches to environmental health assessment is analyzed in terms of nine attributes: purpose, problem owner, question, answer, process, use, interaction, performance and establishment. The conclusions of the analysis underline the multitude and complexity of issues in environmental health assessment as well as the variety of perspectives taken to address them. In response to the challenges, a tendency towards developing and applying more inclusive, pragmatic and integrative approaches can be identified. The most interesting aspects of environmental health assessment are found among these emerging approaches: (a) increasing engagement between assessment and management as well as stakeholders, (b) strive for framing assessments according to specific practical policy needs, (c) integration of multiple benefits and risks, as well as (d) explicit incorporation of both scientific facts and value statements in assessment. However, such approaches are yet to become established, and many contemporary mainstream environmental health assessment practices can still be characterized as relatively traditional risk assessment.



**Contents**



*Abbreviations:* BENERIS, benefit–risk asessment for food: an iterative value-of-information approach; CSA, chemical safety assessment; DALY, disability adjusted life years; ECHA, european chemical agency; EIA, environmental impact assessment; EU, european union; HIA, health impact assessment; HEIMTSA, health and environment integrated methodology and toolbox for scenario assessment; IAEA, international atomic energy agency; IEHIA, integrated environmental health impact assessment; INTARESE, integrated assessment of health risks of environmental stressors in Europe; IRGC, international risk governance council; LCA, life cycle assessment; NGO, non-governmental organization; NRC, national research council (USA); OECD, organization for economic co-operation and development; PBT, persisten, bioaccumulative, and toxic; PSSP, purpose, structure, state, performance; QALY, quality adjusted life years; REACH, registration, evaluation, authorization, and restriction of chemical substances (EU); SAIC, scientific applications international corporation; TEKES, national technology agency of finland; USA, United States of America; U.S. EPA, United States Environmental Protection Agency; vPvB, very persistent, very bioaccumulative; WHO, World Health Organization; YVA, Ympäristövaikutusten arviointi (Finnish for EIA).

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Review

# State of the art in benefit–risk analysis: Economics and Marketing-Finance

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ABSTRACT

All market participants (e.g., investors, producers, consumers) accept a certain level of risk as necessary to achieve certain benefits. There are many types of risk including price, production, financial, institutional, and individual human risks. All these risks should be effectively managed in order to derive the utmost of benefits and avoid disruption and/or catastrophic economic consequences for the food industry. The identification, analysis, determination, and understanding of the benefit–risk trade-offs of market participants in the food markets may help policy makers, financial analysts and marketers to make well-informed and effective corporate investment strategies in order to deal with highly uncertain and risky situations.

In this paper, we discuss the role that benefits and risks play in the formation of the decision-making process of market-participants, who are engaged in the upstream and downstream stages of the food supply chain. In addition, we review the most common approaches (expected utility model and psychometrics) for measuring benefit–risk trade-offs in the economics and marketing-finance literature, and different factors that may affect the economic behaviour in the light of benefit–risk analyses.

Building on the findings of our review, we introduce a conceptual framework to study the benefit–risk behaviour of market participants. Specifically, we suggest the decoupling of benefits and risks into the separate components of utilitarian benefits, hedonic benefits, and risk attitude and risk perception, respectively. Predicting and explaining how market participants in the food industry form their overall attitude in light of benefit–risk trade-offs may be critical for policy-makers and managers who need to understand the drivers of the economic behaviour of market participants with respect to production, marketing and consumption of food products.



*Abbreviations:* GM, genetically modified; $u(x)$, utility function; SE, bovine spongiform encephalopathy; SMEs, small medium enterprises; EU, expected utility; *CE*, certainty equivalence; MD, mean-standard deviation model; IP, ideal-point model; WT, willingness to trade-off; *X*, uncertain option; *R*, perceived risk; EWT, extended willingness to trade-off; $V(X)$, subjective expected value; $w(x)$, weighting function; *x,z*, outcome(s); *p*, probability; CBR, consumer benefit–risk behaviour; RA, risk attitude; RP, risk perception; UB, utilitarian benefits; HB, hedonic benefits.

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Review

# State of the art in benefit–risk analysis: Consumer perception

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ABSTRACT

Benefit and risk perception with respect to food consumption, have been a part of human daily life from beginning of time. In today's society the food chain is long with many different types of actors and low degree of transparency. Making informed food choices where knowledge of benefits and risks is part of the decision making process are therefore complicated for consumers. Thus, to understand how consumers perceive benefits and risks of foods, their importance in relation to quality evaluations are aspects that need to be addressed. The objective of this paper is to discuss state of the art in understanding consumer perceptions of benefits and risks of foods in order to improve understanding of consumer behaviour in the food domain.

Risks may be associated with both acute and long term consequences, some of which may have serious effects. Perceived risks are connected to morbidity and mortality along two dimensions relating to unknown risk, and to which extent the risk is dreaded by the consumer. Unfamiliar, uncertain, unknown, uncontrollable, and severe consequences are some factors associated with risk perception. Novel food processing techniques, for instance, score high on several of these parameters and are consequently regarded with suspicion and perceived as risky by consumers.

On a daily basis, benefits of foods and food consumption are more important in most consumers' minds than risks. Benefits are often associated with food's ability to assuage hunger, and to provide pleasure through eating and socialising. In addition, two main categories of benefits that are important for acceptance of product innovations are health and environmental benefits.

Benefit and risk perception of foods seem to be inversely correlated, so when something is perceived as being highly beneficial, it is correspondingly perceived as having low risk. However, slightly different paths are used in the formation of these perceptions; benefit perception is based on heuristics and experience, while risk perception is to a larger extent the result of cognitive information processing.

Consumers are particularly conservative when it comes to perception and acceptance of foods compared to other products. Benefit-risk evaluations tend to be skewed towards acceptance of all that is traditional and well-known (benefits), and rejection or suspicion towards anything that is novel or highly processed (risks) regardless of actual risk. Knowledge of how consumers perceive benefits and risks of foods, may contribute to understanding benefit-risk perception in other areas related to personal, societal or environmental perspectives.



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Review

# Looking beyond borders: Integrating best practices in benefit–risk analysis into the field of Food and Nutrition

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ABSTRACT

An integrated benefit–risk analysis aims to give guidance in decision situations where benefits do not clearly prevail over risks, and explicit weighing of benefits and risks is thus indicated. The BEPRARIBEAN project aims to advance benefit–risk analysis in the area of food and nutrition by learning from other fields. This paper constitutes the final stage of the project, in which commonalities and differences in benefit–risk analysis are identified between the Food and Nutrition field and other fields, namely Medicines, Food Microbiology, Environmental Health, Economics and Marketing–Finance, and Consumer Perception. From this, ways forward are characterized for benefit–risk analysis in Food and Nutrition. Integrated benefit–risk analysis in Food and Nutrition may advance in the following ways: Increased engagement and communication between assessors, managers, and stakeholders; more pragmatic problem-oriented framing of assessment; accepting some risk; pre- and post-market analysis; explicit communication of the assessment purpose, input and output; more human (dose–response) data and more efficient use of human data; segmenting populations based on physiology; explicit consideration of value judgments in assessment; integration of multiple benefits and risks from multiple domains; explicit recognition of the impact of consumer beliefs, opinions, views, perceptions, and attitudes on behaviour; and segmenting populations based on behaviour; the opportunities proposed here do not provide ultimate solutions; rather, they define a collection of issues to be taken account of in developing methods, tools, practices and policies, as well as refining the regulatory context, for benefit–risk analysis in Food and Nutrition and other fields. Thus, these opportunities will now need to be explored further and incorporated into benefit–risk practice and policy. If accepted, incorporation of these opportunities will also involve a paradigm shift in Food and Nutrition benefit–risk analysis towards conceiving the analysis as a process of creating shared knowledge among all stakeholders.



*Abbreviations:* CVD, cardiovascular disease; DALY, disability adjusted life year; EFSA, European Food Safety Authority; HTA, health technology assessment; QALY, quality adjusted life year.

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