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1 **Risk-benefit analysis in food safety and nutrition**

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21 **Abstract**

22 Risk-benefit analysis of foods including a formal public health assessment followed by management
23 and communication has been establishing itself as a scientific discipline during the past 15 years. Risk-
24 Benefit Assessments (RBAs), integrating nutrition, toxicology and microbiology, have been
25 increasingly conducted for a variety of foods and food components. Quantitative models in these
26 assessments often use the Disability Adjusted Life Year (DALY) as a common health metric, as it
27 allows for comparison of diverse health effects. Results are typically reported by population group to
28 capture differences in health outcomes and target communication. Strengthening the links between a
29 formal RBA, risk-benefit management decisions and dietary recommendations communicated to the
30 public will improve transparency and potentially public health outcomes. In the coming years,
31 sustainable food production and other factors in addition to public health might result in risk-benefit
32 analysis becoming part of the broader food system analysis.

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34

35 **Introduction**

36 The analysis of risks and benefits in food including a formal quantitative or semiquantitative public
37 health assessment followed by decision making and communication, although initiated 15 years ago,
38 still needs to gain in visibility. It goes beyond food safety risk analysis, as it includes an analysis of the
39 nutritional risks and benefits of food consumption. Its general framework, based on the three key
40 elements assessment, management and communication, comes from risk analysis [6].

41 In risk-benefit assessment (RBA) of foods, the risks and benefits associated with a food component, a
42 food product, and a diet are (quantitatively) compared from a public health perspective [8]. Chemical
43 and microbiological hazards are identified, and the resulting health effects characterized together with
44 an assessment of the nutritional health effects. While chemical and microbiological hazards can
45 contribute to food safety risks, nutritional effects of food on human health can contribute to health
46 benefits (*e.g.* unsaturated fatty acids have been shown to potentially reduce cardiovascular disease risk

47 [9]) and also health risks (*e.g.* heme-iron in red meat have been shown to increase the risk of colorectal
48 cancer [10]).

49 The need for RBA of foods has come forward after separate studies on nutritional health impact and
50 food safety risk assessment for the same food or food component resulted in possible conflicting
51 messages. For example, the consumption of fatty fish might be recommended for pregnant women on
52 the basis of the potential positive effect of fish consumption on the neurological development of a
53 newborn, but discouraged on the basis of negative health effects on the newborn from methylmercury
54 and dioxins [11]. Focusing solely on benefits or risks associated with foods without consideration of
55 other factors in a holistic approach can be confusing when formulating and following dietary
56 recommendations.

57 In Europe, RBA was formally discussed at an EFSA colloquium in 2006 [12] and taken up by several
58 European Union (EU) projects, such as BRAFO [13]. The RBA methodology was based on the food
59 safety risk assessment approach (including hazard identification, hazard characterization, exposure
60 assessment and risk characterization) [14]. In the BRAFO project, the “tiered” approach was
61 developed [15] and applied in several case studies[16-18]. More recently, RBA has been taken up by
62 several research groups. Boué et al. [19] published a review summarizing the available literature
63 which indicated fish is the most widely studied food in RBA. Nauta et al. [20] presented a review of
64 the challenges related to further development of RBA and show these are related to interdisciplinarity,
65 methods, data, health metrics and applications. A workshop held in Denmark 2017 gathered a large
66 international group of experts on RBA, and its conclusions are summarized by Pires et al. [21].
67 Participants of the workshop concluded that while challenges remain in the assessment of risk,
68 communication of uncertainty, and integration of diverse data sources, among others, RBA can
69 extensively support risk-management on decisions with regards to food safety, nutrition and public
70 health. In Nauta et al. [8] , the available methods for RBA are presented and their dependency with the
71 specific risk-benefit question posed is shown.

72 RBA can support science-based decision making when establishing dietary guidelines and
73 recommending foods to a population or a population group. This latter consideration is of crucial
74 importance as research indicates tailoring materials to specific population groups might more

75 effectively promote healthier behaviours that would be missed with messages targeting the general
76 population [22]. Nevertheless, decision making is complicated since different outcomes in different
77 magnitude and timescales are involved, leading to difficult weighting between outcomes. Moreover,
78 there may be uncertainty associated with the results of the assessment. For example, when ranking the
79 health impacts of two different food intake scenarios based on a limited amount of data or knowledge,
80 the risk-benefit balance may not lean clearly in favour of one of the two scenarios. Additionally, RBAs
81 require a large collection of data and expertise as they could cover chemical, microbiological and
82 nutritional aspects of a food. The time required to perform a comprehensive quantitative or
83 semi-quantitative RBA is not always compatible with the decision agenda.

84 Consumers, at least unconsciously, make risk-benefit decisions when purchasing food products and
85 preparing meals. As such, consumers frequently need to make trade-offs between the known risks and
86 benefits associated with consumption of food products. Additionally, issues such as availability, costs,
87 personal preferences, food quality, sustainability, *etc.*, can play a role. A survey in several EU
88 countries in 2019 showed that food safety is as important as other factors such as food origin, cost and
89 taste in consumer purchasing decision-making [23].

90 Communication about food safety risks and benefits is important to allow consumers making a
91 balanced, objective food choice. However, communicating risk and benefit information about foods is
92 challenging. The presentation order of benefits and risks in the message can affect both behavioural
93 intention and consumer perception, with the first message component being generally the most
94 influential [4]. Even more challenging is when the wording of a benefit can bring negative
95 associations. For example, consumers might perceive "fatty", in general, as negative and then associate
96 "fatty fish" with being unhealthy, which may be the opposite of the intended message [24]. To involve
97 the public in the decision making process of developing appropriate communication strategies, citizen
98 science approaches such as the use of consumer focus groups can be useful [25]. The development of
99 the internet and emergence of social media provide additional opportunities to involve and empower
100 consumers in food risk and benefit communication processes [24,26].

101 In this review, the three interconnected elements of risk-benefit analysis (assessment, management and
102 communication), as illustrated in Figure 1, are covered. The first step in risk-benefit analysis is

103 agreeing on the question. Next, a RBA includes health effect identification (adverse and beneficial),
104 exposure assessment, dose-response relationship and risk-benefit characterisation. The results of the
105 RBA can then be used in risk-benefit management to inform food safety, dietary recommendations
106 and setting of legal standards. Finally, the communication of risks and benefits can aid in
107 understanding of the RBA and dietary recommendations made (Figure 1). This general approach
108 linking assessment, management and communication, advocated by EFSA [12], has been illustrated
109 here with fish. We anticipate that other applications will emerge, which illustrate how RBA can be
110 used to make informed decisions, followed by dietary recommendations communicated to the public.
111 [27][11][12][13][14][15][16-18]Boué et al. [19]Nauta et al. [20]Pires et al. [21]Nauta et al. [8]

112 **Risk-benefit Assessments focusing on human health**

113 Weighing risks and benefits related to the various health effects requires a comparison of estimated
114 incidences of diseases/health effects with different severity and duration, as well as mortality. A
115 common health metric is required. The health metric that is used most often in RBAs is the Disability
116 Adjusted Life Year (DALY). The DALY is also applied as the metric to quantify the burden of
117 disease/health effects. One DALY can be thought of as one year of healthy life lost [28]. A recent
118 example of weighing risks and estimating the impact of a food substitution using DALYs as the
119 common health metric includes a case study which explored exposure to inorganic arsenic (iAs) and
120 aflatoxins through consumption of infant cereals in the U.S. and the risk of developing lung, bladder
121 and liver cancer over a lifetime [29]. Estimated additional DALYs in the U.S. population from
122 exposure to iAs and aflatoxin during the first year of age based on contamination and consumption
123 patterns of infant rice and oat cereal in the study (the baseline) was 4,900 DALYs (CI 90% 400; 8,800)
124 or 0.7 DALYs per 100,000 people per year. If all consumers shifted (maintaining equivalent serving
125 size and frequency) to only infant rice or only infant oat cereal, the model predicted DALYs would
126 increase 1.4 times or decreased 0.4 times relative to the baseline, respectively.

127 An example of estimating risks as well as quantifying the benefits assuming a diet shift using the
128 DALY metric includes a recent study by De Oliveira Mota, et al. [10,30,31] using red meat
129 consumption in France as the example. Per 100,000 people per year, red meat consumption was
130 estimated to account for a mean of 19 DALY from colorectal cancer (CRC), 21 DALY from

131 cardiovascular disease [10] and 6.6 DALY from foodborne pathogen infections [30]. Evaluation of
132 consumption of iron in the diet led to a mean estimate of 16 DALY/100.000 due to iron-deficiency
133 anaemia (IDA) [31]. These 16 DALY could be reduced if the IDA-suffering population changed their
134 diet to consume more iron-rich foods. An interesting finding in this set of studies is that the population
135 group at risk from CRC is different from the one suffering from IDA showing there might be a
136 possibility to mitigate overall risks by developing a communication plan which is population group
137 specific. For example, one in which, based on the findings [10,30,31], the male adult population would
138 be encouraged to reduce their red meat consumption while the young female adult population would
139 be encouraged to increase consumption of iron-rich foods.

140 When estimating the health impact of food intake, and specifically nutrients, a special challenge arises
141 from the fact that the impact of an increase or decrease from one food or one nutrient in isolation does
142 not consider the substitution food and/or nutrient which will generally impact the overall health
143 outcomes [2]. It also does not consider the synergy, interaction and potentially cumulative
144 relationships that occur in total diet exposures from all dietary components which may not equally
145 contribute to the associated health outcome [32]. Thomsen, et al. [1,33] specifically studied the
146 substitution of red and processed meat with fish, following the Danish food-based dietary guidelines.
147 The RBA performed included health effects associated with an increase of fish consumption, as well
148 as those associated with a decrease in red and processed meat intake. In addition to the health effects
149 associated with fish consumption (Figure 1), including the substitution of red and processed meat
150 introduced additional health effects from the diet shift such as reduction in colorectal cancer and non-
151 cardia stomach cancer and increases in iron-deficiency anaemia. Model results predicted that
152 substituting red and processed meat with fish further increased the benefit compared to considering
153 fish consumption alone, by an additional 20 DALYs averted/100,000 per year [8]. This example
154 illustrates the importance of considering substitutions when conducting RBAs.

155 [34][35]

156 **Risk-Benefit Analysis in a broader perspective**

157 Although the DALY is a common health metric often used in RBAs, there are cases where, even for
158 quantifying public health issues, it is difficult to apply this metric. In the domains of toxicology and

159 nutrition it is not always possible to accurately quantify diseases/health effects per capita (number of
160 cases, number of fatalities) resulting in the inability to obtain a DALY measure [34]. In those cases,
161 risk ranking techniques based on multi-criteria decision analysis (MCDA) can help by bringing the
162 flexibility of including in the assessment ordered values (e.g low, medium, high) beside quantitative
163 data [36]. This MCDA approach has been illustrated by a ranking microbial and chemical risks
164 associated with emerging dietary practices in France [35].

165 Moreover, while RBA typically focusses on health impact assessment, making recommendations or
166 decisions on dietary choices can include other factors such as costs, personal preferences,
167 sustainability, and ethics (Figure 2). The EU Agenda for “Food 2030” considered food safety to be
168 part of a food system driven mainly by nutrition, climate, circularity (resource efficiency) and
169 innovation (empowering communities) [37]. In the EU, there are societal expectations with regards to
170 sustainable food production, particularly concerning food safety and food quality as well as
171 environmental and animal welfare standards [38]. Initiatives to integrate Life Cycle Assessment
172 (LCA) into the risk-based decision process have emerged recently [39,40]. Using a multi-faceted
173 framework presented by Zijp et al. [41], which integrates elements of risk assessment, governance,
174 adaptive management and sustainability assessment, Hollander et al. [9] compared several foods rich
175 in fatty acids. The analysis introduced public health criteria to quantify nutritional benefits and food
176 safety risks, as well as sustainability criteria such as land and water use, chemical pollution and
177 disruption of local ecosystems (both qualitative and quantitative). The study showed the impact of
178 policy when based on a single metric versus inclusion of other dimensions such as food safety and the
179 environment and emphasized the use of integrative assessments when designing recommendations [9].

180 To integrate multi-dimensional and not easily comparable variables with differing impacts into the
181 decision-making process, again, MCDA is a helpful technique. FAO has recommended to apply
182 MCDA in order to rank public health impacts and include factors such as economic losses, food
183 security, consumer perception and socio-cultural concerns [42]. Similarly, Ruzante et al. [43] has
184 prioritized six “pathogen bacteria – food matrix” pairs considering public health but also market
185 impact, consumer perception and social sensitivity. A challenge in using MCDA is to assign weights
186 to criteria. This can be done, for example, at the assessment stage based on uncertainties and/or at the

187 management stage according to stakeholder priorities and the question being posed. Among MCDA
188 methods, mathematical optimisation techniques are useful to understand the trade-offs between
189 variables like food safety, nutritional health impact, sustainability and costs [44]. This technique was
190 recently applied to evaluate the trade-off between health impact, cost and personal preference when
191 looking at fish consumption [45] and to integrate environmental, health, economic, and cultural
192 dimensions of diet sustainability in the food supply for school meals [46]. Hollander et al. [9][9]
193 In the near future, risk-benefit analysis on food and health could be merged into a broader food system
194 analysis [27,37]. In this broader perspective, one can use MCDA, mathematical optimisation or other
195 modelling frameworks to assess, manage and communicate the complex factors and ranking outcomes.
196 Criteria are difficult to characterize and compare, as in the EAT-Lancet Report [27] where health and
197 environmentally sustainable factors like greenhouse-gas emissions, land and freshwater use as well as
198 biodiversity loss are indicators. The challenge can be greater if economic, social and ethical
199 considerations are taken into account. Broad multidisciplinary interaction and collaboration will likely
200 be required [47] and the examples above show that this is possible.

201

202 **Concluding remarks**

203 Risk-benefit analysis in food safety and nutrition has established itself in the last 15 years with key
204 research projects in assessment [7,13] and communication [24] in addition to academic studies
205 covering methodological developments and/or applications. Strengthening the links between a formal
206 RBA, management decisions and dietary recommendations communicated to the public can improve
207 transparency. This approach can potentially also improve public health outcomes by ensuring the best
208 science informed management decisions, and that communications are accurate and developed with
209 enhanced knowledge of the decision-making process. Even though significant progress has been made,
210 challenges remain [20]. RBA faces specific challenges in traditional risk assessments like availability
211 of data, variability between groups of consumers and individuals, the strength of the evidence and the
212 uncertainty in the dose-response and in defining how uncertainty is communicated. The integration of
213 diverse data sources, heterogeneous information between risks and benefits and the selection of
214 metrics to evaluate and compare these risks and benefits is challenging. It is also a challenge to

215 estimate the impact on health of the synergy in total diet exposure from all dietary components versus
216 looking at dietary components in isolation or a food substitution. Additional challenges include the
217 time that it takes and deciding on which factors should be considered in the process. For example, the
218 question of whether RBA should be limited to public health or include other factors such as personal
219 preferences, the economy, sustainability or other aspects. Multi-disciplinary teams will be required in
220 this effort and it can take a significant amount of time. To continue advancing the application of RBA,
221 efforts should keep ensuring it is fit-for-purpose and conducted in a timely manner. Once an RBA has
222 been completed, data and scientific discoveries related to the underlying model and assumptions may
223 need to be monitored and incorporated, to ensure the assessment reflects the best available science.
224 Emerging consumer practices [24,35], possible global transformations of the food system [27], and
225 agri-food innovation [48] are likely drivers for future research in risk-benefit applications. Examples
226 are studies on consumption of raw food products [49], fermented foods [50], plant-origin protein based
227 products, and nanotechnology [51]. With the methods developed and the international experience
228 gained, it is now possible to more fully exploit the potential of risk-benefit analysis and increasingly
229 apply quantitative RBAs to support decision making in food safety and nutrition.

230

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382 **Figures**

383 Figure 1: Overview of the steps in risk-benefit analysis, with an example for risk-benefit analyses of
384 fish.

385

386 Figure 2: Traditionally, risk-benefit assessment (RBA) of foods is applied to assess the combined
387 health impact of microbiological, toxicological and nutritional risks and benefits, preferably into a
388 single metric. As consumption and food policies are not only guided by health, the scope of RBA is
389 increasingly broadened up to include aspects that are important for decision making in relation to
390 dietary choices, but not related to the impact on health.

391

Step 1. Risk-Benefit Question

A risk-benefit question is agreed upon between risk-benefit assessor and risk-benefit manager

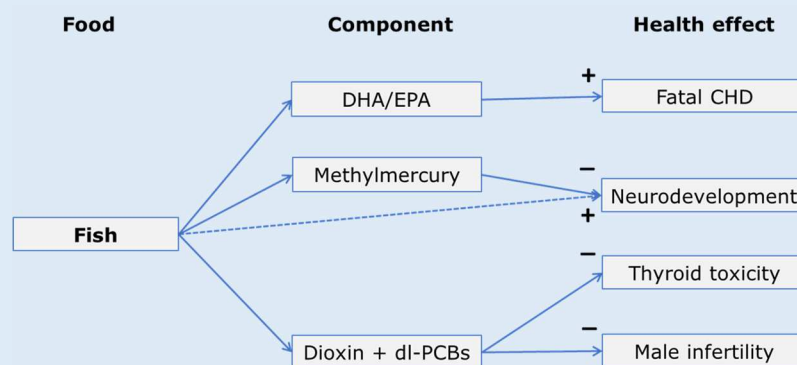
For example: What will the overall health impact be, in DALYs, of increasing the current fish consumption in a population to a recommended level? Next to the reference intake scenario (current intake), different fish intake scenarios can be defined with combinations of fish species.

Step 2. Risk-Benefit Assessment (RBA)

As many RBAs have been performed for fish, the elements of this step are illustrated by an example based on the study of Thomsen et al. [1].

2.1 Health Effect Identification: Adverse and beneficial health effects are identified based on scientific evidence, along with the food component (nutritional, chemical or microbial) linked to the health effect. The health effect might also be directly linked to the food. Identification of health effects, components and foods is preferably done on the basis of predefined selection criteria, and includes considerations on potential substitution scenarios.

An example for fish, adopted from [2,3], is shown below. It does not necessarily include all relevant health effects related to fish intake.



The food and its components are found to be associated with both beneficial (+) and adverse (-) health effects, making a RBA relevant. CHD: Coronary Heart Disease, DHA: Docosahexaenoic Acid, EPA: Eicosapentaenoic Acid and dl-PCB: Dioxin-Like Polychlorinated Biphenyls.

2.2 Exposure Assessment: The intake of the food and the relevant components are described as a distribution expressing the variability of mean daily intakes per consumer.

Exposure to each component can be assessed by integrating the individual mean daily fish consumption, based on dietary survey data, with the concentration of the individual components.

2.3 Dose-Response: Dose-response relations for the food and/or its components are obtained from scientific publications.

Dose response relations can be of different nature. In [7], the dose response relations for neurodevelopment and male infertility are for maternal intake. The dose response relations for dioxins are based on animal experiments [7].

2.4 Risk-Benefit Characterisation: Exposure assessment and dose response relations are combined and expressed as changes in disease incidence and mortality. By using a common health metric (i.e. DALY), severity and duration of a disease can be considered and quantitative health impact estimates can be combined and integrated.

In [1], an overall health gain was estimated when increasing the fish consumption in the Danish

Step 3. Risk-Benefit Management

Results of a RBA can inform food safety, dietary recommendations and setting of legal standards.

In the Thomsen et al. fish example [1], the RBA confirmed the current dietary recommendation on fish consumption in Denmark provides a health benefit to the Danish population.

Examples of dietary advice on eating fish based on risk-benefit assessments include those published in France [2] and Norway [5].

DALY estimates are not only used in RBA to support risk management. DALYs can be used to support or disqualify advice or recommendations in public health, and help when weighing the recommendation based on estimated public health impacts against other factors such as sustainability, the economy and societal impact.

Step 4. Risk-Benefit Communication

Communication of risks, benefits and the overall health impact can facilitate understanding of the RBA and the dietary recommendations made. The perception of risks versus benefits remains an important challenge [4].

In the ANSES [2] and VKM [5] advice on fish consumption, a summary of the benefits and specific risks is presented together with a recommendation which targets a sensitive population group (i.e. women who are or might become pregnant, breastfeeding mothers, and young children).

Figure 1

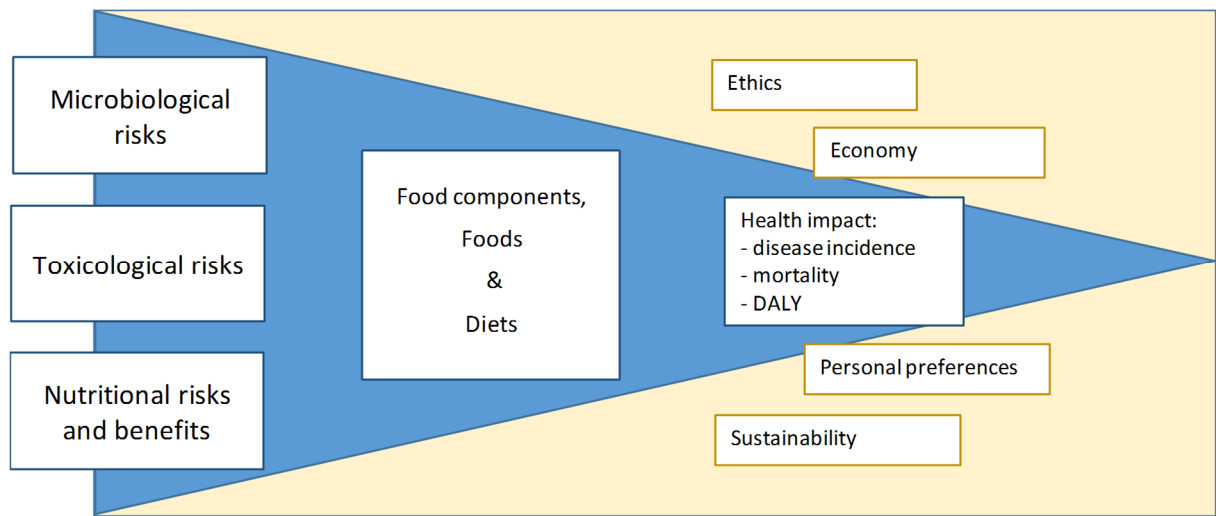


Figure 2

