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26 – 28 SEPTEMBER 2023, Parma

Innovative food products

Assessing risks and benefits of novel foods - Basic principles -

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Risk benefit assessment (RBA) of foods

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"RBA aims to assess both risks and benefits under a single methodological framework, providing a consolidated perspective on the impact that single foods, dietary options, or even whole diets may have on public health." (Boehm et al 2021)

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What are we assessing

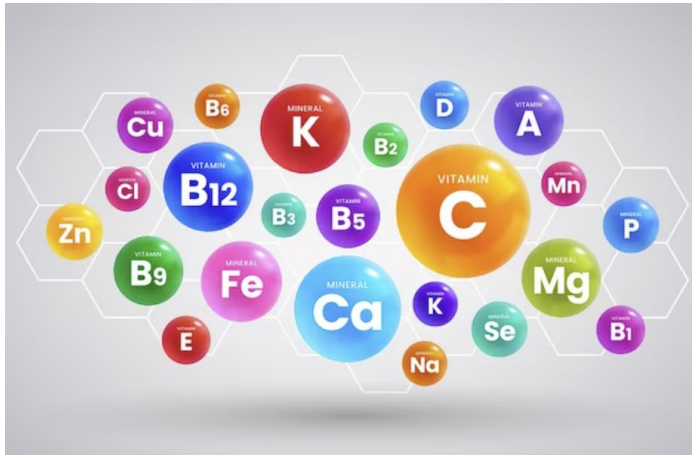
Diets

	Plant-Based	Vegan	Vegetarian
Meat & Poultry	--	✗	✗
Seafood	--	✗	✗
Dairy	--	✗	✓
Eggs	--	✗	✓
Oil	✓	✓	✓
Fruits & Veggies	✓	✓	✓
Grains	✓	✓	✓
Legumes	✓	✓	✓

✗ - No -- - Avoid ✓ - Yes

Individual foods

Nutrients



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Different diets

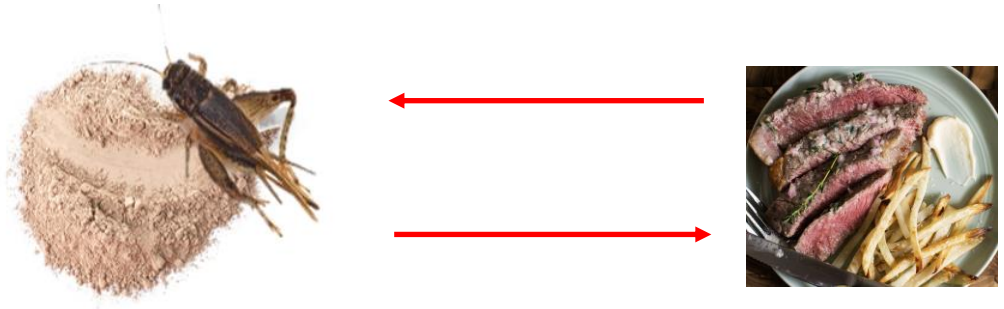
- Dietary habits are becoming more diverse
- Some diets may be characterised by consumption of novel foods
- Important to assess risks and benefits of different diets from public health point of view

	Plant-Based	Vegan	Vegetarian
Meat & Poultry	--	✗	✗
Seafood	--	✗	✗
Dairy	--	✗	✓
Eggs	--	✗	✓
Oil	✓	✓	✓
Fruits & Veggies	✓	✓	✓
Grains	✓	✓	✓
Legumes	✓	✓	✓

✗ - No -- - Avoid ✓ - Yes

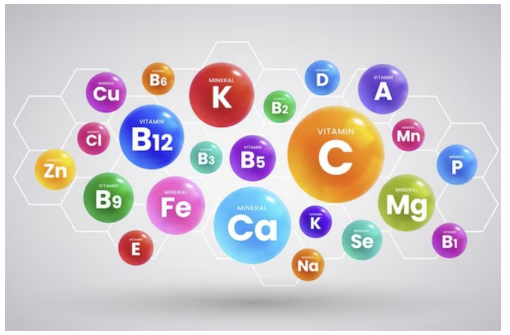
Different foods

- Perhaps more “focused” compared to assessment of whole diets
- More relevant in the context of novel foods
- Important to define the comparator (what is being replaced)
- The outcome is highly dependent on the underlying study population

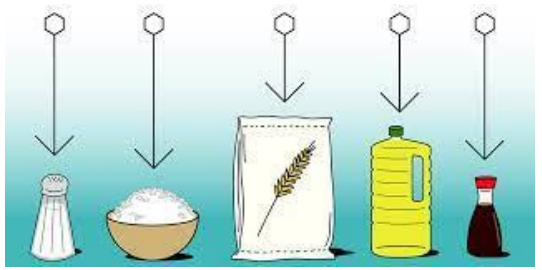


Nutrients

- **Risks and benefits of food fortifications:**
  - Iodine in salt
  - Vitamin D in fats/oils
  - Folic acid in wheat flour



- **Risks and benefits of supplemental use:**
  - Infants (vitamin A and D)
  - Women of childbearing age (folic acid)
  - Pregnant women (iron)
  - Elderly adults (vitamin D, B12, ….)



Risk Benefit assessment is in principle not so different from any other risk or benefit assessment….. except for the problematic risk benefit comparison

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EFSA Journal 2010; 8(7):1673

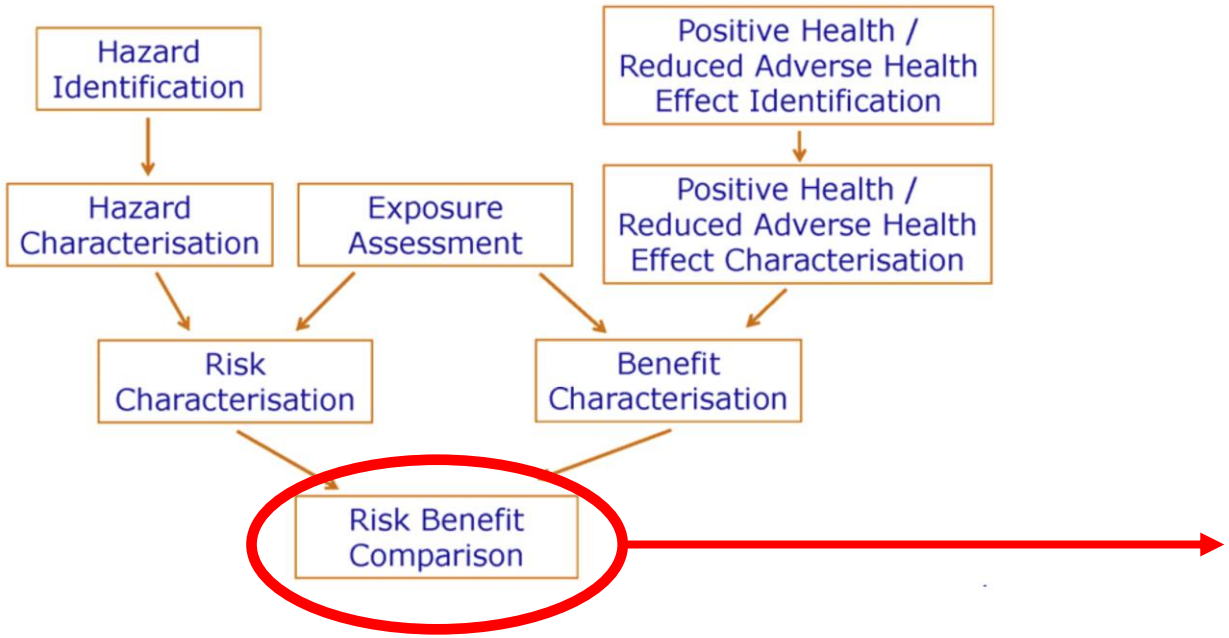

Figure 1: The risk-benefit assessment paradigm, as recommended by the EFSA Scientific Committee and based on the discussions of the EFSA scientific colloquium on risk-benefit analysis of foods[4].

Risk benefit methods

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- There are many excellent frameworks to conduct risk benefit assessment ….
- … using both qualitative and quantitative methods
- However, the main pillar of any risk benefit assessment is not the methods …
- **… it is how we define the risk and benefits**

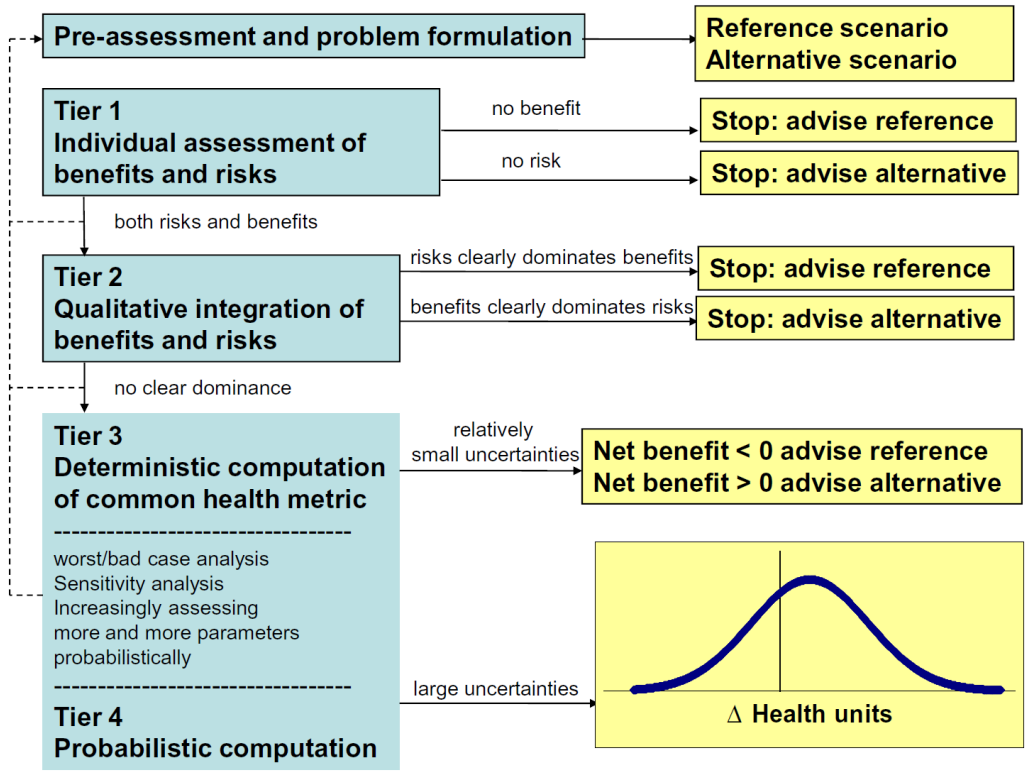

Fig. 1. A flow-chart of the BRAFO tiered approach.

Boobis et al 2013

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Defining risk and benefits is key

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- **Benefits**
  - **Dietary reference values** set by public health authorities
  - Conclusions from systematic literature reviews
  - Our own literature review or expert judgment

Level of robustness/acceptance

- **Risk**
  - **Health based guidance values** set by public health authorities
  - Conclusions from systematic literature reviews
  - Our own literature review or expert judgment

Level of robustness /acceptance

Chemical risk possibly associated with food intake

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Flavourings

Residues

Additives

Processing

Contaminants

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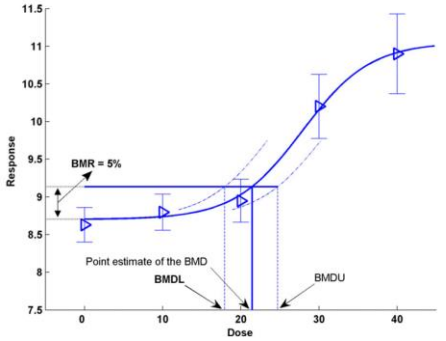
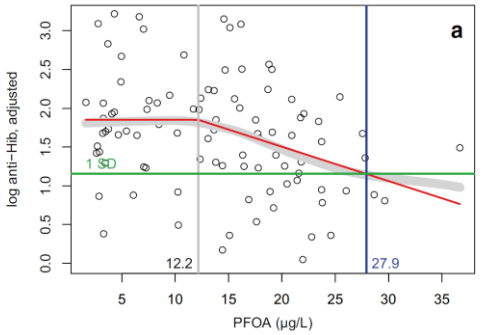
Health Based Guidance Values (HBGV)

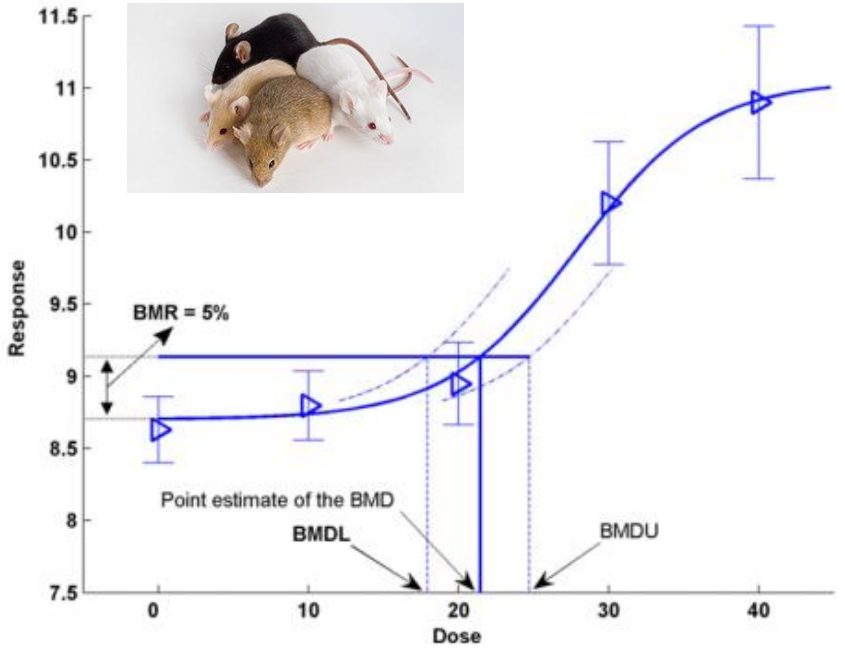
- HBGV for additives, flavourings, residues and contaminants are often set on the basis of animal models
- Animal models may be reliable for identifying adverse causal health effects relevant for humans.
- However, how close the reference point derived from animal studies compare to the true reference point in humans is anyones guess
- Risk derived from human studies offers more accuracy at the expense on uncertenty on causality





Health based guidance values for chemical risk

- We are very conservative when setting health-based guidance values



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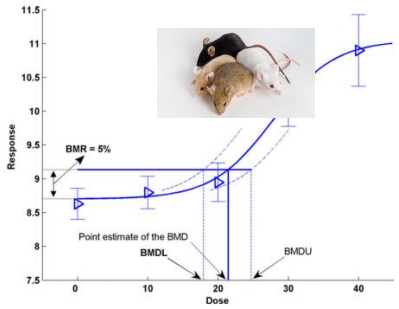
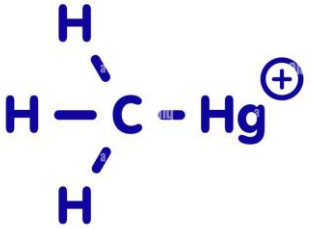
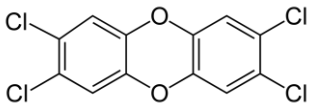


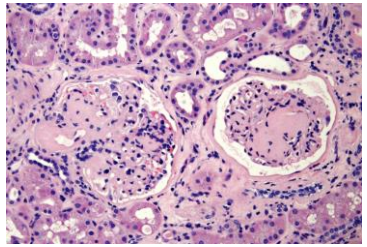
Uncertainty factor of ~100

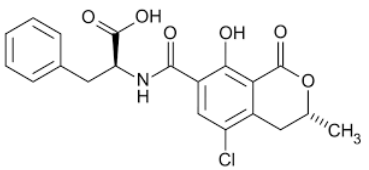
Health based guidance values for chemical risk

- We are very conservative when setting health-based guidance values
- They are usually set based on
  - Lowest adverse effect observed in an animal or human study
  - Often relevant for a specific sub-population









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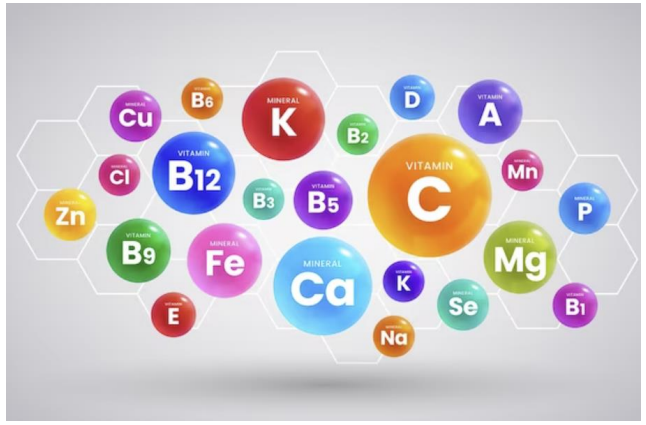
Benefits and risks of foods/nutrients



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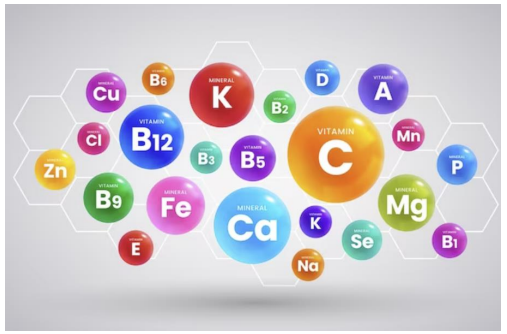
Benefits

- All foods provide nutrients (to varying degree)
- Nutrients provide benefits when we are deficient (too low intake)
- Too high intakes are associated with risk not benefits
- As such, benefits are usually associated with balanced intake



When it comes to food and nutrients more is not better

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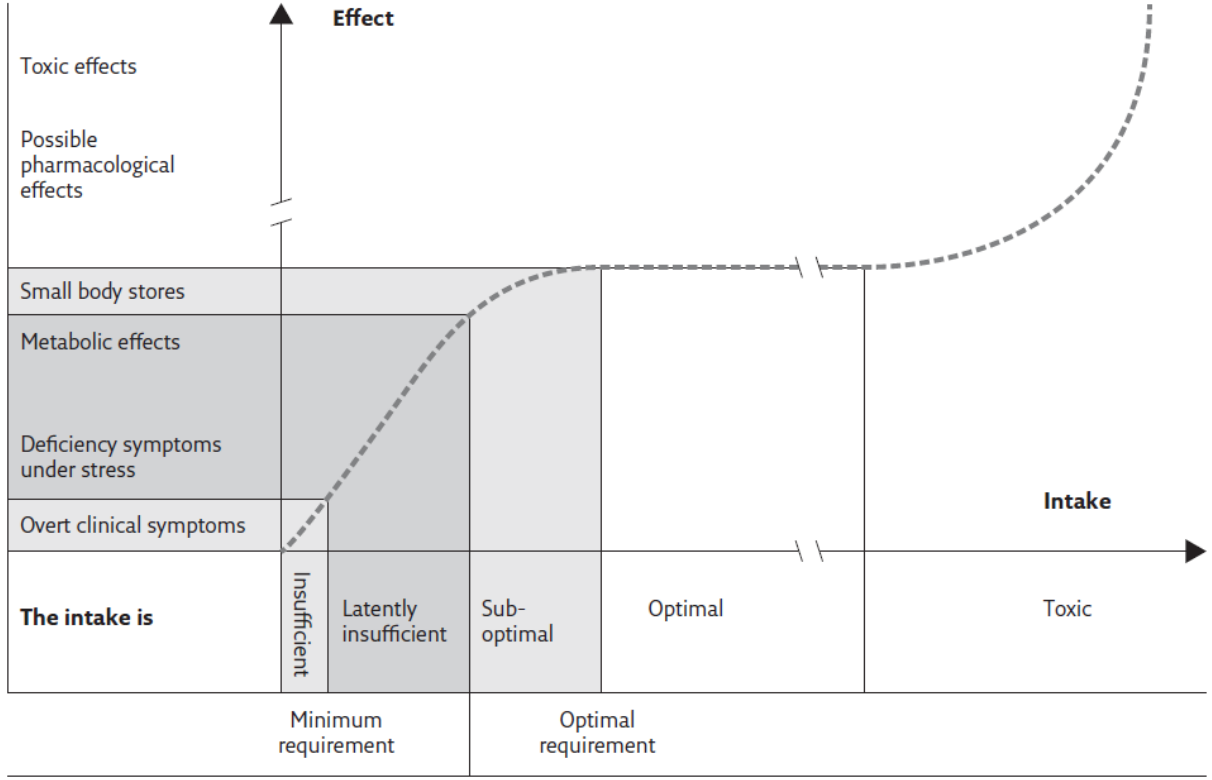
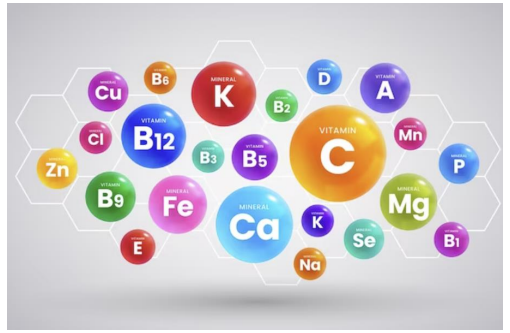


Figure 2.1. The theoretical relationship between intake of a nutrient and the effect on the organism



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Dietary reference values provide measures of risks and benefits on group level

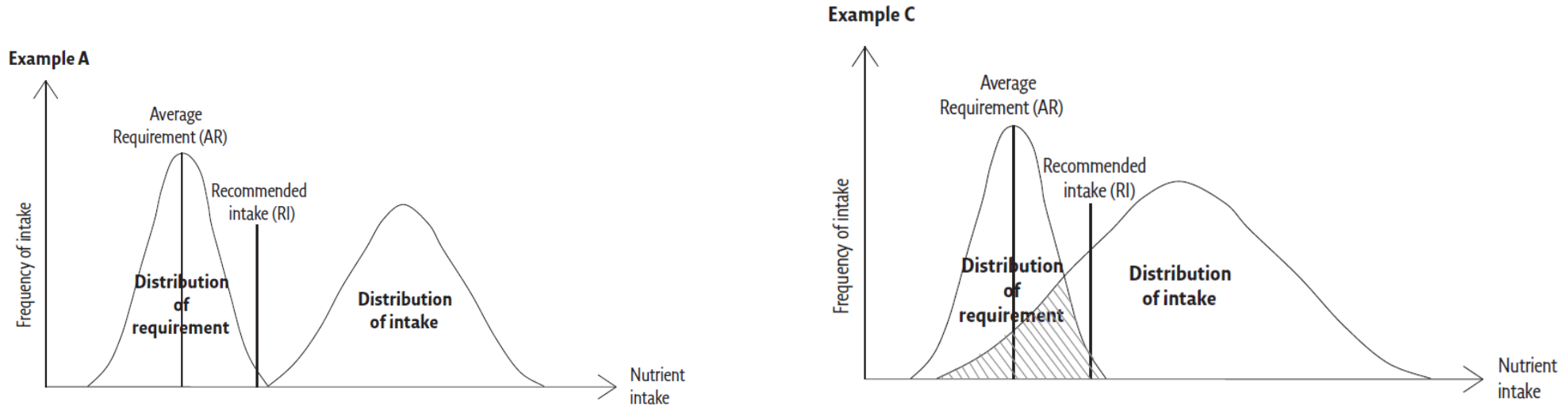

Figure 3.2. Examples of distributions of average requirements (AR) and average usual intakes of micronutrients illustrating different scenarios in assessment and planning of nutrient intakes

For further reading

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Food and Chemical Toxicology 42 (2004) 1903–1922

Food and Chemical Toxicology

www.elsevier.com/locate/foodchemtox

Risk–benefit analysis of micronutrients☆

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Abstract

Traditionally, different approaches have been used to determine the recommended dietary allowances for micronutrients, above which there is a low risk of deficiency, and safe upper levels, below which there is a negligible risk of toxicity. The advice given to risk managers has been in the form of point estimates, such as the recommended dietary allowance (RDA) and the tolerable upper level (UL). In future, the gap between the two intake–response curves may become narrower, as more sensitive indicators of deficiency and toxicity are used, and as health benefits above the recommended daily allowance are taken into account. This paper reviews the traditional approaches and proposes a novel approach to compare beneficial and adverse effects across intake levels. This model can provide advice for risk managers in a form that will allow the risk of deficiency or the risk of not experiencing the benefit to be weighed against the risk of toxicity. The model extends the approach used to estimate recommended dietary allowances to make it applicable to both beneficial and adverse effects and to extend the intake–incidence data to provide a range of estimates that can be considered by the risk manager. The data-requirements of the model are the incidence of a response at one or more levels of intake, and a suitable coefficient of variation to represent the person-to-person variations within the human population. A coefficient of variation of 10% or 15% has been used for established recommended dietary allowances and a value of 15% is proposed as default for considerations of benefit. A coefficient of variation of 45% is proposed as default for considerations of toxicity, based on analyses of human variability in the fate and effects of therapeutic drugs. Using this approach risk managers, working closely with risk assessors, will be able to define ranges of intake based on a balance between the risks of deficiency (or lack of benefit) and toxicity.

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Benefits of foods

- Sometimes we have too high hopes or over-believe in possible benefits of certain foods

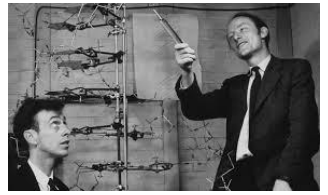
open Biology
rsob.royalsocietypublishing.org
Perspective
Cite this article: Watson J. 2013 Oxidants, antioxidants and the current incurability of metastatic cancers. Open Biol 3: 120144. http://dx.doi.org/10.1098/rsob.120144
Received: 4 October 2012
Accepted: 3 December 2012

Oxidants, antioxidants and the current incurability of metastatic cancers

Jim Watson
Cold Spring Harbor Laboratory, Cold Spring Harbor, New York, NY 11724, USA

1. Summary

The vast majority of all agents used to directly kill cancer cells (ionizing radiation, most chemotherapeutic agents and some targeted therapies) work through either directly or indirectly generating reactive oxygen species that block key steps in the cell cycle. As mesenchymal cancers evolve from their epithelial cell progenitors, they almost inevitably possess much-heightened amounts of antioxidants that effectively block otherwise highly effective oxidant therapies. Also key to better understanding is why and how the anti-diabetic drug metformin (the world's most prescribed pharmaceutical product) preferentially kills oxidant-deficient mesenchymal p53$^{-/-}$ cells. A much faster timetable should be adopted towards developing more new drugs effective against p53$^{-/-}$ cancers.



"Blueberries best be eaten because they taste good, not because their consumption will lead to less cancer."

Benefits of foods

- In other cases, we focus too much on one single nutrient component but not the whole picture


Latest Newsletters *The Atlantic*

HEALTH

Fish Oil Is Good! No, Bad! No, Good! No, Wait.

Americans love it. But the science is getting even weirder.

By Jacob Stern

https://www.theatlantic.com/health/archive/2022/08/vascepa-fish-oil-omega-3/671064/


HARVARD HEALTH BLOG

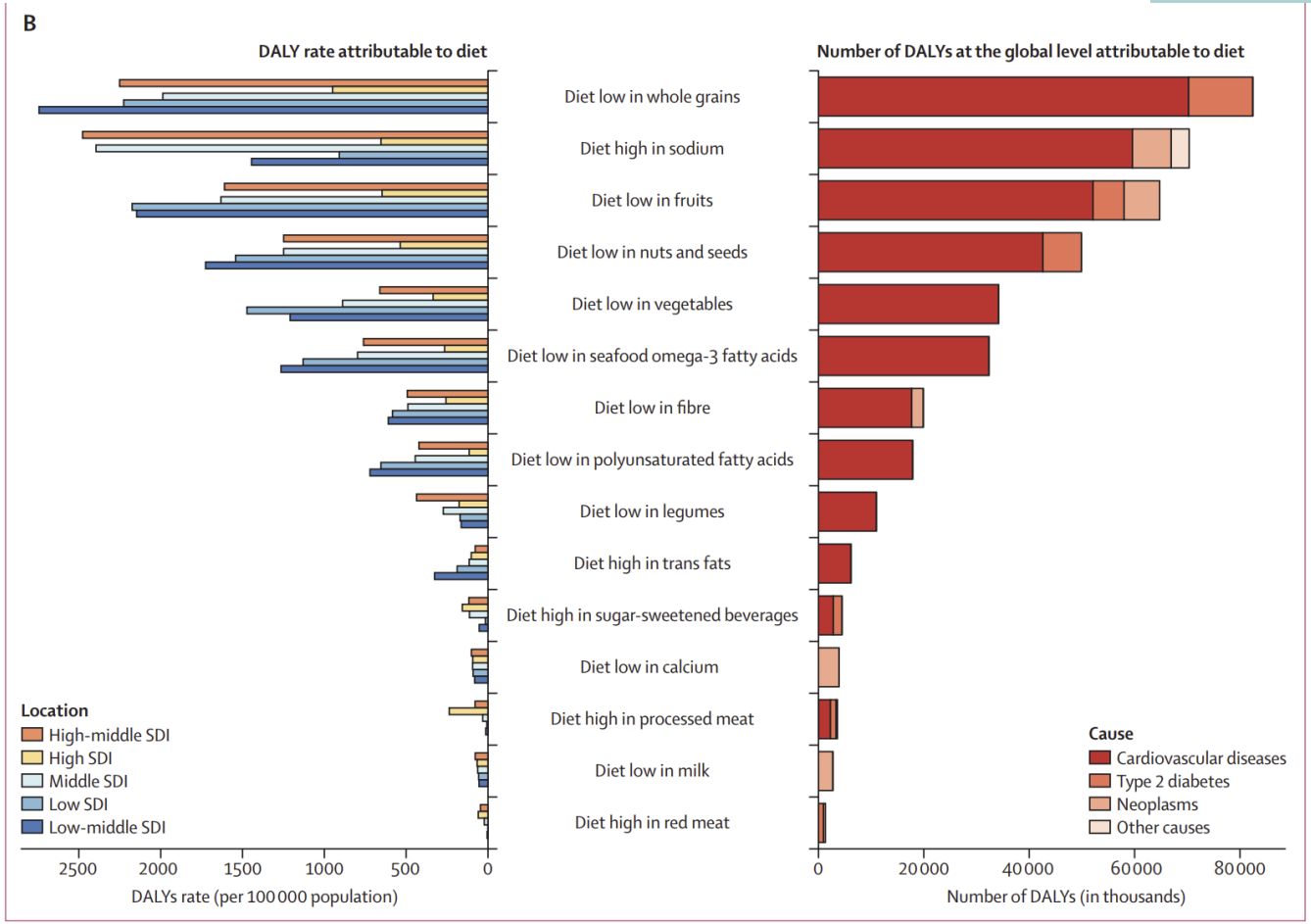
The complicated relationship between fish oil and heart health

December 12, 2019

https://www.health.harvard.edu/blog/the-complicated-relationship-between-fish-oil-and-heart-health-2019120418399

Benefits of foods

- In the absence of nutrient deficiency (relatively rare in affluent countries) imbalanced macronutrient composition is strongly related to risk of non-communicable diseases



Lancet 2019; 393: 1958–72
Published Online
April 3, 2019
http://dx.doi.org/10.1016/S0140-6736(19)30041-8

Figure 3: **Number of deaths and DALYs and age-standardised mortality rate and DALY rate (per 100 000 population) attributable to individual dietary risks at the global and SDI level in 2017**
DALY=disability-adjusted life-year. SDI=Socio-demographic Index.

Previous work and where are we now

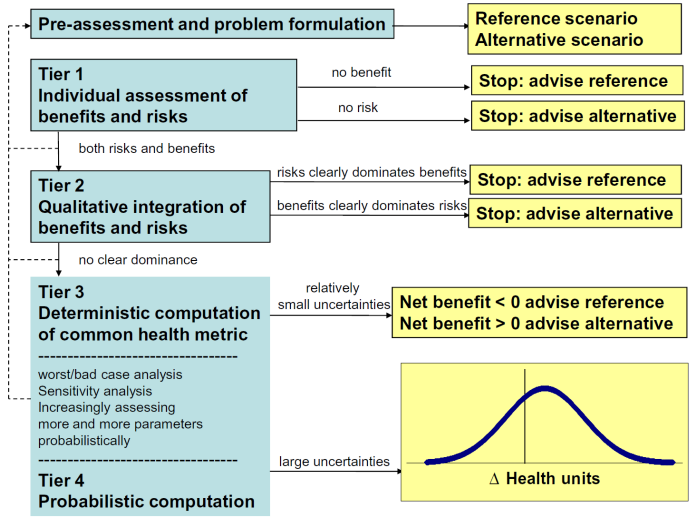


Fig. 1. A flow-chart of the BRAFO tiered approach.

Previous research focus

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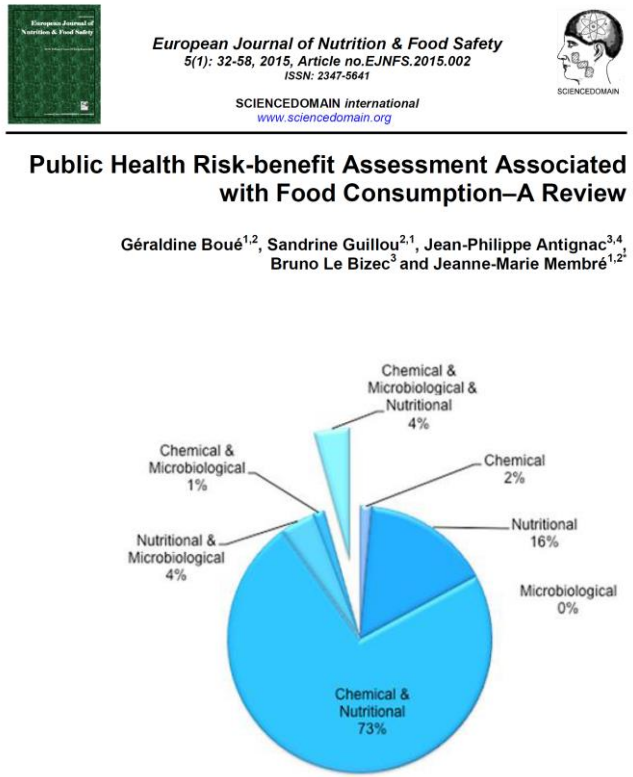

European Journal of Nutrition & Food Safety
5(1): 32-58, 2015, Article no.EJNFS.2015.002
ISSN: 2347-5641
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Public Health Risk-benefit Assessment Associated with Food Consumption–A Review

Géraldine Boué[1,2], Sandrine Guillou[2,1], Jean-Philippe Antignac[3,4], Bruno Le Bizec[3] and Jeanne-Marie Membré[1,2]*

Fig. 4. RBA studies performed classified by scientific fields, based on 70 studies

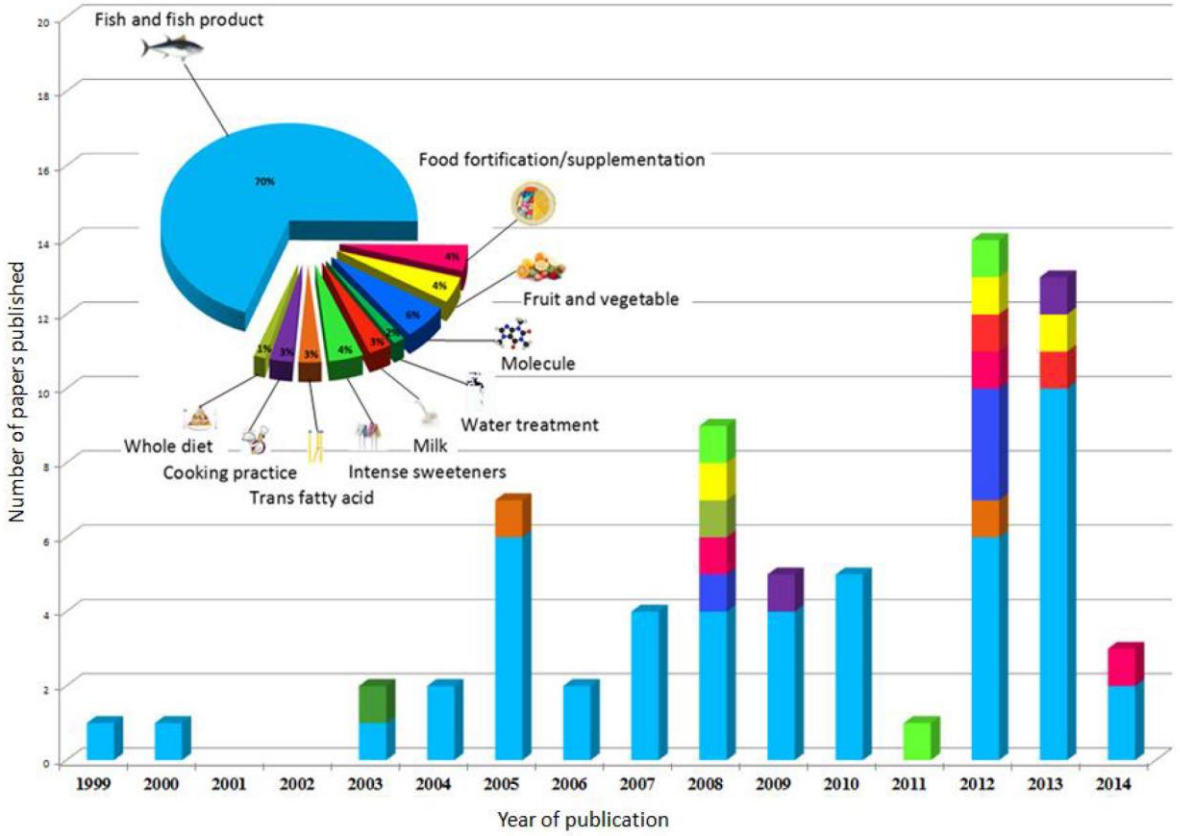

Fig. 3. Classification of the 70 studies performed by year and food category

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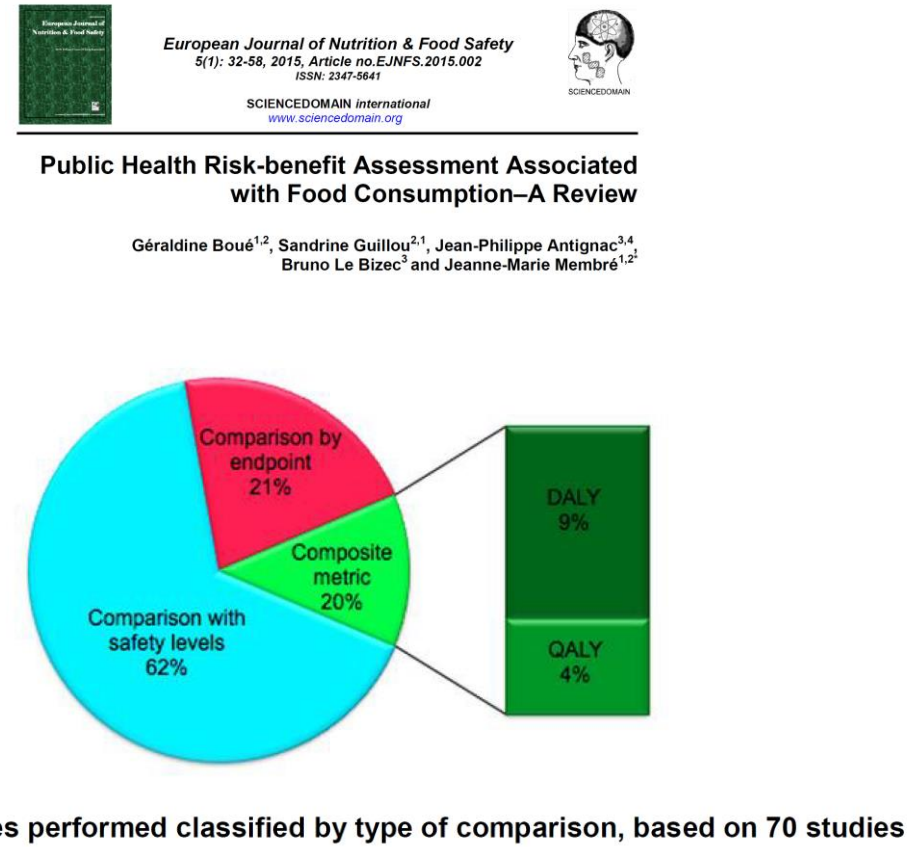
Methods for comparing risks and benefits

- **Qualitative methods**
  - Expert judgment
  - Simple comparison with dietary reference values and health based guidance values
  - Narrative description/reflection

- **Quantitative methods**
  - Usually done though use of composite metric (DALYs/QUALYs)
  - Probabilistic method or other mathematical modelling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Public Health Risk-benefit Assessment Associated with Food Consumption–A Review

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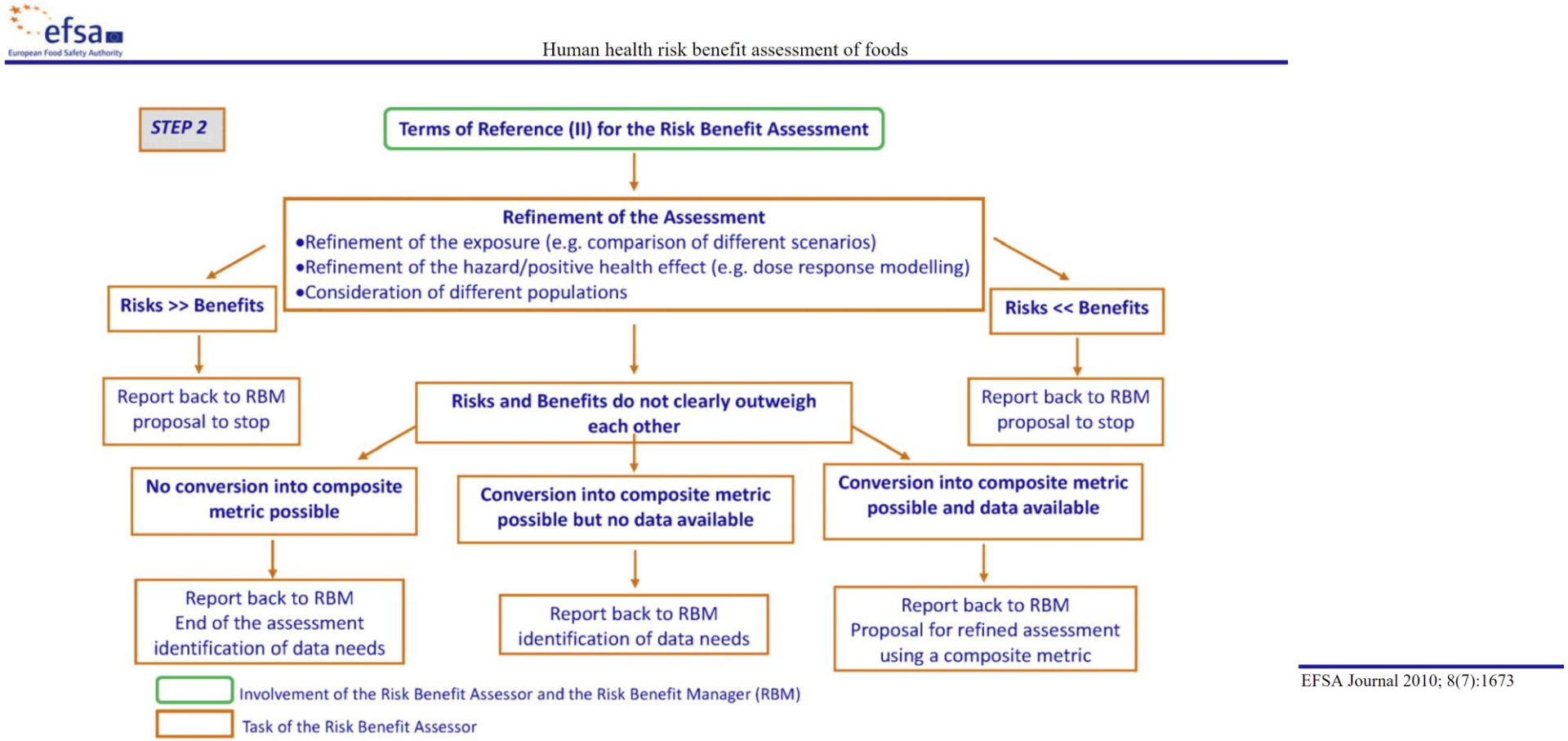
Fig. 5. RBA studies performed classified by type of comparison, based on 70 studies

EFSA guidance on risk benefit assessment from 2010 was very focused on qualitative (composite) metric



EFSA Journal 2010; 8(7):1673

Composite metric
Global Burden of Disease

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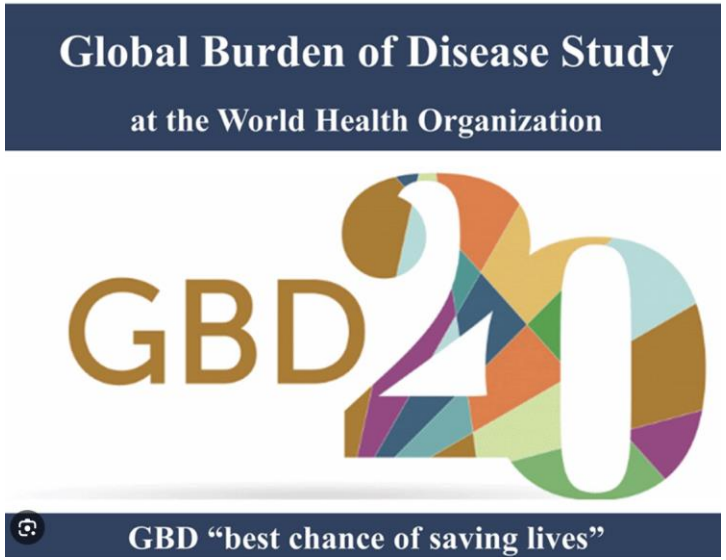
- The Global Burden of Disease (GBD) approach endeavors to measure disability and death from a multitude of causes worldwide. It has grown over the past two decades into an international consortium of nearly 5,500 researchers, and its estimates are being updated annually.

- Published in *The Lancet* in October 2020, GBD 2019 provides for the first time an independent estimation of population, for each of 204 countries and territories and the globe, using a standardized, replicable approach, as well as a comprehensive update on fertility and migration. GBD 2019 incorporates major data additions and improvements, and methodological refinements.



https://www.healthdata.org/research-analysis/about-gbd/history

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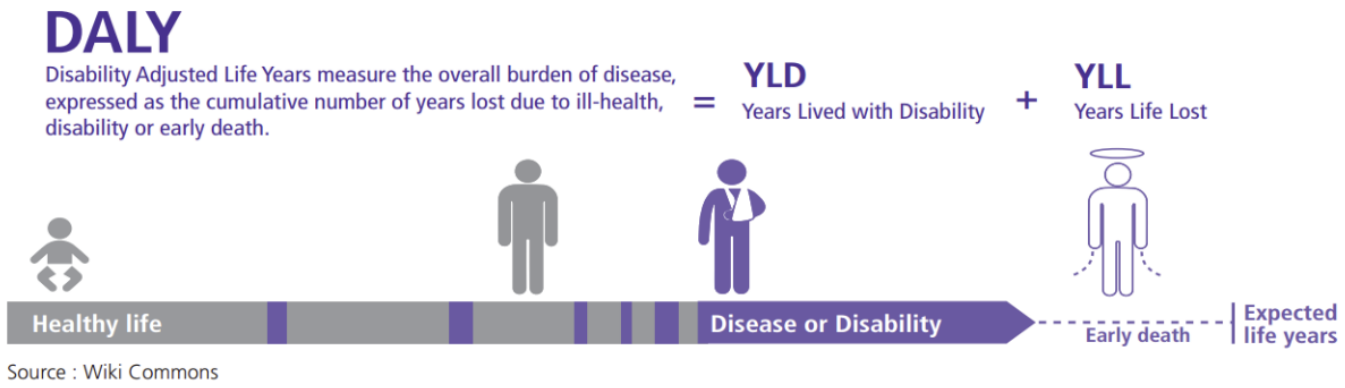
Composite metric: DALYs



Source : Wiki Commons

DALYs = Years of life lost due to premature mortality (YLL) + Years lived with disability (YLD)

Examples of disability weight

Condition	DW 2004[4]	DW 2010[5]
Alzheimer's and other dementias	0.666	0.666
Blindness	0.594	0.195
Schizophrenia	0.528	0.576
AIDS, not on ART	0.505	0.547
Burns 20%–60% of body	0.441	0.438
Fractured femur	0.372	0.308
Moderate depression episode	0.350	0.406
Amputation of foot	0.300	0.021–0.1674
Deafness	0.229	0.167–0.281
Infertility	0.180	0.026–0.056
Amputation of finger	0.102	0.030
Lower back pain	0.061	0.0322–0.0374

DALYs = Years of life lost due to premature mortality (YLL) + Years lived with disability (YLD)

YLD = I (number of incident cases) x DW (disability weight) x L (average duration of the case until remission or death in years)

Composite metric: QALYs

Quality-Adjusted Life Years (QALYs)

ABOUT QALYs

Quality-adjusted life years are usually used to analyse clinical interventions. The goal is to maximize the "good" of quality of life.

QALYs use utility weights (0 = death and 1 = perfect health) generated through techniques such as standard gamble (asking respondents to assess which health states are more valuable to them).

- **Example**
  - Blindness
  - Time trade-off value is 0.5
  - Life span = 80 years
  - 0.5 x 80 = 40 QALYs

https://www.healthdata.org/research-analysis/about-gbd/history

Example of qualitative comparison

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From fish chemical characterisation to the benefit-risk assessment – Part A

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ABSTRACT

Proximate composition, fatty acid profile, cholesterol, α-tocoferol content and essential (K, Na, Cl, S, Mg, Ca, Zn, Cu, Fe, Mn, and Se) and contaminant element (Hg/MeHg, Cd, Pb, and As) levels in silver scabbard-fish (*Lepidopus caudatus*), hake (*Merluccius merluccius*), and ray (*Raja* spp.) were investigated.

Results showed that these species contain high protein, low cholesterol and energy levels, being its consumption recommended. Polyunsaturated fatty acids (PUFA) were the dominant group of the fatty acids, being 80% of the n-3 family. Attending to the dietary reference intakes (DRIs), these fish species are a good source of Se and the other minerals can give a relevant contribution to the DRIs in a balanced diet. More than one weekly meal of silver scabbardfish has to be avoided due to the organic mercury concentration. More accurate dietary recommendations require a probabilistic assessment, which will be the focus of this study's Part B.

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Example of qualitative comparison

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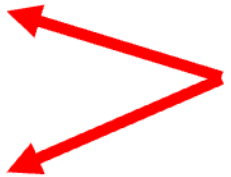
Table 4
Concentration (mean ± standard deviation) and nutritional contribution, of a serving portion of 150 g, of silver scabbardfish, hake, and ray in terms of essential elements.

		Silver scabbardfish			Hake			Ray		
Element	DRI (mg/day)	mg/kg	EDI (mg/150 g)	% DRI	mg/kg	EDI (mg/150 g)	% DRI	mg/kg	EDI (mg/150 g)	% DRI
K	**4700**[*]	3638 ± 305a	546	11.6	3511 ± 224ab	526.6	11.2	3261 ± 246b	489	10.4
Na	1200–**1500**[*]	929 ± 286a	139	11.6	2187 ± 356b	328.1	27.3	1295 ± 351a	194	16.2
Cl	1800–**2300**[*]	1131 ± 458a	170	9.4	1333 ± 493a	200.0	11.1	1541 ± 387a	231	12.8
S	800–**1000**[*a]	1289 ± 192a	193	24.2	1463 ± 158a	219.5	27.4	2005 ± 283b	301	37.6
Mg	310–**420**[**]	248 ± 23a	37	12.0	366 ± 31b	54.9	17.7	266 ± 18a	40	12.9
Ca	1000–**1200**[*]	82 ± 16a	12	1.2	215 ± 197b	32.2	3.2	144 ± 57b	22	2.2
Zn	8–**11**[**]	2.8 ± 0.2a	0.42	5.2	3.4 ± 0.42b	0.50	6.3	4.0 ± 0.3c	0.60	7.5
Cu	**0.90**[**]	0.13 ± 0.04a	0.02	2.2	0.31 ± 0.07b	0.05	5.2	0.17 ± 0.05a	0.03	2.8
Fe	8–**18**[**]	2.4 ± 0.3a	0.36	4.5	3.9 ± 2.9a	0.58	7.3	2.8 ± 0.5a	0.42	5.3
Mn	1.8–**2.3**[*]	0.25 ± 0.03a	0.04	2.1	0.12 ± 0.10b	0.02	1.0	0.24 ± 0.06a	0.04	2.0
Se	**0.055**[**]	0.37 ± 0.11a	0.06	102.0	0.29 ± 0.07a	0.04	78.6	0.29 ± 0.08a	0.04	78.7

DRI (bold) – recommended daily values (IOM, 2005) used in the calculation of % DRI. EDI – estimated daily intake. Different letters in the same line denote significant differences ($p < 0.05$).
[a] Belitz et al. (2004).
[*] AI – Adequate intakes.
[**] RDA – Recommended Dietary Allowances.



Risk Benefit Comparison

Table 6
Contribution of a serving portion of 150 g of silver scabbardfish, hake, and ray in terms mercury, cadmium, lead, and arsenic and considering an adult of 60 kg.

Elements	Silver scabbardfish		Hake		Ray	
	EDI (μg/kg bw)	% PTWI	EDI (μg/kg bw)	% PTWI	EDI (μg/kg bw)	% PTWI
Hg	1.34	–	0.53	–	0.61	–
MeHg	1.16	72.4	0.57	35.7	0.54	33.6
Cd	0.01	0.29[*]	0.03	1.09[*]	0.01	0.57[*]
Cd	0.01	0.87[**]	0.03	3.26[**]	0.01	1.72[**]
Pb	0.04	0.18	0.15	0.59	0.07	0.28
As	5.9	–	16.7	–	77.1	–

PTWI – provisional tolerable weekly intake.
[*] PTMI – provisional tolerable monthly intake.
[**] TWI – tolerable weekly intake.

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Example of quantitative comparison, next speaker ☺

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Moving forward …….

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Agenda

Scientific Colloquium N°26 on Risk Benefit Assessment of combined exposure to Nutrients and Contaminants through food | On-line meeting, 15-16-17 February 2022

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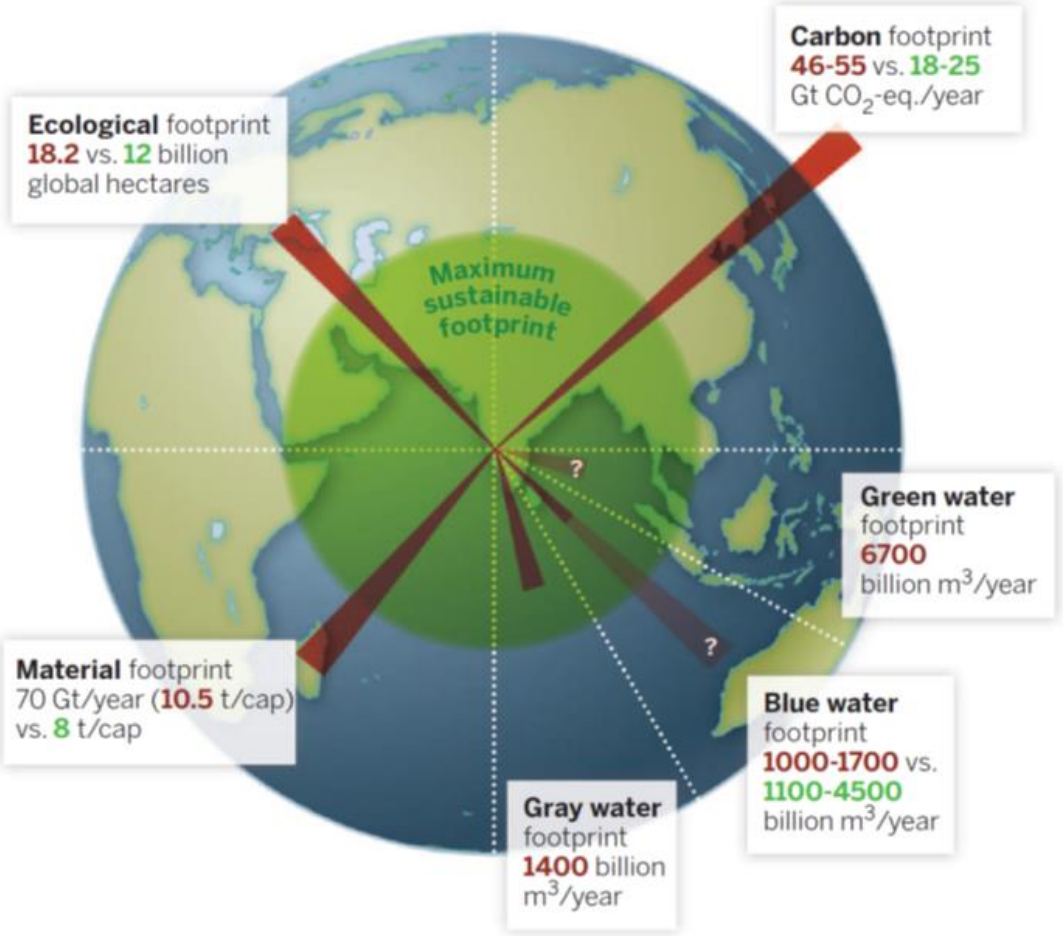
Global warming and demand for more sustainability food production will change everything

Science

Humanity's unsustainable environmental footprint

Arjen Y. Hoekstra and Thomas O. Wiedmann



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Conclusions

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- We have well established procedures for assessing risks and benefits
- Chemical risk assessment aims to eliminate risk (without further quantification)
- Benefits of foods is are largely related to eliminating deficiency through balanced diets (which is quantifiable)
- As such direct comparison of benefits and risks are often problematic
- Competition for land/resources and global warming will be a key driver for how we assess risks and benefits future

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