General introduction into risk-benefit of food and nutrition

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Risk Analysis: Functional and Institutional Separation

- Risk Assessment (scientific advice and analysis)
- Risk Management (regulation and control)
- Risk Communication

Risk-Benefit: same separation between assessment, management and communication
“LIFE WOULD BE PRETTY DULL WITHOUT RISK”

“voluntary risk taking and its pleasures”*

• Three dominant discourses:

1. Self improvement
2. Emotional engagement
3. Control

“LIFE WOULD BE PRETTY DULL WITHOUT RISK”
“LIFE WOULD BE PRETTY DULL WITHOUT RISK”

Pufferfish (fugu)

Gall bladder:

tetrodotoxin

(neurotoxin)

Emerging risk: *Vibrio spp* in Northern Waters and detection of tetrodotoxin in European bivalves (UK, NL, BE) → EFSA 2017 Opinion
CHEMICALS IN FOOD

- Contaminants
- Additives
- Pesticides
- ...
- Natural toxins
- Non-nutrients
- Macronutrients
- Micronutrients
- ...
- Why is feed safe?
- Process contaminants
- Food processing:
  - Fermentation
  - Smoking
  - Drying
  - Roasting (120°C)
- Chemicals in food: establishing safe levels
  - ADI: Acceptable Daily Intake
  - TDI: Tolerable Daily Intake
DIETARY REFERENCE VALUES

The diagram illustrates the distribution of individual requirements within a population. It shows the percentage of the population with lower threshold intake, the average requirement, and the population reference intake. The data is spread out symmetrically with 2 SD (standard deviation) on either side of the average requirement.
TOLERABLE UPPER INTAKE LEVELS

Graph showing the relationship between intake and risk of adverse supply level.

- Lower threshold intake
- Average requirement
- Population reference intake
Example: vit C

- PRI: 110mg
- UL: 2g
- LOAEL: 3g

Source: ERNA
DIETARY REFERENCE VALUES

Population distribution \textit{versus} intake

Average intake = 120

Daily intake

Number of subjects

Intake giving benefit
Population distribution \textit{versus} intake

\begin{center}
\begin{tikzpicture}
\begin{axis}[
    xlabel={Daily intake},
    ylabel={Number of subjects},
    xmin=0, xmax=300,
    ymin=0,
    ymax=500,
    xtick={0,50,100,150,200,250,300},
    ytick={0,100,200,300},
    xticklabels={0, 50, 100, 150, 200, 250, 300},
    yticklabels={0, 100, 200, 300},
    width=\textwidth,
    height=4in,
]
\addplot[blue, thick] table [x index=0, y index=1, col sep=comma] {data.csv};
\end{axis}
\end{tikzpicture}
\end{center}

Average intake = 180

Intake giving toxicity
Population distribution *versus* intake
Nicotinic acid daily intake

% Incidence

Nicotinic acid daily intake

Requirement
Flushing
Cholesterol lowering
Hepatotoxicity

RISK-BENEFIT – NICOTINIC ACID

Courtesy: Prof. A. Renwick
FOLIC ACID FORTIFICATION OF FLOUR

• Neural Tube Defects (benefit)
• Masking B12-deficiency (risk)
• Colorectal Cancer (benefit and risk)
• Folate deficiency (benefit)
# Folic Acid Fortification of Flour

## Public Health Effects of Fortification at 70 μg per 100 g of Flour

<table>
<thead>
<tr>
<th>Condition</th>
<th>Incidence (#)</th>
<th>Incidence (%)</th>
<th>DALYs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neural tube defects</td>
<td>- 83</td>
<td>- 37%</td>
<td>5474</td>
</tr>
<tr>
<td>B₁₂ deficiency</td>
<td>53</td>
<td></td>
<td>53</td>
</tr>
<tr>
<td>Colorectal Cancer</td>
<td>- 405</td>
<td>- 4.1%</td>
<td>2217</td>
</tr>
</tbody>
</table>

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**Additional Information:***

Integrated risk–benefit analyses: Method development with folic acid as example

Jelger Hoekstra*, Janneke Verkaik-Koolsterman, Cath Nijhoff, Henk van Kranen, Margo Zehmke, Hans Verhagen, Nynke de Jong

*National Institute for Public Health and the Environment, Bilthoven, The Netherlands

Received 30 June 2010; accepted 10 October 2010
## Public health burden (DALYs)

<table>
<thead>
<tr>
<th>Condition</th>
<th>DALYs</th>
</tr>
</thead>
<tbody>
<tr>
<td>NTD</td>
<td>5474</td>
</tr>
<tr>
<td>B12</td>
<td>-53</td>
</tr>
<tr>
<td>CRC</td>
<td>2217</td>
</tr>
<tr>
<td>Total</td>
<td>7662</td>
</tr>
</tbody>
</table>

FOLIC ACID FORTIFICATION OF FLOUR
## FOLIC ACID FORTIFICATION OF FLOUR

### Public health burden (DALYs)

<table>
<thead>
<tr>
<th></th>
<th>70 µg</th>
<th>140 µg</th>
<th>280 µg</th>
<th>420 µg</th>
</tr>
</thead>
<tbody>
<tr>
<td>NTD</td>
<td>5474</td>
<td>7710</td>
<td>9812</td>
<td>10855</td>
</tr>
<tr>
<td>B12</td>
<td>-53</td>
<td>-76</td>
<td>-120</td>
<td>-165</td>
</tr>
<tr>
<td>CRC</td>
<td>2217</td>
<td>4146</td>
<td>167</td>
<td>-21740</td>
</tr>
<tr>
<td>Total</td>
<td>7662</td>
<td>11812</td>
<td>9899</td>
<td>-11006</td>
</tr>
</tbody>
</table>
PARADIGM SHIFT

Nutrition / epidemiology: effective dose levels
(minimum effective dose ....to elicit an effect)

Toxicology: ineffective (= safe) dose levels
(point of departure/reference point = no effect / safety factor)
RISK-BENEFIT ASSESSMENT

Compare effects with effects

Megaloblastic anaemia

PRI

330 μg (folate)

1mg (folic acid from fortification and supplements)

SAFE RANGE OF INTAKE
Best Practises for Risk - Benefit Analysis of Foods (BEPRARIBEAN)
Best Practises for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

Food and nutrition: Risk not accepted

Medicine: Risk accepted

Economics and Marketing-Finance: Risk a neccessity
Risk – Benefit characteristics

1. Problem formulation: at least 2 scenario’s

2. A common currency to describe the health impacts

3. Tiered approach
The burden of foodborne diseases is substantial

Every year foodborne diseases cause:
- almost 1 in 10 people to fall ill
- 33 million healthy life years lost
- 420,000 deaths
- Children account for almost 1/3 of deaths from foodborne diseases

Foodborne diseases are deadly, especially in children:
- Children account for almost 1/3 of deaths from foodborne diseases

Foodborne diseases are caused by types of:
- Bacteria
- Viruses
- Parasites
- Toxins
- Chemicals

But in a globalized world they can spread quickly along the food chain and across borders
unsafe food

unhealthy diet

2004/2006
### Comparing health loss and potential health gain by healthy diet and unsafe food in the Netherlands

<table>
<thead>
<tr>
<th>Factor</th>
<th>DALY’s / year</th>
<th>Deaths / year</th>
<th>Cases / year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diet composition #</td>
<td>245,000</td>
<td>13,000</td>
<td>ca. 40,000</td>
</tr>
<tr>
<td>Bodyweight</td>
<td>215,000</td>
<td>7,000</td>
<td>ca. 40,000</td>
</tr>
<tr>
<td>Healthy diet</td>
<td>&gt; 350,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Micro-organisms</td>
<td>1,000-4,000</td>
<td>20-200</td>
<td>300-750 x10³</td>
</tr>
<tr>
<td>Allergens</td>
<td>ca. 1,000</td>
<td>&lt; 1</td>
<td>ca. 32,000</td>
</tr>
<tr>
<td>Chemicals</td>
<td>500-1,000</td>
<td>100-200</td>
<td>200-300</td>
</tr>
<tr>
<td>Food safety</td>
<td>2,500-6,000</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

# dietary composition (5 factors)
BIOLOGICAL RELEVANCE

1. Is the effect in itself an adverse/positive effect?
   - Yes
   - No

2. Is the effect directly or indirectly linked to an adverse/beneficial outcome?
   - Yes
   - No

Is the size of the effect relevant for the assessment?
   - Yes
   - No

Irrelevant

Relevant
WEIGHT OF EVIDENCE APPROACH

Three basic steps of weight of evidence assessment:

1. Assemble the evidence
2. Weigh the evidence
3. Integrate the evidence

WEIGHT OF EVIDENCE CONCLUSION

- Assess consistency across lines of evidence
- Assess the relevance and reliability of each line of evidence

LINES OF EVIDENCE

- Identify, filter and organise the evidence
  
  Includes preliminary consideration of relevance and reliability

AVAILABLE INFORMATION
Uncertainty? Don’t scientists know everything?
PROMETHEUS

PROmoting METHODS for Evidence Use in Scientific assessments

SCIENTIFIC REPORT

APPROVED: 23 April 2015
doi:10.2903/j.efsa.2015.4121

Principles and process for dealing with data and evidence in scientific assessments

European Food Safety Authority (EFSA)
“Life would be pretty dull ....... without risk - benefit”

Thank you 😊