Risk-Benefit assessment of foods in a European perspective

Hans Verhagen, Head, Risk Assessment and Scientific Assistance Department
“LIFE WOULD BE PRETTY DULL WITHOUT RISK”
DIETARY REFERENCE VALUES

- average requirement (AR)
- population reference intake (PRI)
TOLERABLE UPPER INTAKE LEVELS FOR VITAMINS AND MINERALS

Scientific Committee on Food
Scientific Panel on Dietetic Products, Nutrition and Allergies
Population distribution *versus* intake

Average intake = 120

Intake giving benefit
Population distribution *versus* intake
Population distribution *versus* intake

![Graph showing population distribution versus intake.](image-url)
FOLIC ACID FORTIFICATION OF FLOUR

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

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• Neural Tube Defects (benefit)
• Masking B12-deficiency (risk)
• Colorectal Cancer (benefit and risk)
• Folate deficiency (benefit)
FOLIC ACID FORTIFICATION OF FLOUR

Public health burden (modelling)

<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>1 %</td>
<td>- 53</td>
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<tr>
<td>Colorectal Cancer</td>
<td>- 405</td>
<td>- 4.1 %</td>
<td>2217</td>
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## FOLIC ACID FORTIFICATION OF FLOUR

### Public health burden (DALYs)

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<th>140 µg</th>
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<th>420 µg</th>
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<td>NTD</td>
<td>5474</td>
<td>7710</td>
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<td>10855</td>
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<td>-76</td>
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<td>-165</td>
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<td>CRC</td>
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<td>4146</td>
<td>167</td>
<td>-21740</td>
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# FOLIC ACID FORTIFICATION OF FLOUR

## Public health burden (DALYs)

*(sensitivity analysis / uncertainty*)

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<td>6841</td>
<td>4452</td>
<td>-19636</td>
<td>-57963</td>
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*different cut-off cancer*
EFFECTS VERSUS ABSENCE OF EFFECTS

Nutrition / epidemiology: effective dose levels

Toxicology: ineffective (= safe) dose levels
RISK-BENEFIT ASSESMENT

Compare effects with effects

Megaloblastic anaemia
PRI

330 µg (folate)

SAFE RANGE OF INTAKE

330 µg (folate)

1mg (folic acid from fortification and supplements)

5mg

UL

LOAEL

Uncertainty Factor 5

May result in diagnosis of vitamin B12 deficiency

RISK OF INADEQUACY

RISK OF ADVERSE EFFECT

INTAKE/DAY
Best Practises for Risk - Benefit Analysis of Foods (BEPRARIBEAN)
Risk – Benefit characteristics

1. Problem formulation: at least 2 scenario’s
2. A common currency to describe the health impacts
3. Tiered approach
Ranking of foodborne hazards-global DALYs

- Trichinella spp.
- STEC
- C. perfringens
- Listeria monocytogenes
- Brucella spp.
- Escherichia coli
- Clostridium perfringens
- Cryptosporidium spp.
- E. coli
- Salmonella
- Campylobacter
- Yersinia spp.
- Vibrio cholerae
- ETEC
- Norovirus
- EHEC
- V. parahaemolyticus
- Pseudomonas aeruginosa
- E. coli O157

FOODBORNE DISEASES
WHO ESTIMATES OF THE GLOBAL BURDEN OF FOODBORNE DISEASES
FOODBORNE DISEASE BURDEN EPIDEMIOLOGY REFERENCE GROUP 2007-2015
unsafe food

unhealthy diet

RISK-BENEFIT & RISK RANKING & RISK-RISK
1. Is the effect in itself an adverse/positive effect?

2. Is the effect directly or indirectly linked to a(n) adverse/beneficial outcome?

Is the size of the effect relevant for the assessment?

- Yes: Relevant
- No: Irrelevant
WEIGHT OF EVIDENCE APPROACH

Three basic steps of weight of evidence assessment:

1. Assemble the evidence
   Includes preliminary consideration of relevance and reliability

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

AVAILABLE INFORMATION
UNCERTAINTY IN RISK ASSESSMENT

Uncertainty? Don’t scientists know everything?

Guidance on Uncertainty in EFSA Scientific Assessment

EFSA Scientific Committee¹,²

European Food Safety Authority (EFSA), Parma, Italy
Principles and process for dealing with data and evidence in scientific assessments

European Food Safety Authority (EFSA)
RESULT

EVIDENCE-BASED SCIENTIFIC ADVICE

New evidence
“Life would be pretty dull ....... without risk - benefit”

Thank you 😊

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