

Best Practises for Risk - Benefit Analysis of Foods (BEPRARIBEAN)



BEPRARIBEAN Workshop

Reykjavik, Iceland, 14 April – 15 April 2010

Workshop Booklet



BEPRARIBEAN Workshop

Reykjavik, Iceland, 14 April – 15 April 2010

Place of venue: Matis, Vinlandsleid 12, 113 Reykjavik,
+3544225000, www.matis.is

FINAL PROGRAMME

Chair: Dr. Helga Gunnlaugsdottir
Co-Chair: Prof. Hans Verhagen
Rapporteurs: Finn Holm and Mariken Tijhuis

Wednesday 14 April

15:00 – 17:00 Registration, display of posters, poster session (posters on display at all times)

SESSION 1 Opening

17.00-17.15 Welcome and introduction to Safefoodera: *Finn Holm*
17.15-17.35 Introduction to Bepraribeian - content: *Mariken Tijhuis*
17.35-17.45 Introduction to Bepraribeian - organisation: *Finn Holm*
17.45-17.55 Introduction to the symposium: *Helga Gunnlaugsdottir*
17:55-18:25 Key note speaker on risk-benefit: *Hans Verhagen*
18:25-18:55 Key note speaker on food law in EU: *Margherita Poto*

20:00 Dinner

Thursday 15 April

SESSION 2 state of the art presentations

08:30-09:00 Best practices risk benefit 1: medicine, *University of Ulster* (Video conference)
09:00-09:30 Best practices risk benefit 2: microbiology, *Matis*
09:30-10:00 Best practices risk benefit 3: environment, *THL*



10:00 – 10:30 Coffee break and posters

10:30-11:00 Best practices risk benefit 4: economics, *Maastricht University Faculty of Economics*

11:00-11:30 Best practices risk benefit 5: food and nutrition, *RIVM*

11:30-12:00 Best practices risk benefit 6: consumer science, *Nofima*

12:00- 13:00 Lunch break and posters

SESSION 3 selected short presentations

13:00-13:25 BRAFO, *Stephane Vidry*, ILSI Europe

13:25-13:50 Fish consumption R&B, *Jogier Toppe*, FAO Rome

13:50-14:30 Coffee break and poster presentations by *Jeljer Hoekstra*, RIVM (4 posters), and *Jouni Tuomisto*, THL

SESSION 4 working groups

14:30-16:30 Three parallel working groups to identify communalities and differences in benefit-risk assessment to be used as input for Bepraribeian consensus group work (chairs and rapporteurs from 6 core institutes)

Questions for the WG:

- What are the similarities between the various benefit-risk approaches?
- What are the differences between the various benefit-risk approaches?
- How can the experiences from the other approaches be used to improve benefit-risk assessment of food and nutrition?
- What are good next steps to convey to the consensus group?
- Other suggestions?

16:30-17:15 Break

Options: short tour of Matis institute; time for rapporteurs to prepare reporting back; posters

17:15-18:15 Three short reports back from rapporteurs and discussions

18:15-18:30 Wrap up and closure: Hans Verhagen

18:30-19:15 Steering Group meeting (members only)

20:00 Drinks

20:30 Dinner



List of participants

Name	Organisation / country	E-mail	Discussion group no
Castenmiller, Jacqueline	VWA, NL	jacqueline.castenmiller@vwa.nl	2
Daníelsdóttir, Anna K.	Matis, IS	anna.k.danielsdottir@matis.is	1
Georgson, Franklin	Matis, IS	franklin.georgsson@matis.is	2
Gunnarsson, Guðjón	Icelandic Food and Veterinary Authority, IS	gudjon.gunnarsson@mast.is	3
Gunnlaugsdóttir, Helga	Matis, IS	Helga.gunnlaugsdottir@matis.is	3
Hagtvedt, Therese	Nofima, NO	therese.hagtvedt@nofima.no	1
Hoekstra, Jeljer	RIVM, NL	Jeljer.hoekstra@rivm.nl	1
Holm, Finn	Foodgroup Denmark, DK	Finn.holm@foodgroup.dk	3
Kalogeras, Nikos	Maastricht University, NL	N.Kalogeras@maastrichtuniversity.nl	1
Leino, Olli	THL, FI	olli.leino@thl.fi	2
Luteijn, Johannes Michiel	University of Ulster, UK	j.m.luteijn@gmail.com	-
Magnússon, Sveinn H.	Matis, IS	sveinn.haukur.magnusson@matis.is	1
Marteinsson, Viggó Þór	Matis, IS	viggo.th.marteinsson@matis.is	2
Poto, Margherita	Wageningen University, NL	margherita.poto@wur.nl	1
Reynisson, Eyjólfur	Matis, IS	eyjolfur.reynisson@matis.is	3
Rompelberg, Cathy	RIVM, NL	Cathy.Rompelberg@rivm.nl	3
Tharaldsen, Anders	Norwegian Food Safety Authority, NO	antha@mattilsynet.no	3

Best Practises for Risk - Benefit Analysis of Foods (BEPRARIBEAN)



Tijhuis, Mariken	RIVM, NL	mariken.tijhuis@rivm.nl	2
Toppe, Jogier	FAO, Rome, IT	Jogier.toppe@fao.org	2
Tuomisto, Jouni	THL, FI	jouni.tuomisto@thl.fi	1
Ueland, Øydis	Nofima, NO	oydis.ueland@nofima.no	2
Verhagen, Hans	RIVM / Maastricht University, NL	hans.verhagen@rivm.nl	1
Vidry, Stephane	ILSI, BE	svidry@ilsieurope.be	3
White, Bronagh	University of Ulster, UK	bc.white@ulster.ac.uk	-



SafeFoodEra
&
BEPRARIBEAN

Second workshop
Iceland, April 2010



Finn Holm
FoodGroup Denmark

- Magister, Chemistry
- 35 years in food science and management
- 15 years in **functional foods & Novel Foods**
- **Administrative coordinator**, BEPRARIBEAN



BEPRARIBEAN
is a European project within
SAFEFOODERA



SAFEFOODERA

**Cooperation of National Food Safety
Research Programs**

Coordinated by The Nordic InnovationCentre (NICe)





**The SAFEFOODERA
primary objective**

is to establish a European platform
for protecting consumers against
health risks

through a co-ordination action ERA-
NET of
15 Member States, 3 Associated
Countries
and 3 regional organisations

representing
in total 450 million European
citizens



**SAFEFOODERA and the European Steering Committee
(ESC)**

- ✓ The members of SAFEFOODERA-ESC are funding bodies from countries that are willing to coordinate the food safety aspects of their ongoing national/regional programmes
- ✓ The **first** joint pilot-call was launched on October 1, 2006
- ✓ The **2nd** call was launched June 2008


SAFEFOODERA
European excellence in food safety research programming

The provisional strategic topics

- Emerging risks** - A potential food or feed borne or diet-related hazard that may become a risk for human health in the (near) future.
- Risk analysis in food safety** - Methodologies in protecting the consumers against health risks and misleading information, including crisis management, consumer perception and risk/benefit analysis.
- Contaminants** - Health risks from natural- and environmental contaminants in the food chain.
3.1 Process induced risk - Health risks from chemical pollution formed during processing of foods.
- Traceability** - Documented and harmonised routines for recall of food products from the value chain - Development of reliable traceability methods and systems.
- Pathogens** - Pathogen free production systems - From reactive to preventive and predictive actions.

Safe FOOD Era

- ✓ **35 million cases of food poisoning within the EU each year, unknown number of deaths (population: 480 million)**
- ✓ **76 million illnesses and 5000 deaths in US each year (population: 268 million)**
- ✓ **One-third of the populations of developed countries may be effected by foodborne illness each year**
- ✓ **Only a fraction of outbreaks is reported**
- ✓ **Risks (traditional) : health loss due to unhealthy diet**



Safe FOOD Era

Pilot Call programme

- Network budget is 3,5 MEURO
- Participating countries: CY, DE, ES (Basque Country), FI, IS, LV, NL, NO, NMR & Nordic InnovationCenter (Denmark, Finland, Iceland, Norway, Sweden), PT, SI, UK
- Kick Off meeting May 2007
- Period: March 2007 – August 2008
- **4 projects** are funded (out of 11 received before deadline).

Safe FOOD Era

Pilot Call

Number	Project title	Coordinator
06453-P	Pathogen & ugly microbe free food industry network – PUFFIN	Viggó Þór Marteinsson viggjo.th.marteinsson@matis.is - www.matis.is
06454-E	Network of information sources for an identification system of emerging mycotoxins in international plant production chains (MYCONET)	Dr. ir. H.J. (Ine) van der Fels-Klerx ine.vanderfels@wur.nl
06458-P	Increased safety of fermented sausage by the application of production exposure assessment for VTEC	Permilla Arinder permilla.arinder@slk.se www.slk.se
6465-Z	Foodborne zoonoses - Campylobacter and E. coli - a network project (CampEco-NET)	Merete Hofshagen, merete.hofshagen@velinlst.no Web: www.zoonose.no

Safe FOOD Era

2nd Call (2008)

- **DETECTION OF TRACES OF ALLERGENS IN FOOD**
- **BIOACTIVE INGREDIENTS**: Safety of bioactive ingredients in functional foods
- **CHEMICAL FOOD CONTAMINANTS**
- **EMERGING RISK**: Effects [Consequences] of climate change on [for] feed and food safety
- **GMO**: Development of screening methods of GMO
- **MRSA/ANTIBIOTIC RESISTANCE**: The zoonotic potential of methicillin-resistant Staphylococcus aureus (MRSA) – antibiotic resistance and non-typable (NT) strains
- **RISK-BENEFIT ANALYSIS**
- **RISK ASSESSMENT OF FOOD-BORNE PATHOGENS**
- **TRACEABILITY COMMON POT**

Safe FOOD Era

2nd Call programme

- Network budget is 6,5 MEURO
- Participating countries: CY, CZ, DE, ES (Basque Country), FI, IS, NL, NO, NMR & Nordic InnovationCenter (Denmark, Finland, Iceland, Norway, Sweden), PT, SI, UK
- Kick Off meeting Amsterdam 2nd April 2009
- Period: March 2009 – August 2011
- **10 projects** are funded (out of 24 received before deadline).
- Midterm meeting 2nd June 2010

Funded projects in SAFEFOODERA Call 2008

ID	Title	Topic	Coordinator
08185	Detection of traces of allergens in foods	Allergens	Jorge Martinez-Quesada jorge.martinez@bch.uia.no ; jorge.martinez@bch.uia.no
08183	Piglet model for safety testing of probiotic Bacillus species	Bioactive	Simon Hardy Simon.Hardy@nrmh.no ; Perinjar.garum@nrmh.no
08202	BIOTRANSPORT Safe transportation of marine bioactive's from source to active site	Bioactive	I ngrid Unelund Unelund@bchalmers.se
08184	RISKFOODCONT – BioAvailability and risk assessment of polycyclic aromatic hydrocarbons (PAHs) and toxic elements (As, Cd, Hg and Pb) in processed meat and seafood products	Che. Contami	Maria and António Marques mfmunes@himer.pt ; A.Marques@himer.pt
08187	Effects of climate change on emerging natural toxins in plant and seafood production (EMTOX)	Emerging	Felix Ine van der Kleen f.vanderkleen@wur.nl
08200	GMOseak The role of commensal microflora of animals in the transmission of extended spectrum β-lactamases (ESBLs)	GMO	Dany Morisset Dany.Morisset@uhb.ac.be ; DanyMorisset@gmail.com
08176	DEPRARIBEAN Best Practices for Risk-Benefit Analysis: experience from out of food into food	MRSA	Dik Mevius Dik.mevius@wur.nl
08192	Risk assessment of Listeria in traditional ready-to-eat food items (LisRisk)	Risk Benefit Risk assess.	Finn Holm and Håns Verhagen Finn.holm@bioforsk.se ; Hans.Verhagen@ru.nl
08198	eTrace - electronic Traceability using EPCIS	Traceability	Hörfleur Einarsson h@eipcis.is Carl-Fredrik Sørensen CarlFredrik.Sorensen@stir.ac.uk Carl.F.Sorensen@stir.ac.uk

<http://www.safefoodera.net>



Best Practices for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

WS2: Introduction to BEPRARIBEAN - Content

Mariken J. Tijhuis

Best Practices for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

2010 BEPRARIBEAN state of the art in benefit-risk analysis food & nutrition

2008 Benefit-risk case study: added sugar vs sweeteners

PhD in Nutrition "Fruits and Vegetables, Detoxification Genes and Intermediate Endpoints in Colorectal Cancer Prevention"

epidemiology nutrition

food fortification blood pressure heart failure

ADHD birth weight homocysteine CHD

cancer genetics weight cycling metabolic syndrome

food consumption survey

Introduction to BEPRARIBEAN content - M.J. Tijhuis

Best Practices for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

Outline of presentation

Safefoodera project BEPRARIBEAN

- Background
- Aim
- Current state
- Future

ERA-net
↓
safefoodera
↓
BEPRARIBEAN

Introduction to BEPRARIBEAN content - M.J. Tijhuis

Best Practices for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

"Our food, our health"

Healthy diet and safe food in the Netherlands"

RIVM 2004, 2006



Introduction to BEPRARIBEAN content - M.J. Tijhuis

Best Practices for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

Comparing health loss and potential health gain by healthy diet and unsafe food in the Netherlands (2004)

Factor	DALY's / yr	Deaths / yr	Cases / yr
Diet composition #	245,000	13,000	ca. 40,000
Overweight	215,000	7,000	ca. 40,000
Healthy diet	> 350,000		
Micro-organisms	1,000-4,000	20-200	300-750,000
Allergens, natural toxins	ca. 1,000	< 1	ca. 32,000
Chemicals	500-1,000	100-200	200-300
Food safety	2,500-6,000		

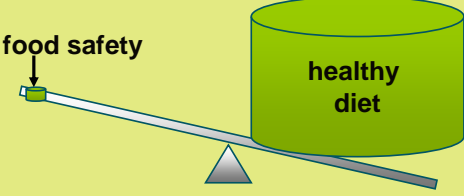
5 factors: SFA, TFA, Fish, Fruit, Vegetables

Introduction to BEPRARIBEAN content - M.J. Tijhuis

Best Practices for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

food safety

healthy diet



"The health loss due to unhealthy diet is many times greater than that attributable to unsafe food"

→ greater health gains are to be made through encouraging a healthy diet than through improving food safety

Introduction to BEPRARIBEAN content - M.J. Tijhuis

Best Practices for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

“The **health gains** to be made through the consumption of more
-fruit and vegetables
-wholegrain products
-fish
-breastfeeding
are many times greater than the **health risks** involved”






→ Consider both the beneficial and adverse potential in food

Introduction to BEPRARIBEAN content - M.J. Tijhuis

Best Practices for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

Beneficial and adverse potential can be in the same food or even in the same ingredient

“Famous” examples:



Type	Example	Benefits	Risks
Traditional	Fish	Coronary heart disease ↓	Neurological damage in fetus Microbiological contamination
Component	Folic acid	Neural tube defects Cancer ↓	B12 deficiency masking Cancer ↑
Functional	Margarine with phytosterols	Cholesterol level ↓	β-carotene level ↓

Introduction to BEPRARIBEAN content - M.J. Tijhuis

Best Practices for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

The approaches and policies followed and measures taken to guarantee food safety may lead to suboptimal/too low levels or absence of ingredients from the perspective of benefits.



→ Conceptual shift from assessment of risk only (safety) to assessment of balance of risks and benefits

Introduction to BEPRARIBEAN content - M.J. Tijhuis

Best Practices for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

Exposure to personal risk is recognized as a **normal aspect of everyday life**. We accept a certain level of risk in our lives as necessary to achieve certain benefits.

Paradox: dosages of nutrients that induce risks in sensitive populations commonly overlap with those which induce benefits in the majority

Introduction to BEPRARIBEAN content - M.J. Tijhuis

Best Practices for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

There is a growing body of opinion in favor of a more balanced view



Integration of Risk and Benefit Analysis—The Window of Benefit as a New Tool?

ANDRÉ PALOZ*, CATALINA FROU* and JAAP KEIZER*

Toxicology

The paradox of overlapping micronutrient risks and benefits obligates risk/benefit analysis

Robert H.J. Verheek*

Introduction to BEPRARIBEAN content - M.J. Tijhuis

Best Practices for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

But as of yet... benefit-risk assessment in food and nutrition is a relatively new area

In title/abstract	Pubmed	Scopus	In title/abstract	Pubmed	Scopus
'Risk-benefit':	4209	31503	'Benefit-risk'	1388	2399
'Risk-benefit' AND 'food or nutrition':	207	2668	'Benefit-risk' AND 'food or nutrition':	56	196

Reference date: april 2nd 2010

→ The food and nutrition area could benefit from experiences in other areas (and possibly vice versa)

Introduction to BEPRARIBEAN content - M.J. Tijhuis

Best Practices for Risk - Benefit Analysis of Foods (BEPRARIBEAN)



BEPRARIBEAN

Best Practices for Risk-Benefit Analysis:

experience from out of food into food*

*pharma/medicines, microbiology, environment, societal/economy, perception

Aim: to identify best practices and experiences from other areas and transpose those onto the food and nutrition area

Introduction to BEPRARIBEAN content - M.J. Tijhuis



Best Practices for Risk - Benefit Analysis of Foods (BEPRARIBEAN)



European collaboration

UK
IS
FI
NL
NO
DK

- Best practices distilled from several areas
- Possibly leading into one overall approach across disciplines
- Improve food safety assessment from benefit-risk approach
- Spread high national expertise in European dimension
- Bring in experience from recent projects and activities

Introduction to BEPRARIBEAN content - M.J. Tijhuis



Best Practices for Risk - Benefit Analysis of Foods (BEPRARIBEAN)



BEPRARIBEAN current state

'State of the art' drafts written for

- Pharma/medicine
- Microbiology
- Environment
- Economics
- Food and nutrition
- Consumer science

→Content is to be presented tomorrow morning

Introduction to BEPRARIBEAN content - M.J. Tijhuis



Best Practices for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

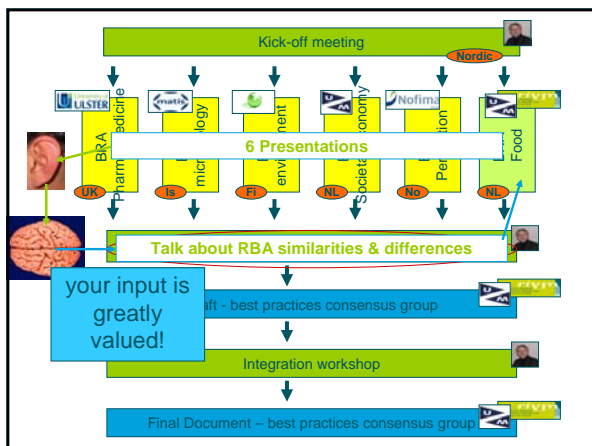


BEPRARIBEAN Future
(starting tomorrow afternoon during workshops):

- Identification of commonalities and differences
- Creation of consensus on general principles or approaches for conducting benefit-risk analyses
- Result published in consensus paper




Introduction to BEPRARIBEAN content - M.J. Tijhuis

Best Practices for Risk - Benefit Analysis of Foods (BEPRARIBEAN)




**Thank you
for your attention !**



Introduction to BEPRARIBEAN content - M.J. Tijhuis





Introduction to the Workshop
Helga Gunnlaugsdottir



Welcome to the
BEPARAIBEAN
Workshop
&
Matis new building
in Reykjavik, at
Vínlandsleið 12
we moved in 18th of
December 2009



14.04.2010 Helga Gunnlaugsdottir 2

BEPARAIBEAN Workshop 2 in Iceland



•**Agenda 14th of April 2010**
17:55-18:25 Key note speaker on risk-benefit: *Hans Verhagen*
18:25-18:55 Key note speaker on food law in EU: *Margherita Poto*

•**Agenda 15th of April 2010**
SESSION 2 state of the art presentations
08:30-09:00 Best practices risk benefit 1: medicine, *University of Ulster*
09:00-09:30 Best practices risk benefit 2: microbiology, *Matis*
09:30-10:00 Best practices risk benefit 3: environment, *THL*

10:00 – 10:30 Coffee break and posters

14.04.2010 Helga Gunnlaugsdottir 3



•**Agenda 15th of April 2010 continued**
10:30-11:00 Best practices risk benefit 4: economics, *Maastricht University Faculty of Economics*
11:00-11:30 Best practices risk benefit 5: food and nutrition, *RIVM*
11:30-12:00 Best practices risk benefit 6: consumer science, *Nofima*

12:00- 13:00 Lunch break and posters

SESSION 3 selected short presentations
13:00-13:25 BRAFO, *Stephane Vidry*, *ILSI Europe*
13:25-13:50 Fish consumption R&B, *Jogier Toppe*, *FAO Rome*
13:50-14:30 Coffee break and poster presentations by *Cathy Rompelberg*, *RIVM*, *Jeljer Hoekstra*, *RIVM* (4 posters), and *Jouni Tuomisto*, *THL*

SESSION 4 working groups

14.04.2010 Helga Gunnlaugsdottir 4

Practical information



Dinner 1 – April 14th
VOX-Restaurant
Hilton Reykjavik Nordica
Sudurlandsbraut 2, Reykjavik

Dinner 2 – April 15th
DILL restaurant
Nordic House
Sturlugötu 5, Reykjavik

Both restaurants emphasise on Nordic raw material

14.04.2010 Helga Gunnlaugsdottir 5

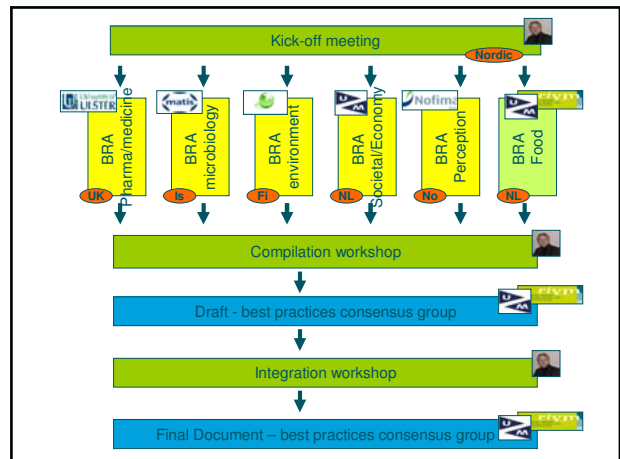
BEPRARIBEAN

Best Practices in Risk Benefit Analysis



Hans Verhagen et al.

Reykjavik 14-4-2010



Contents

- Voluntary risk taking
- A small tour in history of diet and health
- Developing benefit-risk assessment:
 - Micronutrients
 - Safe food versus healthy diet
 - Folic acid as an example
- Conclusion



3

“Life would be pretty dull without risk”

*“voluntary risk taking and its pleasures”**

- Three dominant discourses:

1. Self improvement
2. Emotional engagement
3. Control



*Lupton & Tulloch, Health, Risk and Society, 4 [2002] 113-124



5



6



rivm

7



rivm



rivm

9



rivm

Contents

- Voluntary risk taking
- **A small tour in history of diet and health**
- Developing benefit-risk assessment:
 - Micronutrients
 - Safe food versus healthy diet
 - Folic acid as an example
- Conclusion

rivm

11



rivm

12

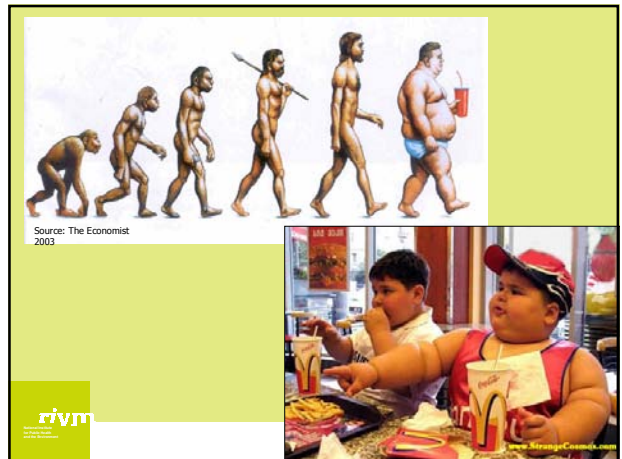


13

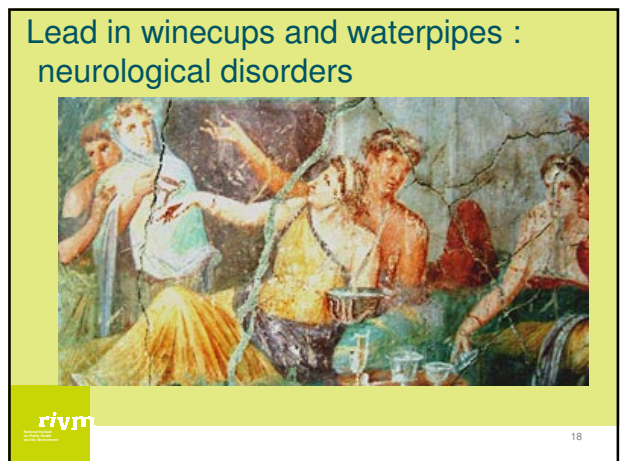
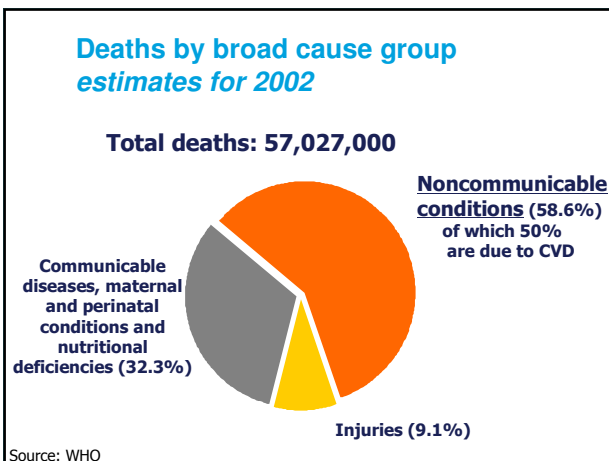


“Food-based dietary guidelines”

15



rivm




18

Claviceps purpurea
 “ergotism”
 “St. Antony’s fire”




19


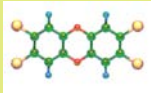
All things are poison and nothing is without poison, only the dose permits something not to be poisonous.



“Paracelsus”

1990’s

- BSE
- Dioxins
-etc

rivm

21

European Commission White Paper (2000)



rivm

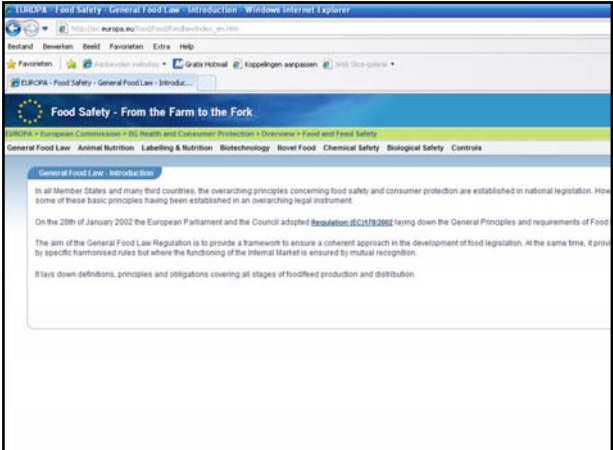
22

Contents

- Voluntary risk taking
- A small tour in history of diet and health
- **Developing benefit-risk assessment:**
 - Micronutrients
 - Safe food versus healthy diet
 - Folic acid as an example
- Conclusion

rivm

23



Food Safety - From the Farm to the Fork.

General Food Law - Introduction

In all Member States and many third countries, the overarching principles concerning food safety and consumer protection are established in national legislation. However, some of these basic principles having been established in an overarching legal instrument.

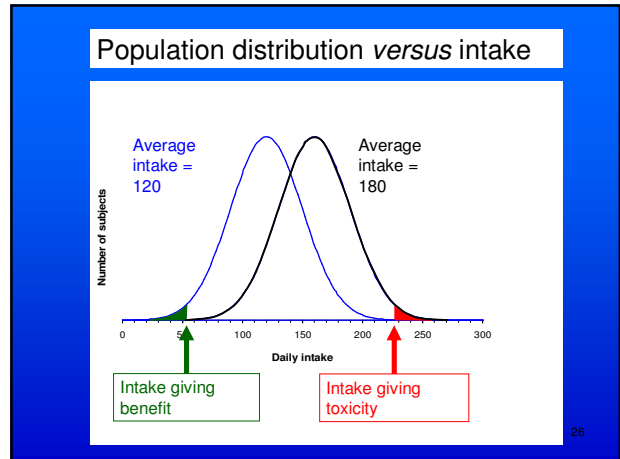
On the 28th of January 2002 the European Parliament and the Council adopted [Regulation \(EC/1831/2003](#) laying down the General Principles and requirements of Food Law.

The aim of the General Food Law Regulation is to provide a framework to ensure a coherent approach in the development of food legislation. At the same time, it provides specific harmonised rules but where the functioning of the Internal Market is ensured by mutual recognition.

It lays down definitions, principles and obligations covering all stages of food/food production and distribution.



25

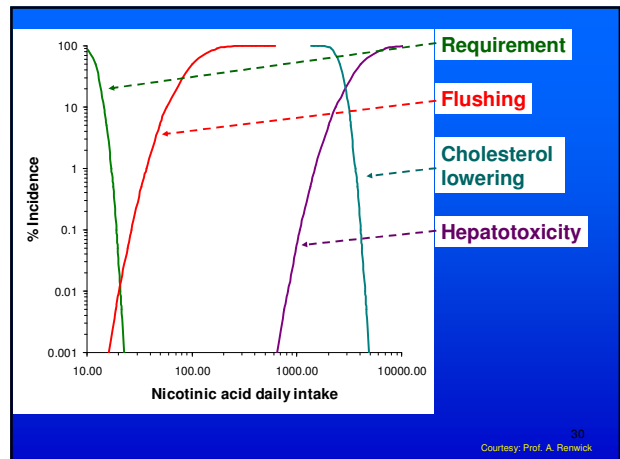


26

Intake (mg/day)	Incidence of deficiency	Incidence of not experiencing the additional health benefit	Incidence of toxicity
50	1 in 2		
57	1 in 5		
61	1 in 10		
64	1 in 20		
68	1 in 50		
71	1 in 100		
75	1 in 300	1 in 2	
85	1 in 5000	1 in 5	
91	1 in 25000	1 in 10	
96	1 in 200,000	1 in 20	
102	1 in 1,000,000	1 in 50	
106	< 1 in 1,000,000	1 in 100	
119		1 in 1000	< 1 in 1,000,000
130		1 in 10,000	1 in 1,000,000
160		< 1 in 1,000,000	1 in 100,000
200			1 in 10,000
270			1 in 1000
290			1 in 500
370			1 in 100
490			1 in 20

Intake (mg/day)	Incidence of deficiency	Incidence of not experiencing the additional health benefit	Incidence of toxicity
50	1 in 2		
57	1 in 5		
61	1 in 10		
64	1 in 20		
68	1 in 50		
71	1 in 100		
75	1 in 300	1 in 2	
85	1 in 5000	1 in 5	
91	1 in 25000	1 in 10	
96	1 in 200,000	1 in 20	
102	1 in 1,000,000	1 in 50	
106	< 1 in 1,000,000	1 in 100	
119		1 in 1000	< 1 in 1,000,000
130		1 in 10,000	1 in 1,000,000
160		< 1 in 1,000,000	1 in 100,000
200			1 in 10,000
270			1 in 1000
290			1 in 500
370			1 in 100
490			1 in 20

Intake (mg/day)	Incidence of deficiency	Incidence of not experiencing the additional health benefit	Incidence of toxicity
50	1 in 2		
57	1 in 5		
61	1 in 10		
64	1 in 20		
68	1 in 50		
71	1 in 100		
75	1 in 300	1 in 2	
85	1 in 5000	1 in 5	
91	1 in 25000	1 in 10	
96	1 in 200,000	1 in 20	
102	1 in 1,000,000	1 in 50	
106	< 1 in 1,000,000	1 in 100	
119		1 in 1000	< 1 in 1,000,000
130		1 in 10,000	1 in 1,000,000
160		< 1 in 1,000,000	1 in 100,000
200			1 in 10,000
270			1 in 1000
290			1 in 500
370			1 in 100
490			1 in 20



30
 Courtesy: Prof. A. Renwick

Contents

- Voluntary risk taking
- A small tour in history of diet and health
- Developing benefit-risk assessment:
 - Micronutrients
 - **Safe food versus healthy diet**
 - Folic acid as an example
- Conclusion

Risks and benefits of the diet

“Our food, our health

Healthy diet and safe food in the Netherlands”

RIVM 2004, 2006



Health gain for healthy diet versus other life style factors

Factor	DALY's/ year	deaths/ year	Life expectancy total
Healthy diet	- 245.000	- 13.000	+ 1.2
Healthy weight	- 215.000	- 7.000	+ 0.8
Not smoking	- 350.000	- 16.000	+ 1.2
no alcohol	+ 60.000	+ 4.000	- 0.2
exercise	- 150.000	- 7.000	+ 0.7



Comparing health loss and potential health gain by healthy diet and unsafe food in the Netherlands

Factor	DALY's / year	Deaths / year	Cases / year
Micro-organisms	1,000-4,000	20-200	300-750 x10 ³
Allergens	ca. 1,000	< 1	ca. 32,000
Chemicals	500-1,000	100-200	200-300
Food safety	2,500-6,000		

dietary composition (5 factors)



Comparing health loss and potential health gain by healthy diet and unsafe food in the Netherlands

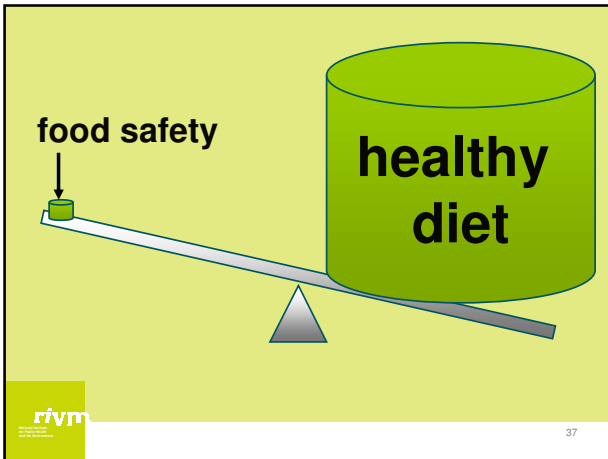
Factor	DALY's / year	Deaths / year	Cases / year
Diet composition #	245,000	13,000	ca. 40,000
Bodyweight	215,000	7,000	ca. 40,000
Healthy diet	> 350,000		
Micro-organisms	1,000-4,000	20-200	300-750 x10 ³
Allergens	ca. 1,000	< 1	ca. 32,000
Chemicals	500-1,000	100-200	200-300
Food safety	2,500-6,000		

dietary composition (5 factors)



Estimated health loss or potential health gain following improved diet and avoidance of exposure

Unfavourable diet	128.000 - 245.000	DALYs
Foodborne infections	1.000 - 4.000	DALYs
Chemical contamination	1.500 - 2.000	DALYs



Contents

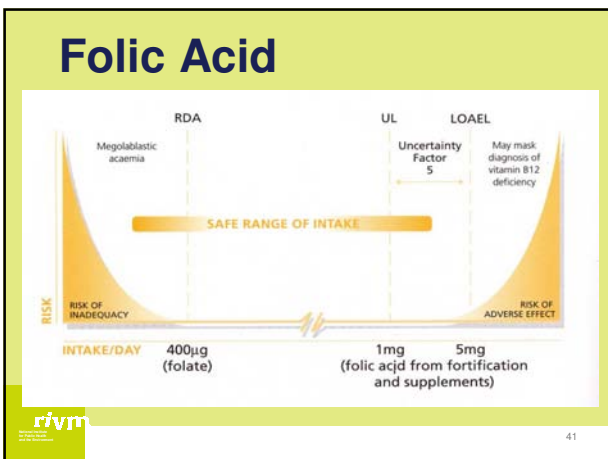
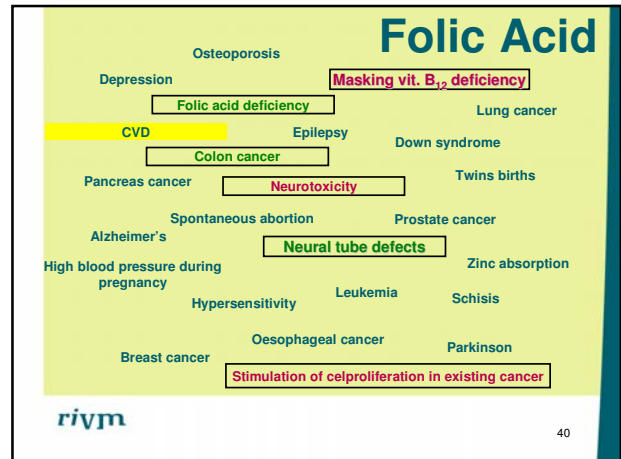
- Voluntary risk taking
- A small tour in history of diet and health
- Developing benefit-risk assessment:
 - Micronutrients
 - Safe food versus healthy diet
 - Folic acid as an example
- Conclusion

Available online at www.sciencedirect.com
 ScienceDirect
 Food and Chemical Toxicology 46 (2008) 893–909
www.elsevier.com/locate/foodchemtox

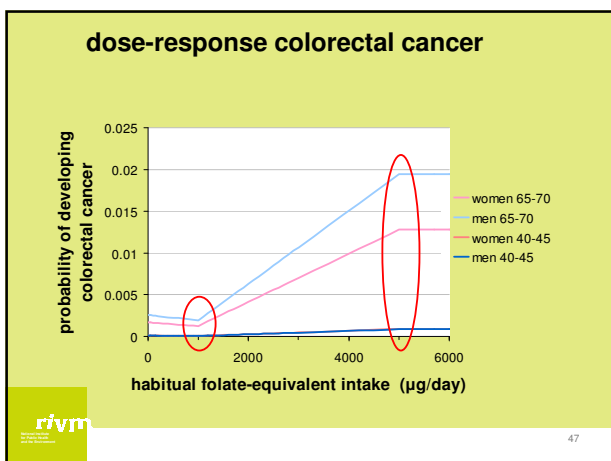
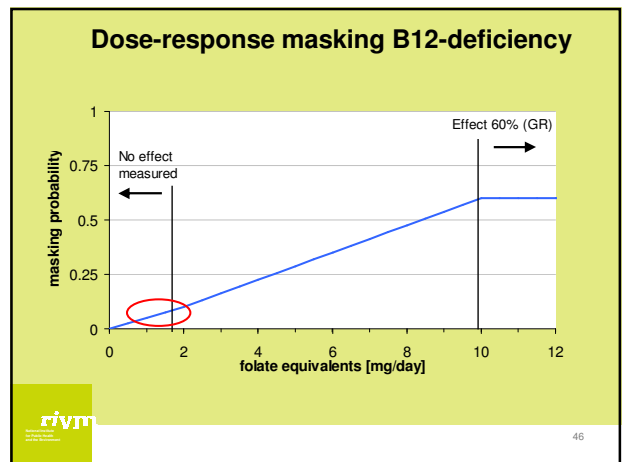
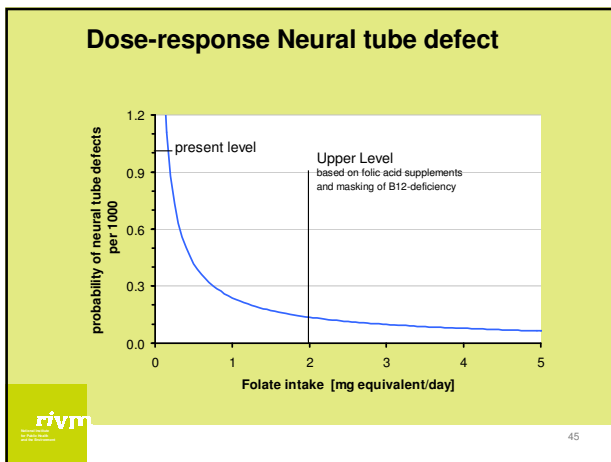
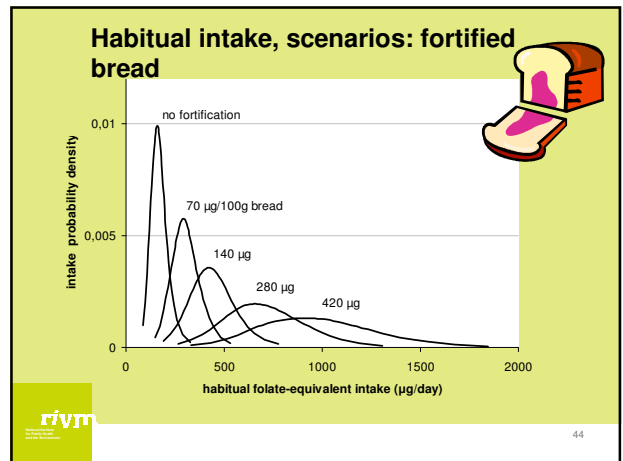
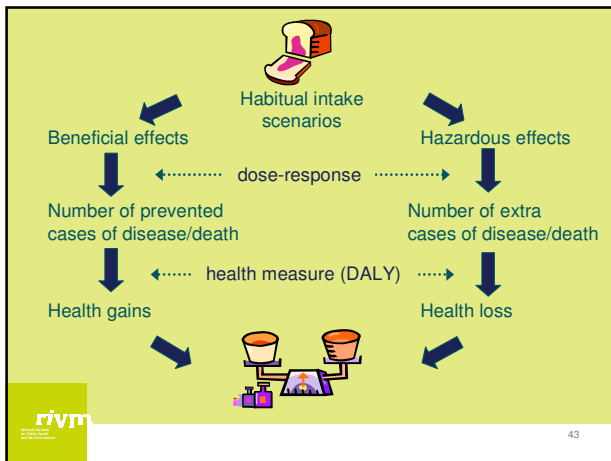
Integrated risk–benefit analyses: Method development with folic acid as example

Jeljer Hoekstra *, Janneke Verkaik-Kloosterman, Cathy Rompelberg, Henk van Kranen, Marco Zeilmaker, Hans Verhagen, Nynke de Jong

National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands
 Received 18 June 2007; accepted 10 October 2007



- ## Effects
- Neural Tube Defects (benefit)
 - Masking B12-deficiency (risk)
 - Colorectal Cancer (benefit and risk)
 - Folate deficiency (benefit)



Results: change in incidence*

	70 µg	140 µg	280 µg	420 µg
NTD	-37% (-83)	-53% (-118)	-67% (-150)	-74% (-166)
B12	1% (53)	2% (76)	3% (121)	4% (166)
CRC	-4.1% (-405)	-7.6% (-749)	-4.5% (-445)	19.9% (1954)

* Many assumptions and uncertainties (see paper)

rivm 48

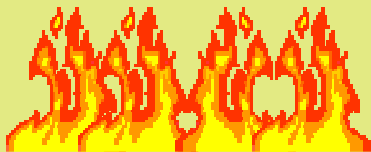
Folic acid: change in DALYs

	70 µg	140 µg	280 µg	420 µg
NTD	5474	7710	9812	10855
B12	-53	-76	-120	-165
CRC	2217	4146	167	-21740
Total	7662	11812	9899	-11006

Contents

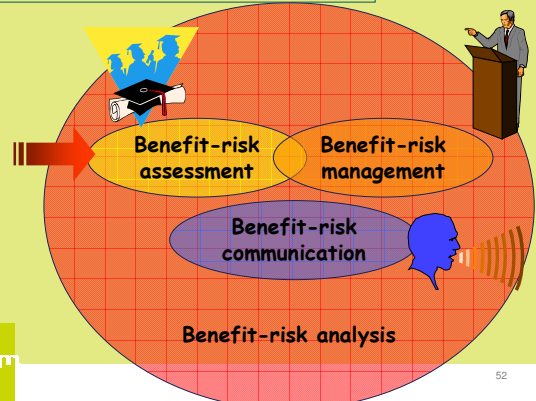
- Voluntary risk taking
- A small tour in history of diet and health
- Developing benefit-risk assessment:
 - Micronutrients
 - Safe food versus healthy diet
 - Folic acid as an example
- **Conclusion**

Risk-Benefit is hot



“Benefit-Risk is hot”

Benefit-risk analysis paradigm



Benefit-risk : “any choice is a choice”



“Doing nothing is equally well a choice”

Thank you!



and a little surprise



=====
Prof. Hans Verhagen
Head, Centre for Nutrition and Health
National Institute for Public Health and the Environment (RIVM)
PO Box 1
3720 BA Bilthoven
The Netherlands
Tel +31 30 274 3391
Secretariat +31 30 274 3318
Fax +31 30 274 4466
Hans.Verhagen@rivm.nl
<http://www.rivm.nl/en/aboutrivm/organization/vgc/cvg/index.jsp>
=====

rivm

Food Law in EU

14 April 2010

Dr. Margherita Poto/Prof. Bernd van der Meulen



WAGENINGEN UNIVERSITY
WAGENINGEN NL

SUMMARY

1. EUROPEAN SYSTEM: A SLICE OF A CAKE (GLOBAL SYSTEM)
2. EUROPEAN LAW: COMBINATION OF PUBLIC AND PRIVATE RULES
3. ACTORS: EU INSTITUTIONS, EFSA, MS
4. RISK ANALYSIS: AN EXAMPLE OF ADMINISTRATIVE PROCEEDING INVOLVING ALL THE ACTORS IN THE NETWORK

WAGENINGEN UNIVERSITY
WAGENINGEN NL

Subject of the Food Law

- Concentrating on European Law (Sources of law: Treaty, Regulations: GFL, Directives)
- Including interaction with global law (hourglass structure: International/European/National level)

WAGENINGEN UNIVERSITY
WAGENINGEN NL

European Institute for Food Law
European Institute for Food Law

Subject of the Food Law

Global administrative law: three levels (Int/Eu/Dom)



WAGENINGEN UNIVERSITY
WAGENINGEN NL

European Institute for Food Law
European Institute for Food Law

Some tools...to understand the Global Administrative Law

1. Non hierarchical system: marble cake system
2. Not clear boundaries between the private and the public sector
3. Network of authorities



WAGENINGEN UNIVERSITY
WAGENINGEN NL

PRINCIPLES APPLICABLE TO GLOBAL ADMINISTRATIVE LAW

General administrative law principles:

- Legality
- Participation to the decision making process
- Right to access
- Motivation of the decisions
- Judicial review

WAGENINGEN UNIVERSITY
WAGENINGEN NL

Law: one word two meanings

- System ('the law'): food law
 - D: Recht
 - F: droit
 - NL: recht
- Piece of legislation (Act): the General Food Law
 - D: Gesetz
 - F: loi
 - NL: wet

WAGENINGEN UNIVERSITY
WAGENINGEN

Law (system)

Peaceful social organisation and resolution of conflicts by:

- Rights and duties based on
- General rules (law: statute/act)
 - Authority (vertical)
- Agreements
 - Co-operation (horizontal)
- Enforcement
 - Criminal sanctions
 - Administrative measures
 - Civil liability
- Settlement of disputes

WAGENINGEN UNIVERSITY
WAGENINGEN

Law Sources of law

- International treaties (EU Treaty)
- Legislation (Regulations, Directives, Decisions: BINDING, Recommendations and Opinions: NOT BINDING)
- Unwritten law
 - legal principles (Subsidiarity principle)
 - Custom (*opinio juris* and *diuturnitas*)
- Case law (jurisprudence)

WAGENINGEN UNIVERSITY
WAGENINGEN

European Institute for Food Law

Law

Law provides instruments for peaceful settlement of disputes

- Decision by impartial third party (judge)
- On the basis of prior rules
- Enforceable

Branches of law

Handbook p. 50-51

WAGENINGEN UNIVERSITY
WAGENINGEN

Law

National state law

Public

- Constitutional law
- Criminal law
- Administrative law

Private

- Civil law
 - Contract
 - Tort → product liability

Does the EU have a Constitution?

- Does the EU have constitutional law?

GFL: Objectives of food law (Reg. 178/2002)

- Protect human life and health
- Protect (other) consumers' interests
 - Taking into account: animal health and welfare, environment
 - Achieve free movement of food

SOCIAL SCIENCES GROUP WAGENINGEN 20091112 Food LAW 30806 14 European Institute for Food Law

What is the General Food Law?

12280 Official Journal of the European Union L 31/13

(Date when publication is obliged)

- Scope
- General principles
 - For the legislator
 - For public authorities
 - For industry
- EFSA & Science
- Crisis management

REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, Having regard to the Treaty establishing the European Community, and in particular Articles 17, 19, 131 and Article 135(a) thereof,

the Member States, When Member States adopt measures governing food, these differences may impede the free movement of food, cause unequal conditions of competition, and may thereby directly affect the functioning of the internal market.

SOCIAL SCIENCES GROUP WAGENINGEN 20091112 Food LAW 30806 15 European Institute for Food Law

Structure of rules

- Conditions → legal consequences
 - Facts → obligations
- Art. 2 GFL definition of food
 - Elements fulfilled → food
- Art. 14 ban on unsafe food
 - Elements fulfilled → don't bring to market
- Art. 19 incident
 - Unsafe food on market → withdrawal / recall

WAGENINGEN UNIVERSITY WAGENINGEN

Example

- Art. 14 GFL do not bring unsafe food to the market!
- Was the customer poisoned?
 - Crime
 - Tort
 - Close restaurant
- Did I order this fish?
 - Agreement → Contract
- I'll see you in court!

WAGENINGEN UNIVERSITY WAGENINGEN

Independent Administrative Authorities

Example of GAL players:

- Private/Public Powers
- Technical powers
- Judicial review

SOCIAL SCIENCES GROUP WAGENINGEN 20091112 Food LAW 30806 18 European Institute for Food Law

EFSA: AN INDEPENDENT ADMINISTRATIVE AUTHORITY?

EFSA (European Food Safety Authority)

- Reg. n. 178/2002: EFSA is subject to principles of good administration, transparency and participation
- It can provide technical expertise
- Its decision shall be reviewed

European Food Safety Agency (EFSA)

- Article 6(2) GFL:
- Risk assessment:
 - Independent
 - Objective
 - Transparent



- Responsible for risk assessment (scientific evaluation of risks, safety evaluations, identification of emerging risks)
- Responsible for communication of scientific and technical information directly to the public
- Risk management by Commission, Council and EP

How do we put the risk analysis within the European Framework?

- Art. 6/7 GFL
- Food Law: based on risk analysis
 - Risk assessment
 - Hazard identification
 - Hazard characterisation
 - Exposure assessment
 - Risk characterisation
 - Risk communication
 - Risk management
 - Weighing policy alternatives
 - Assessment
 - Other legitimate factors
 - Precaution

Rapid Alert System Food and Feed (RASFF)

This system helps out with determination and elimination of that product from market. It is organized in the form of net, in which centrals are national contact points, situated in all membership states, and also European Institutions (Commission, EFSA)

Rapid Alert System Food and Feed (RASFF)

- Network for the notification of a (in)direct risk to human health by food
- Commission manages the network
- Existed already (1992) for product safety (RAPEX)
- Commission, EFSA and national FSAs involved
- Serious risk to human health must immediately be notified to Commission who informs other members

Criminal & civil law

- EU has no criminal & civil law → depends on member states
- Criminal law
 - Crimes
 - Punishments
 - Procedures
- Civil law → relations between people/companies
 - Law of persons
 - Contract law
 - Property law
 - Tort law





Food law: functional area

- Combines aspects of constitutional, administrative, civil & criminal law as far as they relate to food
- **Focus: administrative law**
 - Legislation prescribing behaviour for FBOs
 - Implemented and enforced by administrative authorities

Thank you for your kind attention

Q & A

© B.M.J. van der Meulen Wageningen UR / European Institute for Food Law



WAGENINGEN UNIVERSITY
WAGENINGEN 

Risk Benefit Management of Medicinal Products

Mrs Bronagh White BSc MPSNI
Lecturer in Pharmacy Practice University of Ulster
Mr Michiel Luteijn MSc
PhD Student in Epidemiology University of Ulster

Benefit of living in Northern Ireland

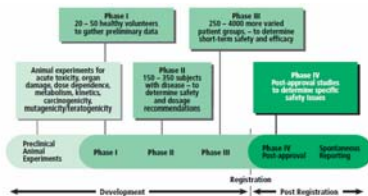


Risk of living in Northern Ireland



Clinical development of medicines

Figure 1 (below): clinical development of medicines. WHO 2004



Phases of Clinical trials

Phase 1 – the effect of the drug tested in healthy volunteers or patients unresponsive to usual therapies (pharmacodynamics & pharmacokinetics considered)

Phase 2 – examines dose-response curves in patients and what benefits might be seen in a small group of patients with a particular disease

Phase 3- a new drug is tested in a controlled fashion in a large patient population against a placebo or standard therapy

-----**Dossier on phase 1-3** -----

Phase 4 – a postmarketing study as the drug has already been granted regulatory approval/license

Legislative Background

Directive 2001/83/EC European community code relating to medicinal products for human use and specific rules for medicinal products authorised by member states

Regulation EC No 726/2004 lays down community procedures for authorisation and supervision of medicinal products for human and veterinary use and establishes European medicines agency

Regulatory Bodies

- Europe: European Medicines Agency (EMA)
- US: Food & Drug Administration (FDA)

In Europe: 1 or 2 member states will assess the dossier

- UK: Medicines Health Regulatory Authority (MHRA)
- NL: Dutch Medicines Evaluation Board (CBG-MEB)

General principles of benefit - risk assessment

- Under community law (reg 726/2004)
- Decisions should be taken on the basis of **objective** scientific criteria of safety, quality and efficacy
- Assessment based on all available tests and clinical trials under normal conditions of use under ideal conditions

Assessment of dossier

Experts assess all studies of dossier:

Preclinical studies: carcinogenicity, teratogenicity, long term toxic effects → relevance for humans

Clinical studies: efficacy, side effects, dose range (therapeutic window)

Pharmaceutical studies: formulation, composition, dissolution of tablet

Risk-benefit assessment

3 assessment reports for each new drug application



Medicines evaluation board:

Meeting of experts: read assessment reports

In meeting: **qualitative risk benefit assessment**

On expert judgement!!

Meeting is not public

Risk Benefit Assessment

- Needs to take into consideration the perspective of other stake holders in the benefit-risk assessment in particular patients and clinicians
- Expected performance of treatment under real conditions any available information on misuse and abuse, off license etc which may have an impact on the evaluation.

2 important documents

Report of CHMP working group on benefit-risk assessment models and methods -January 2007

Reflection paper on benefit-risk assessment methods in the context of the evaluation of marketing authorisation applications of medicinal products for human use – March 2008

Risk Benefit Assessment

- Number needed to treat/harm

$$NNT = 1/(P_1 - P_2)$$

$$= 1/((P_1 - P_2) * [1 - (Q_1 - Q_2)])$$
- "Principle of three"
 Tables on disease indication, disease amelioration and adverse effects

	High	Medium	Low
Seriousness			
Duration			
Incidence			

Risk Benefit Assessment

- Transparent Uniform RB Overview (TURBO)

ESTIMATE	Frequency	5
Attributable risk	Common	4
	Not Uncommon	3
	Rare	2
	Very Rare	1
		Minor Slight Moderate Severe Very Severe
Estimated severity		

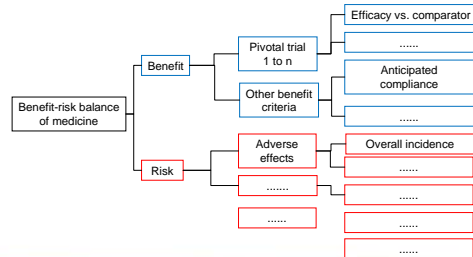
Risk Benefit Assessment

- Transparent Uniform RB Overview (TURBO)

R-factor								B Factor
7	T=1	T=2	T=3				T=4	
6							T=4	
5					T=4		T=7	
4					T=4		T=6	
3					T=4		T=5	
2					T=4			
1					T=4			
	1	2	3	4	5	6	7	

Risk Benefit Assessment

- Multi Criteria Decision Analysis (MCDA)



Council for International Organisation of Medical Sciences (CIOMS)

- "It is a frustrating aspect of benefit-risk evaluation that there is no defined and tested algorithm or summary metric that combines benefit and risk data that might permit straight forward quantitative comparisons of different treatment options which in turn might help decision making"

Clinical Evaluation

- Clarify the unmet clinical need that is addressed by the new product
- Confirm that the clinical database is adequate to characterise both the risks and the benefits
- Present the analysis of clinical benefit
- Present the analysis of clinical risk
- Address the questions do the benefits outweigh the risks

Communicating Clinical Benefit

Clinical Trials

- Trial methodology and endpoints used must be valid and relevant to the intended use of the product
- Population studied needs to be relevant to the intended prescribing population
- Robust and appropriate methods of statistical analysis
- Clinically relevant effect on variables

MHRA

- Clinical Trials Directive
- Clinical Trials Unit
- Good clinical practice
- Inspection Role
- Eudravigilance CT
- Post registration (Pharmacovigilance)
- Periodic Safety update reports

Communicating Clinical Risk

- ADR in clinical trial population
- Are there effects that might be expected based on the pharmacological activity of the product or a related class effect
- Are there unconfirmed safety signals based on low frequency adverse effects in clinical trials
- Are there fatal, significant or serious adverse effects that warrant special investigation
- Variable bioavailability, pharmacokinetic, pharmacodynamic activity resulting in variable exposure to active drug or metabolite

- Unwanted pharmacological effects at therapeutic doses
- Risks in toxicological studies in animals but for which there is no clinical evidence (carcinogenicity or teratogenicity)
- Risk remains for humans until there has been extensive exposure in patients with no ill effects.

Do the benefits outweigh the risks

- comparing benefits and risks is there a variable that can be applied
- Is the benefit risk appropriate to intended use
- Is the risk benefit similar in all groups for intended use or more prevalent in smaller subgroup
- How does it fit in to current treatment guidelines
- Mitigating possible harm measures do these require high patient and clinican education
- How effectively can risk management be applied

Pharmacovigilance

- "Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem."

VOLUME 9A

of The Rules Governing Medicinal Products in the European Union

- Guidelines on Pharmacovigilance for Medicinal Products for Human Use -

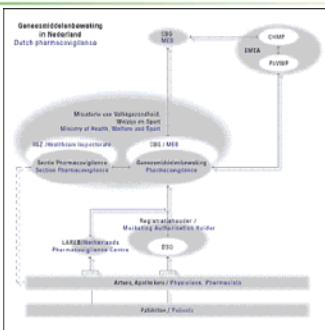
Pharmacovigilance

Overview of EU Risk Management Plan Template

Section	
	Product information
1	Safety Specification
2	Pharmacovigilance Plan
3	Evaluation of the need for risk minimisation activities
4	Risk Minimisation Plan
5	Summary of the EU-RMP
6	Contact person details
Annex 1	Interface between EU-RMP and Eudravigilance <i>To be provided in electronic form only</i>
Annex 2	Current (or proposed if initial EU-RMP) SPC, Package Leaflet
Annex 3	Synopsis of ongoing and completed clinical trial programme
Annex 4	Synopsis of ongoing and completed pharmacoepidemiological study programme
Annex 5	Protocols for proposed and ongoing studies in pharmacovigilance plan
Annex 6	Newly available study reports
Annex 7	Other supporting data
Annex 8	Details of proposed educational programme (if applicable)

Pharmacovigilance

- Involvement of both the manufacturer and the national competent authorities
- Pharmacovigilance Working Party (PhVWP)
- Periodic Safety Update Report (PSUR)






**BEPRARIBEAN
Workshop
Reykjavik, Iceland
14 April – 15 April 2010**

**Risk benefit assessment:
Microbiology**

Sveinn Magnússon,
Department of food safety and environment, Matis




Risk benefit analysis: Microbiology

Presentation overview:

- Foodborne illnesses
- Microbiological food safety
- Risk benefit assessment in food microbiology /Current activities
- Possible applications
- Conclusions


Sveinn Haukur Magnússon © Matis 2010 2



Foodborne illnesses

- Foodborne illness due to microbiological hazards
 - Large and growing public health problem
 - Affecting 1/3 of the population of industrialised countries each year
 - 76 million cases annually in US
 - US \$6.5–35 billion annual cost

Sveinn Haukur Magnússon © Matis 2010 3



Foodborne illness

- Foodborne pathogens
 - Bacteria: *Campylobacter jejuni*, *Salmonella*, *E. coli* O157, *Clostridium perfringens*
 - Viruses: Norovirus (NoV), hepatitis A virus (HAV)


Sveinn Haukur Magnússon © Matis 2010 4



Microbiological food safety

- Microbiological food safety management
 - Minimizing risk of foodborne pathogens
- Management methodology
 - Microbiological risk assessment (MRA)
 - HACCP (Hazard Analysis and Critical Control Point)
- Improving food safety

Sveinn Haukur Magnússon © Matis 2010 5



Risk-benefit assessment: microbiology

- Risk-benefit assessment
 - New field of research in food microbiology
 - How to approach RBA in food microbiology under discussion
 - Limited available data
- Disease burden
 - Standard metrics – DALYs

Sveinn Haukur Magnússon © Matis 2010 6

RBA in microbiology



- **Balancing the risks and benefits of drinking water disinfection: Disability adjusted life-years on the scale**

AH Havelaar et al., 2000

- **Risks** – Ozonation by-products (bromate - potentially carcinogenic)
- **Benefits** – Reduced exposure to protozoan parasite (*Cryptosporidium parvum*)

RBA in microbiology



- **Balancing the risks and benefits of drinking water disinfection: Disability adjusted life-years on the scale**

AH Havelaar et al., 2000

- **Results**
 - Health benefits outweigh the risks by factor of >10
 - DALYs – allows for comparison of disease with very different health impacts and end-points.

RBA in microbiology



- **Benefits and risks of the use of chlorine-containing disinfectants in food production and food processing**

Report of a Joint FAO/WHO Expert Meeting, 2008

- **Risks** - chlorine by-products (trihalomethanes – potentially carcinogenic)
- **Benefits** – reduced exposure to pathogens

RBA in microbiology



- **Benefits and risks of the use of chlorine-containing disinfectants in food production and food processing**

Report of a Joint FAO/WHO Expert Meeting, 2008

- **Results**
 - No scenarios with both health risks and benefits identified
 - Large datagaps identified

RBA applications in food microbiology



- **Sodium nitrate addition (e.g. cured meat)**
 - **Risks** – Formation of nitrosamine (carcinogenic)
 - **Benefits** – Prevents *Clostridium botulinum* toxin production
- **Salt as preservative**
 - **Risks** – High sodium intake linked with hypertension and heart disease.
 - **Benefits** – Inhibits microbial growth

RBA applications in food microbiology



- **Consumption of minimally processed food (e.g. fruits and vegetables)**
 - **Risks** – Foodborne illness increasingly associated with consumption of fresh fruits and vegetables
 - **Benefits** – Essential part of human diet, health and well being

RBA applications in food microbiology



- Probiotics
- Risks – Potential drug insensitivity. Transfer of genetic elements to pathogens
- Benefits – Increasing evidence of health benefits of probiotic bacteria

Conclusions



- Microorganisms in food - usually only adverse effects
- Peer reviewed publications few
- RBA in microbiology - Field in its infancy

THANK YOU.



National Institute for Health
and Welfare, THL
**State of the Art in Environmental
Health benefit risk assessments**

Olli Leino, Virpi Kollanus, Mikko V. Pohjola, Jouni T. Tuomisto

3.5.2010

1

Contents

- **Introduction**
 - Aims
 - Approaches
- **Methods**
 - Information production
 - Linking information production and use
- **Results**
 - Examples and preliminary results
- **Conclusions and discussion**
 - What is the current state of the art in environmental health?

TERVEYDEN JA HYVINVOINNIN LAITOS

3.5.2010

2



INTRODUCTION

TERVEYDEN JA HYVINVOINNIN LAITOS

3.5.2010

3



Approaches

- 1) Traditional risk assessment
 - NRC: the Red Book (1983)
- 2) Deliberative risk assessment
 - NRC: Understanding risk (1996)
- 3) Risk governance framework
 - The International Risk Governance Council (IRGC)
- 4) Chemical risk assessment
 - Regulatory approach (REACH)
- 5) Environmental impact assessment
 - YVA legislation in Finland
- 6) Health impact assessment
 - WHO approach
- 7) Integrated environmental health impact assessment
 - INTARESE project
- 8) Open assessment
 - THL

TERVEYDEN JA HYVINVOINNIN LAITOS

3.5.2010

4



Inclusion criteria for approaches

- Not ment to be all inclusive list of approaches
- Broad enough range of approaches
 - Commonly known and used
 - Also some new developments included
 - Regulatory/normative/legislative vs. conceptual/academic

TERVEYDEN JA HYVINVOINNIN LAITOS

3.5.2010

5



Aims

- To review and compare approaches used in the field of environmental health
 - Similarities and differences
 - Evolution from the beginning of evaluations
- To draw conclusions about what is the current state of the art in environmental health assessment
- To identify possible avenues for going beyond the state of the art

TERVEYDEN JA HYVINVOINNIN LAITOS

3.5.2010

6



METHODS

Attributes for characterizing and comparing approaches

A) Information production

- The attributes are adapted from the PSSP language (Problem – Structure – State – Performance)
 - originally in the context of process design
 - how the approach defines the purpose
 - how both the assessment process and its outcomes are structured
 - how the performance, the goodness, of assessment is perceived to be constituted.

Information production attributes

Attribute	Explanation
Purpose	What is the purpose of assessment according to the approach?
Question	What kind is the principal question asked in assessment according to the approach?
Problem owner	Who has the intent, need or responsibility to find an answer to the question?
Process	How is the answer to the principal assessment question sought for according to the approach?
Answer	What kind is the answer provided to the principal assessment question by the assessment?
Performance	What factors are perceived to constitute the goodness, or sufficient level of goodness, of assessment?

B) Linking information production and use

- According to an adaptation of the categorization developed by Kerkhoff and Lebel (2006)
- Level of engagement and power sharing between information production and use

Linking information production and use

- I trickle-down
- II transfer and translate
- III participation
- IV integration
- V negotiation
- VI learning

Linking information production and use

- I trickle-down
- II transfer and translate
- III participation
- IV integration
- V negotiation
- VI learning

Power sharing and engagement increases from I to VI

TERVEYDEN JA HYVINVOINNIN LAITOS

3.5.2010

13

Explanation for the views

View	Explanation
Trickle-down	Information producer's responsibility ends at publication of result.
Transfer & translate	One-way transfer of results to assumed users.
Participation	Individual or small-group level engagement on specific topics or issues.
Integration	Organizational level engagement on shared agendas and aims. Shared problem definition.
Negotiation	Strong engagement, ongoing process. Produced information as one of the inputs to guide action.
Learning	Strong engagement. Learning is in itself a highly valued goal.

TERVEYDEN JA HYVINVOINNIN LAITOS

3.5.2010

14

Results

TERVEYDEN JA HYVINVOINNIN LAITOS

3.5.2010

15

Table 1: Characterization of information production (2 examples)

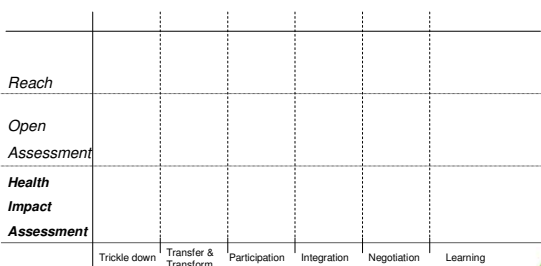
Parameters	REACH	Open Assessment
Purpose	Acceptance of chemical in the EU market	Produce useful info for societal decision-making
Question	Is exposure below acceptable level?	What should be done to the problem given current knowledge
Problem owner	Producer	Anyone
Answer	Acceptable exposure scenario / use scenario	Identification of preferred decision option
Performance	Formal requirements for a) process b) assessment product c) QC by ECHA	Holds against open criticism, applicability and efficiency

TERVEYDEN JA HYVINVOINNIN LAITOS

3.5.2010

16

Figure 1: Linkages between info production and use (3 examples)

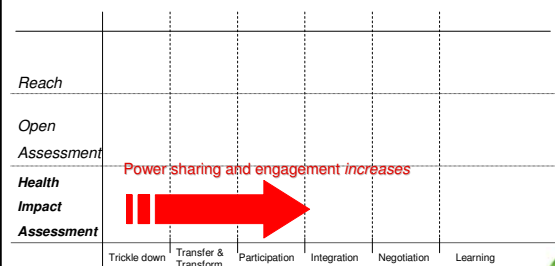


TERVEYDEN JA HYVINVOINNIN LAITOS

3.5.2010

17

Figure 1: Linkages between info production and use (3 examples)

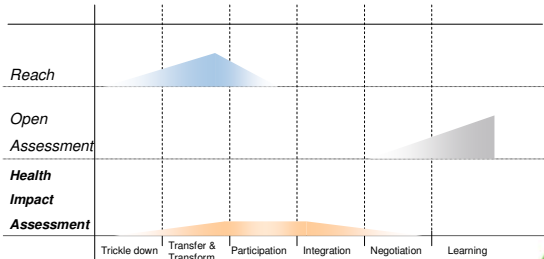


TERVEYDEN JA HYVINVOINNIN LAITOS

3.5.2010

18

Figure 1: Linkages between info production and use (3 examples)



TERVEYDEN JA HYVINVOINNIN LAITOS

3.5.2010

19

Conclusions and discussion

TERVEYDEN JA HYVINVOINNIN LAITOS

3.5.2010

20

State-of-the-art

- Mainly builds on the conventional models of trickle-down and transfer and translate tweaked with some engagement power sharing
- The task is not to rank the selected approaches because approaches serve a particular need
 - However, we try to find out future trends and needs

TERVEYDEN JA HYVINVOINNIN LAITOS

3.5.2010

21

Going beyond the state of the art

- Increased engagement and power sharing
 - How to do? (see OA)
- Abandonment of the conventional model that builds on demarcation of science and policy
 - Incremental improvements will not solve the fundamental problems

TERVEYDEN JA HYVINVOINNIN LAITOS

3.5.2010

22

Manuscript online

- Available online on the secured Opasnet web site: http://heande.opasnet.org/wiki/State_of_the_art_of_environmental_health_assessments
 - Username: bioher
 - Password: qADaC4h
- Commenting and discussion provided on the discussion page
 - Editing requires personal login
- Presentation online on an open site: <http://en.opasnet.org/w/Bepraribeau>
- Contact information:

olli.jeino@thl.fi	virpi.kollanus@thl.fi
mikko.pohjola@thl.fi	jouni.tuomisto@thl.fi

TERVEYDEN JA HYVINVOINNIN LAITOS

3.5.2010



23

Thank you

TERVEYDEN JA HYVINVOINNIN LAITOS

3.5.2010

24



 Faculty of Economics and Business Administration
 University of Maastricht
 Business School

Decoupling Consumers' Risk-Benefits in the Retailing Food Sector: Concepts, Trends, Managerial Actions

Nikos Kalogeras and Gaby Odekerken-Schroder
Marketing-Finance Research Group
Maastricht University
The Netherlands
.....and the
BEPRARIBEAN Research team

1



 Faculty of Economics and Business Administration
 University of Maastricht
 Business School

What is Marketing-Finance ?

- *Intefying Marketing Actions that Drive Financial Performance*
 - A unique multidisciplinary approach that bridges theory and practice and integrates knowledge from:
 1. Marketing & Consumer Behavior
 2. Finance
 3. Decision Sciences
 4. Psychology

More info : www.marketing-finance.nl



 Faculty of Economics and Business Administration
 University of Maastricht
 Business School

What Drives Market Participants Behavior in Food Markets?

- What drives the behavior of market participants (e.g., consumers, investors, producers, etc) when faced with product-related crisis, such as that involving food contamination or life threatening design flaws?
- While some crises have influenced the recall, redesign, and communication efforts of individual companies (e.g., Perrier, Ford, Goodyear), others, such as the food-related crises – can compromise an entire industry.

3





 Faculty of Economics and Business Administration
 University of Maastricht
 Business School

What Drives Consumers' Risk-Benefit Behavior?

- Yet, the behavior of consumers in a crisis situation is not always consistent with the true level of risk they face.
- We conceptualize and study how:
 - seemingly inconsistent behaviors of consumers in the US and EU economies can be explained by a combination of risk attitude and risk perception as well as utilitarian and hedonic perceived benefits.
 - Consumers react to different phases of a product-related crisis.

4



 Faculty of Economics and Business Administration
 University of Maastricht
 Business School

Modeling Consumer Reactions to a Crisis

- We argue that by **decoupling** the
 - risk response behavior of consumers into the separate components of RA and RP, and
 - perceived benefits into UTB and HB
We can develop a more robust segment-level conceptualization & prediction of consumer reactions.

5





 Faculty of Economics and Business Administration
 University of Maastricht
 Business School

Solution to the crisis.....

- Knowing the drivers of behavior at different crisis phases provides insights on whether the solution to the crisis lies in more:
 - effective communication efforts; OR
 - Drastic measures with respect to product supply (such as recalls or product elimination, effective communication)
 - How marketers and policy makers in agribusiness and food industry can deal with different segments of consumers in different crisis phases



6



 Faculty of Economics and Business Administration

Background (1): Product-related Crisis

- Effects of product-related crises on:
 - Consumer perceptions and attitudes for benefits and risks → buying behavior
 - Businesses reputation and sales
 - Entire industry
 - Marketing Effectiveness


7



 Faculty of Economics and Business Administration

Background (2): Food Safety Crisis

- Potential to dramatically illustrate the need marketers, industry managers and policy-makers have to understand HOW and WHY consumers react to crisis because:
 - Unexpended events
 - Wide-spread
 - Catastrophic, and
 - Irrevocable consequence

8





 Faculty of Economics and Business Administration

Background (3): Food Safety Crisis

- Calamities in agri-food markets
 - foot and mouth disease; mad cow disease; avian influenza; pig fever
- Consumer panic
 - devastated impact on demand of food products: consumption of beef meat in Germany decreased about 70% just after the BSE outbreak in 2000.
 - US beef industry and food supply chain had losses of \$4.0 billion after BSE fanned out in December 2003



9



 Faculty of Economics and Business Administration

Background (4): Gap in Risk Behavior Literature

- Business Economics and Marketing literature on product related crises: often uses one-dimensional risk measures, ignores multidimensionality of benefits, one time event studies
- Yet, RP and RA as well as UTB and HB of consumers may change over time due to changes in choice environment (trust, knowledge) → the influence and magnitude of RP, RA, UTB, HB, may change during crisis → consequences for industry, firm's marketing strategy, public policy.



10



 Faculty of Economics and Business Administration

Risk Behavior (1)

- Risk is a key component of consumer behavior, market participants behavior, financial markets behavior – **RISK-RETURN paradigm!**
- In order to **realize a benefit – return – you should take a risk!**
- Knight (1921):
 - risk (known probabilities)
 - uncertainty (not known probabilities associated with possible consequences)
- Consistent with marketing and business economics literature: risk means uncertainty

11



 Faculty of Economics and Business Administration

Risk Behavior in Finance (2)

- **Capital Asset Pricing Model – CAPM model**
 - determining if an asset being considered for a portfolio offers a reasonable expected return for risk – Willingness to Pay –WTP- a *Risk Premium*
- **Risk Attitude** – evaluated mainly by means of time series and panel data analysis using econometric models.
- **Normative Approach** -The decision maker is **RATIONAL**
- **Behavioural Finance** – decision maker's behavior is subject to behavioral anomalies and heuristic driven biases such as
 - Framing, self-control, overconfidence, familiarity, among others
 - By buying a stock, futures contract, option – YOU BUY HOPE!!!

University of Maastricht
Faculty of Economics and Business Administration

Risk in Marketing & Consumer Behavior (3)

Consumer decision-making and behavior is analyzed and reported in terms of

- **Perceived Risk** (e.g., Bauer, 1960; Srinivasan & Ratechhof, 1991):
 - Perception of uncertainty
 - Seriousness of adverse consequences (potential negative outcomes)
 - Evaluated by means of both hard – secondary - and soft – primary – data
 - Methods
 - Soft data - Case studies, Surveys, Laboratory Experiments, Field Studies using Psychometrics
 - Hard data – Statistical and Econometric Analyses of Different Risk Scenarios
 - Techniques
 - Econometrics, Multivariate Data Analyses (WTP, Multi-attribute Utility Models such as Conjoint Models)

13

University of Maastricht
Faculty of Economics and Business Administration

Risk Behavior Decoupling (1)

- However, focusing only on the adverse consequences or risk presents a specific framing of the risk that is different from the approach that used in *Economics and Statistical Decision Theory*
 - **Decoupling of Market Risk Behavior into Risk Attitude, Risk Perception, and the Interaction of the two.**
- Particularly useful in financial and health-related domains where there can be wide differences in RA and RP
- Individual market participants' **contracting** (e.g., MacCrimmon and Wehrung, 1990; Pennings and Wansink, 2004), **investment** (e.g., March and Shapira, 1987; Weber and Millman, 1997; Nosić and Weber, 2007), and **consumption decisions** (e.g., Pennings *et al.*, 2002 ; Schroeder, *et al.* 2007 ; Kalogeras *et al.*, 2009).

14

University of Maastricht
Faculty of Economics and Business Administration

Drivers of Consumer Risk Behavior (2)

- **Risk Attitude (RA):** consumer general predisposition to the risk content in a consistent way.
- **Risk Perception (RP):** consumers' own interpretations of their chance of being exposed to the content of the risk.
- **RA *RP:** a relatively risk-averse consumer may engage in behavior that reduces risk, and that becomes more prominent as a consumer perceives relatively more risk.

15

University of Maastricht
Faculty of Economics and Business Administration

Drivers of Consumer Risk Behavior (3)

$$CRB_i = f(RA_i + RP_i + RA_i * RP_i)$$

- where i) CRB_i is the risk behavior of consumer i , ii) RA_i is the risk attitude of consumer i , iii) RP_i is the risk perception of consumer i , and iv) $RA_i * RP_i$ is the interaction between risk attitude and perception of consumer i .

University of Maastricht
Faculty of Economics and Business Administration

Drivers of Consumer Benefits: Bidimensional (1)

- **Decoupling Benefits :** Consumers purchase goods and services and perform consumption behaviors for two basic reasons (e.g., Holbrook and Hirschman, 1982; Millar and Tesser, 1986; Batra and Ahtola, 1990) :
 - **Consumatory Affective (Hedonic) Gratification** (Sensory Attributes) and
 - **Instrumental, Utilitarian** reasons concerned with *Expectations of Consequences*

17

University of Maastricht
Faculty of Economics and Business Administration

Drivers of Consumer Benefits: Bidimensional (2)

- Two kinds of consumer evaluations, in which a consumption object (e.g., food item) can be cognitively based on both:
 - **Utilitarian dimension** of instrumentality-functionality: how useful or beneficial the object is, and
 - **Hedonic Dimension :** measuring the experiential affect associated with the object (how pleasant and agreeable those associated feelings are).
- Both of these types of benefits contribute, in differing degrees, to the *Overall Goodness* of a consumer good or behavior.

University of Maastricht
Faculty of Economics and Business Administration
Business School

Drivers of Consumer Benefits: Interactive (2)

The two types of benefits do not need to be mutually exclusive:

- A toothpaste may both prevent cavities and provide pleasure from its taste
- Organic-Health Food Application into Retailing-Consumer Markets?

Nor need these two benefits to be evaluatively consistent :

- A consumption that gives me pleasure now may in fact be bad for me in instrumental sense (smoking, overeating, unhealthy diet, I enjoy eating meat that may be contaminated by a disease)
- A consumption that gives me no pleasure may be instrumentally valuable (e.g., going to dentist, avoid convenient eating and spend time on variety seeking for healthy foods, spend time and money to visit a diet expert, medical doctor for regular health check up)

University of Maastricht
Faculty of Economics and Business Administration
Business School

Measuring Benefits - Review

- Psychometrics Approach** (psychometric scales, conjoint trade-off models)
- Measuring through Semantic Differential items - SDs
 - Utilitarian**
 - Useful-Useless, Valuable-Worthless, Beneficial-Harmful, Ordered-Chaotic, Safe-Dangerous, Wise-Foolish, Sane-Insane; Meaningful-Meaningless
 - Hedonic**
 - Pleasant-Unpleasant, Nice-Awful, Agreeable-Disagreeable, Happy-Sad, Beautiful-Ugly, Interesting-Boring, Comfortable-Uncomfortable
 - Hedonic and Utilitarian**
 - Good-Bad, Positive-Negative, Like-Dislike, Favorable-Unfavorable

University of Maastricht
Faculty of Economics and Business Administration
Business School

Decoupling Consumer Risk-Benefits Behavior

$$CR - BB_i = f(RA_i + RP_i + RA_i * RP_i + UTB_i + HB_i + UTB_i * HB_i)$$

- where (NEW DETERMINANTS) UTB_i is the utilitarian benefit that a consumer i derives from consuming a food item, and HB_i is the hedonic benefit that consumer i derives from the consumption of the x food item, and $UTB_i * HB_i$ is the interaction between utilitarian and hedonic benefits of consumer i

University of Maastricht
Faculty of Economics and Business Administration
Business School

Generic Conceptual Framework

- We assume that risk-benefit variables drive consumer decisions to buy a food item e.g., in times of product-harm crisis
- Heterogeneity in Economic Life – Heckman, Nobel in Economics, 2001
 - It is the latent underlying decision making process that drives heterogeneity in economic life of individuals.
- We assume that individual differences within and across different segments of the population (trust in information, knowledge, cross-cultural differences) drive Risk-Benefit Variables

22

University of Maastricht
Faculty of Economics and Business Administration
Business School

Individuals' Risk-Benefit Behavior Over Time

- Consumers may select different decision-making strategies in different situations/choice environments → consumers may become **adaptive decision-makers**
- Consumers' decision-making strategy may alter at a later phase (t_2) of a market crisis
- The magnitude and the influence of RA , RP , $RA \times RP$, UTB , HB , $UTB \times HB$ may change from the crisis phase t_1 to t_2
- Changes in consumer trust to information provided as well as their information about the disease – risk content- drive RA , RP , UTB , and HB over time.

23

University of Maastricht
Faculty of Economics and Business Administration
Business School

Decision Context: BSE outbreaks

© Original Artist
Reproduction rights obtainable from
www.CartoonStock.com

EAT YOUR VEGETABLES, OR YOU'LL GO MAD LIKE YOUR FATHER!

24

Faculty of Economics and Business Administration

Risk Analysis and Consumer Reactions in USA, Germany and NL in 2001-2004

	Risk Assessment	Risk Management	Risk Communication	Consumer Reactions
USA*	Before Dec 23, 2003: Active surveillance and early (hurdle) protection measures: fast recovery, elimination of the risk. After Dec 23, 2003: continuing robust surveillance program	Incipient Phase: Meat recalls checks at retail stores and destruction of beef and byproducts at landfills. Later phase(s): International panel of scientific expertise to address regulatory and consumption-related aspects	Intensive and Continuous education of producers, veterinarians, industry groups and general public on BSE risks through daily briefings, press conferences, information packets and on-line education.	Unchanged consumer behavior and confidence to American food system. Decline in stock prices for restaurants and other food-related companies.
Germany	Uncoordinated actions between government and federal states: non transparent auditing capacity and industry-led initiatives.	Incipient Phase: Product Elimination Later phase(s): Inspections and tests throughout the beef supply chain (e.g., farms, processing units, supermarkets)	Moderate communication efforts by governmental agencies, industry and media: BSE as a proportion to general food safety issues	Incipient Phase: Hysterical reactions with a tremendous decline in beef consumption and sales. Later phase(s): consumer trust moderately regained. Consumers blamed the government and the industry for low communication transparency.
The Netherlands	Drastic and quick risk assessment; successful coordination among governmental agencies that enforced the application of technical measures.	Incipient Phase: Selective Product Elimination Later Phase(s): Temporal auditing and control of producing and processing units	Extensive public information and communication activities by governmental agencies; media over-emphasized health harms.	Incipient Phase: considerable decrease in beef consumption. Later phase(s): consumers distrust to implementation and monitoring of the quality assurance schemes

Faculty of Economics and Business Administration

Managerial Implications for Marketers & Policy Makers

- Outcome 1:**
 - If RP and/or HB drive behavior at t_1 ; communicate the "true" probability
 - If RP's and/or HB's influence decrease at t_2 → marketing strategy must be adapted (e.g., gradual product recalls)
- Outcome 2:**
 - If RA and/or UTB drive behavior at t_1 ; testing and slaughtered suspected animals
 - If RA and/or UTB influence decrease at t_2 ; abandon tough measures.
- Outcome 3:**
 - If RA x RP and/or UTB x HB drive behavior at t_1 ; combination of strategies
 - If RA x RP's and/or UTB x HB influence decrease at t_2 ; emphasis on higher relative importance of RA or RP and UTB or HB, respectively.

26

Faculty of Economics and Business Administration

Tentative Inferences

- Build on Risk-Benefit Analysis considering not only the technical but also the behavioral dimensions: knowledge of the drivers of the relationship between consumer (buyer) and food retailer (seller)
- Sketching the profile of consumer segments who prefer specific utilitarian vs. hedonic benefits: product placement → strength relationship of consumer-retailer
- Dynamic Decision making (attitudes, perceptions and perceived benefits evolve over time due to changes in experienced-based factors) → Adaptation of Strategies and Public Policies

27

Best Practises for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

WS2: 'State of the Art in Benefit-Risk Analysis: Food and Nutrition'

Mariken J. Tijhuis

Best Practises for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

Aim of presentation (1)

"the level of development (as of a device, procedure, process, technique, or science) reached at any particular time usually as a result of modern methods"

- Present an overview of the current approaches (*state of the art*) to come to an integrated weighing of benefits and risks in the field of Food and Nutrition
- to facilitate scientists and policy makers in carrying out and judging benefit-risk analyses
- and to eventually come to better informed and more balanced decisions about food-related health issues.

'State of the Art in Benefit-Risk Analysis in Food and Nutrition' - M.J. Tijhuis

Best Practises for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

Aim of presentation (2)

Serve as input (1 of 6) for this afternoon's working groups:

- similarities and differences in BRA between the different areas of research
- consensus of best practice for area of food and nutrition

'State of the Art in Benefit-Risk Analysis in Food and Nutrition' - M.J. Tijhuis

Best Practises for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

Benefit-Risk Analysis Paradigm

'State of the Art in Benefit-Risk Analysis in Food and Nutrition' - M.J. Tijhuis

Best Practises for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

Benefit-Risk Assessment Paradigm

Arms are not symmetric!

'State of the Art in Benefit-Risk Analysis in Food and Nutrition' - M.J. Tijhuis

Best Practises for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

State of the art BRA Food and Nutrition

- Risk assessment
- Benefit assessment
- Integration of benefits and risks
- Case studies

'State of the Art in Benefit-Risk Analysis in Food and Nutrition' - M.J. Tijhuis

Best Practices for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

Safe FOOD Era

Risk

- Phytotoxins, phycotoxins, mycotoxins
- Additives (food and feed), pesticides, veterinary drugs
- Contaminants
- Low molecular weight chemicals
- Micronutrients + supplements
- Macronutrients
- Whole foods
- Novel foods
- Food processing

Food Safety in Europe (F...ment of chemicals in food and d...vels

1. Introduction
Food safety policy in the European Union (EU) is based on a comprehensive, integrated approach of risk analysis throughout the food chain (from farm to table) (EC, 2002a). Risk analysis has three main components: risk assessment (scientific advice and information analysis, risk management (regulation and control) and risk communication.

Risk assessment provides the scientific foundation upon which the risk analysis process is built. Risk assessment is defined as "A process of evaluation including the identification of the attendant uncertainties, of the likelihood and severity of an adverse effect occurring to man or the environment following exposure under defined conditions to a risk agent" (EC, 2002b).

guidelines and recommendations as reflecting international consensus regarding the requirements to protect human health from foodborne hazards. Therefore a project reviewing and updating the risk assessment of chemicals in food is a timely activity in the light of:

- the ongoing international harmonisation of WTO
- the setting up of the European Food Authority
- the need to identify key topics for consideration in the EU Sixth Framework allocation of funds for research.

In response to these developments, the International Life Science Institute - European branch (ILSI Europe) elaborated a project proposal for a European Concerted Action on Food Safety, Progress and Further Studies in Food Safety and Nutrition.

© 2006 RIVM

Best Practices for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

Safe FOOD Era

Risk

Role of epidemiology until recently: small

"Because of the many assumptions involved, epidemiologists have often been reluctant to become involved in risk assessment, leaving the task to those with less understanding of epidemiology. The result has been inconsistent evaluations of epidemiologic evidence, inappropriate use of some human data, and unwarranted dismissal of other studies"

Rothman and Greenland. Modern Epidemiology, 1998.

'State of the Art in Benefit-Risk Analysis in Food and Nutrition' - M.J. Tijhuis

© 2006 RIVM

Best Practices for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

Safe FOOD Era

Risk

Role of epidemiology until recently: small

The contribution of epidemiology to the assessment of the health effects of food components

Research
Guidelines to Evaluate Human Observational Studies for Quantitative Risk Assessment

'State of the Art in Benefit-Risk Analysis in Food and Nutrition' - M.J. Tijhuis

© 2006 RIVM

Best Practices for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

Safe FOOD Era

Benefit

- Reduction of risk vs benefit
- Adequate → Optimal nutrition
- Functional foods
- Claims

contribution (human health)

Table 1. Criteria points descriptive for strength of evidence

Convincing evidence: Evidence is based on epidemiological studies showing consistent associations between exposure and disease, with little or no evidence to the contrary. The available evidence is based on a substantial number of studies including prospective observational studies and where relevant, randomized controlled trials of sufficient size, duration and quality allowing consistent effects. The associations should be biologically plausible.

Possible evidence: Evidence is based on epidemiological studies showing fairly consistent associations between exposure and disease, but where there are persistent discrepancies in the available evidence or some evidence to the contrary, providing a more balanced picture. Discrepancies in observational studies and where relevant, randomized controlled trials of modest size, duration and quality allowing consistent associations between exposure and disease in cross-sectional, cohort and case-control studies. Again, the associations should be biologically plausible.

Insufficient evidence: Evidence is based mainly on the findings from case-control and cross-sectional studies. Insufficient randomized controlled trials, observational studies or meta-analyses based on randomized controlled trials. Evidence based on case-control studies, such as clinical and laboratory investigations, is suggestive. More trials are required to support the tentative associations, which should also be biologically plausible.

'State of the Art in Benefit-Risk Analysis in Food and Nutrition' - M.J. Tijhuis

© 2006 RIVM

Best Practices for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

Safe FOOD Era

Benefit

FUFOSE (Functional Food Science in Europe), 1995-1997

PASSCLAIM (Process for the Assessment of Scientific Support for Claims on Foods), 2001-2005

Result: consensus on scientific evidence needed to demonstrate that specific nutrients and food components beneficially affect target functions in the body

Result: criteria for the scientific substantiation of claims on foods

'State of the Art in Benefit-Risk Analysis in Food and Nutrition' - M.J. Tijhuis

© 2006 RIVM

Best Practices for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

Safe FOOD Era

December 2006: publication of EC Regulation 1924/2006 on nutrition and health claims made on foods

'State of the Art in Benefit-Risk Analysis in Food and Nutrition' - M.J. Tijhuis

© 2006 RIVM

Best Practises for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

Safe FOOD Era

Asymmetry Benefit Assessment and Risk Assessment

CLAIMS

- convincing
- probable
- possible
- insufficient

SAFETY ASSESSMENT

'State of the Art in Benefit-Risk Analysis in Food and Nutrition' - M.J. Tijhuis

Best Practises for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

Safe FOOD Era

Benefit-risk assessment

- Approaches
- Integrated measures
- Case studies

'State of the Art in Benefit-Risk Analysis in Food and Nutrition' - M.J. Tijhuis

Best Practises for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

Safe FOOD Era

Benefit-risk projects

Benefis

BRAFO

efsa European Food Safety Authority

Integration of Risk and Benefit Analysis—The Window of Benefit as a New Tool?

AMIRIO PALOU / CATALINA PROU / and JUSP KEEFER

CALIBRA

'State of the Art in Benefit-Risk Analysis in Food and Nutrition' - M.J. Tijhuis

Best Practises for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

Safe FOOD Era

Benefit-risk projects

Palou et al. Critical Reviews in Food Science and Nutrition, 2009

Renwick et al. Food and Chemical Toxicology, 2004

Verkerk. Toxicology, 2010

'State of the Art in Benefit-Risk Analysis in Food and Nutrition' - M.J. Tijhuis

Best Practises for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

Safe FOOD Era

Tiered approach

- Stop when you can answer the question
- Don't answer the question too accurately
- Full quantitative risk-benefit assessment is very data demanding
- Involves large effort (time and money)

Population	Age
	Sex
	Life expectancies
	Weight
	Etc.
For each beneficial and adverse health effect:	
Intake	Actual/Scenario 1
	Scenario 2
Dose-response functions	
Age of disease onset	
Recovery probabilities	
Mortality probabilities	
Severity/Disease weights	
Disease durations	

'State of the Art in Benefit-Risk Analysis in Food and Nutrition' - M.J. Tijhuis

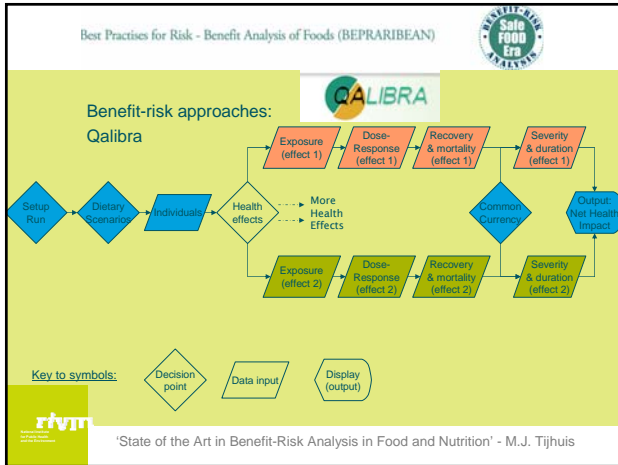
Best Practises for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

Safe FOOD Era

Benefit-risk approaches: BRAFO

Pre-assessment and problem formulation	Reference scenario	Alternative scenario
Tier 1 Individual assessment of risks and benefits	no benefit	no risk
	both risks and benefits	
Tier 2 Qualitative integration of risks and benefits	risks clearly dominates benefits	benefits clearly dominates risks
	no clear dominance	
Tier 3 Deterministic computation of common health metric	relatively small uncertainties	large uncertainties
	worst-case analysis	
	Sensitivity analysis	
	Increasingly assessing more and more parameters probabilistically	
Tier 4 Probabilistic computation	Net benefit < 0 advise reference	Net benefits > 0 advise alternative

'State of the Art in Benefit-Risk Analysis in Food and Nutrition' - M.J. Tijhuis



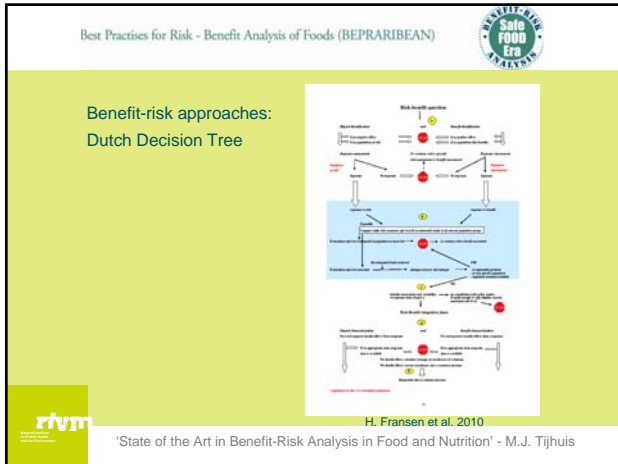
Best Practises for Risk - Benefit Analysis of Foods (BEPRARIBEAN)

Safe FOOD Era

Qalibra web tool

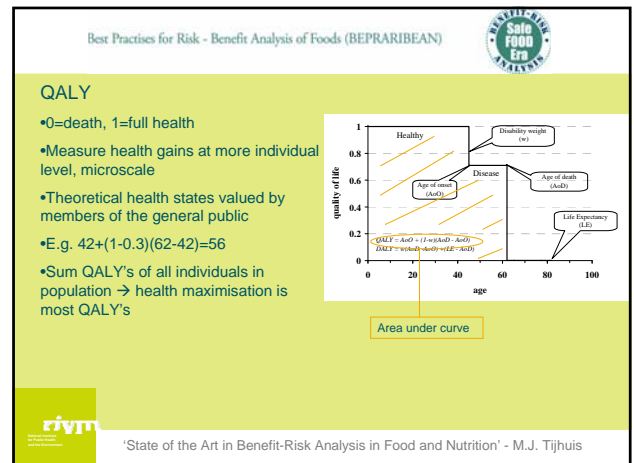
"We are currently preparing a short online training for people to complete before receiving their password"

rivm



- Best Practises for Risk - Benefit Analysis of Foods (BEPRARIBEAN)
- Safe FOOD Era
- Benefit-risk approaches:
EFSA
-
- Step 0, Problem formulation
 - Step 1, Initial assessment
 - Step 2, Refined assessment
 - Step 3, Assessment using a composite metric
- rivm
- 'State of the Art in Benefit-Risk Analysis in Food and Nutrition' - M.J. Tijhuis

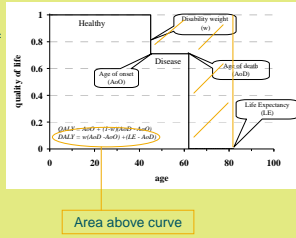
- Best Practises for Risk - Benefit Analysis of Foods (BEPRARIBEAN)
- Safe FOOD Era
- Benefit-risk measures
- Common measures
 - Mortality (risk/rate, life expectancy, years of life lost)
 - Morbidity (incidence, prevalence, risk)
 - Functioning (physical functioning, mental health, health quality)
 - Integrated measures
 - two are being substantially used in food: QALY and DALY
- rivm
- 'State of the Art in Benefit-Risk Analysis in Food and Nutrition' - M.J. Tijhuis





DALY

- 0=no disability, 1=death
- Population-aggregate measure of loss of health – burden of disease daly = loss of one year of equivalent full health
- Standard weights, based on expert judgements using trade-off methods
- Specific diseases valued along a continuum of disability.
- E.g. $0.3(62-42)+(82-62)=27$
- Sum DALY's of all individuals in population → health maximisation is least DALY's




Case studies

BRA QuestionType	Examples
Substitution	Sugar/sweeteners SFA/MUFA or carb
Food	Fish Human milk Vegetables Whole grains
Functional food	Phytosterols added
Component	Folic acid Chlorine



Difficulties to be solved

- Data requirements
- Uncertainties
- Asymmetry in benefit and risk arms
- How to measure true benefits?



Further developments/conclusions

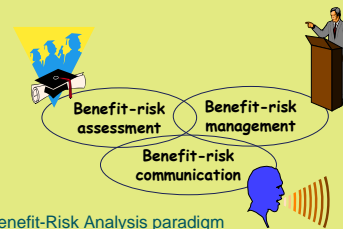
- Direct some attention from establishment of safe levels to calculation of dose-response relationships at relevant intake levels
- Further develop assessment of benefits
- Further develop integration measures



Benefit-risk assessment, provided it is carefully explained, is a valuable approach to systematically show the current knowledge and its gaps and to transparently give the best possible answer to a question with a large potential impact on public health.



Outcome of benefit-risk assessment needs to be contextualised!
For example: costs, ethics, equity, perception





Acknowledgements

- Team from BEPRARIBEAN
H. Gunnlaugsdottir, F. Holm, N. Kalogeras, O. Leino, J.M. Luteijn,
P. McCarron, G. Odekerken, J. Tuomisto, Ø. Ueland, B.C. White,
H. Verhagen
- Team from RIVM
M. Hendriksen, J. Hoekstra, N. de Jong, C. Rompelberg,
- Dutch funding partners in Safefoodera:
Dutch Food and Consumer Product Safety Authority



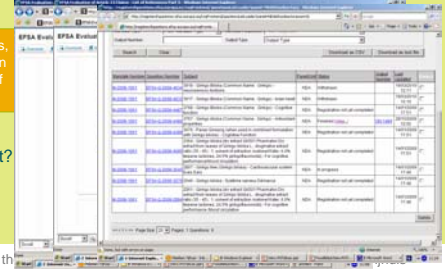
'State of the Art in Benefit-Risk Analysis in Food and Nutrition' - M.J. Tijhuis



Thank you
for your attention !

increased ability to focus,
increased attention span
and a general feeling of
being more awake


EFSA
judgement?



'State of th

State of the art in benefit and risk perception – consumer view

Øydis Ueland, PhD
Director Consumer and Sensory Sciences



15.04.2010 OUE:BEPRAR:BEAN\kolstad ws 1

Food – a prerequisite for survival



- Benefits
 - Avoid hunger and illness
 - Live to see another day
 - Reproduction and propagation of species
- Risks
 - Dangerous food acquisition
 - Hazardous food consumption
 - Incapacitation and death



Cave painting from South Africa
www.ari.org

15.04.2010 OUE:BEPRAR:BEAN\kolstad ws 2

Edible – or not?

Daphne
www.helsetrektoratet.no

Redcurrant

15.04.2010 OUE:BEPRAR:BEAN\kolstad ws 3

Food choice – looking for benefits, not risks




Liking: taste, product quality, freshness..

15.04.2010 OUE:BEPRAR:BEAN\kolstad ws 4

Benefit perception

- Benefits associated with food products have to do with all attributes that make the product attractive to the consumer for one reason or another.
 - Sensory characteristics
 - Fulfils expectations
 - Convenience
 - Price
 - Healthiness
 - Ethical production
 -



15.04.2010 OUE:BEPRAR:BEAN\kolstad ws 5

Benefit – risk evaluations

Some benefits may also constitute a risk





Some benefits or risks lie far ahead

15.04.2010 OUE:BEPRAR:BEAN\kolstad ws 6

Risk perception



- Perceived risks are connected to morbidity and mortality
 - When do consumers start thinking about risks?
 - When do benefits become risks?
 - Who thinks about risks?
 - Which attributes are perceived as more risky?
 - ...



15.04.2010 OUEBEPRARIBEAN\coland ws 7

Risks are perceived along two dimensions



1. Technology axis:
 - New
 - Unfamiliar
 - Unknown
 - Unobservable
 - Delayed consequences



Fischhoff et al. 1978



15.04.2010 OUEBEPRARIBEAN\coland ws 8

2. Severity axis:

- Fatal
- Uncontrollable
- High risk to future generations
- Not easily reduced
- Involuntary
- Potentially catastrophic



15.04.2010 OUEBEPRARIBEAN\coland ws 9

Food risks related to other risks



- Food risks are low on the list of consumers' most feared risks.



- Some food factors are high on the list of technological risks.



15.04.2010 OUEBEPRARIBEAN\coland ws 10

Consumer risk perception – meat example



- Meat is a complex food product
 - Meat has symbolic connotations
 - Meat consumption is gendered
 - Meat has health effects
 - Meat production has ethical issues
 - Meat is associated with many food scandals
- Meat is particularly vulnerable to risk perception



15.04.2010 OUEBEPRARIBEAN\coland ws 11

Consumer perception – Low risk



- Consumers prefer minimally processed meat from a known source characterised by familiar and trusted attributes.



15.04.2010 OUEBEPRARIBEAN\coland ws 12

Consumer risk perception vs. actual risk (I)



- Meat from the butcher (low technology production) is perceived to be more traditional, familiar, the process is observable, and it is therefore perceived as safer and more preferred. Any associated risk is perceived to be under control.

However, this might not be the case.



Consumer perception – Higher risk



- Meat that has been through a number of unknown processes, contains unnatural ingredients, has "suspiciously" long shelf life, ...



EU-IP ProSafeBeef: WPS



Consumer risk perception vs. actual risk (II)



- Meat from meat production company with listed benefits, is perceived to be produced by unknown means, possibly tampered with, and no observable production process, therefore it may not be as safe and is less preferred. Any associated risk is perceived not to be under control.

However, this might not be the case.



Dread factor



- Risk is perceived to be totally out of control, and risk communication is about fatalities and unavoidability.
 - Avian flu
 - BSE mad cow disease
 - Dioxin and pollutants
 - Hormones and antibiotics



Acceptable risk



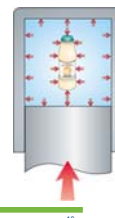
- Benefits can make risks more acceptable
- Benefits can make risks "disappear"
- Perceived control
- Voluntary
- Familiarity



Benefit – risk communication



- Consumers and risk communicators may have different views on what constitutes a risk.
- Introducing new and novel technologies poses particular problems.



Benefit – risk communication



- Benefit communication should always bear in mind the flip side of the coin



BEPRARIBEAN



Thanks for your attention.



SAFEOFODERA
RCN project no:199962/110

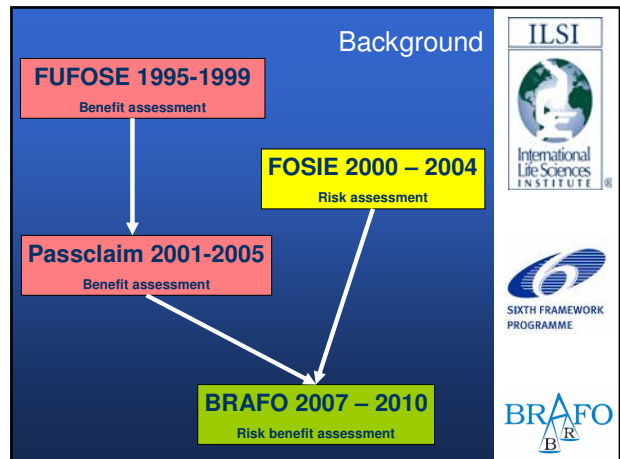
BRAFO
Stephane Vidry
15 April 2010, Iceland

BRAFO

Risk-Benefit Analysis of Foods

A Specific Support Action,
under FP6

Stéphane Vidry
ILSI Europe



BRAFO Objectives

1. To develop a framework that allows quantitative comparison of human health risks and benefits of foods and food compounds based on a common scale of measurement
2. To test the developed methodology on selected case studies
3. To adjust the model according to the outcomes of the case studies
4. To disseminate the results to as wide audience as possible

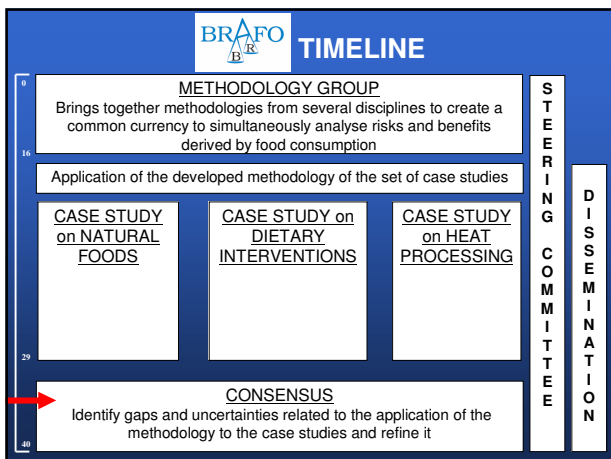
BRAFO

5 Partners: RIVM, MRI, Procter & Gamble, ICL and ILSI Europe

50 External Experts

WHO and EFSA

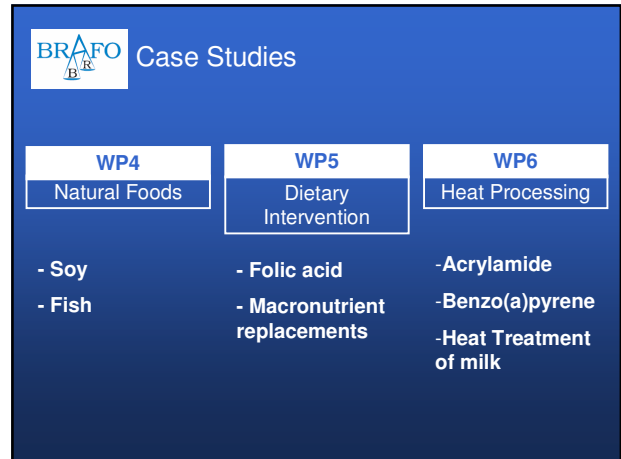
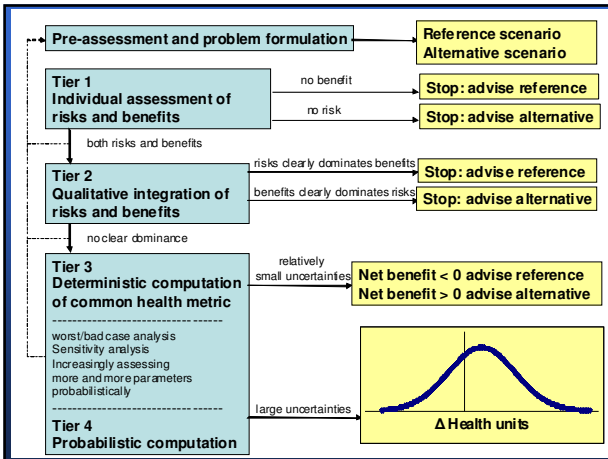
QALIBRA and Beneris



Tiered approach

- Stop when you can answer the question
- How accurate does the answer have to be
- Full quantitative risk-benefit assessment is very data demanding
- Involves large effort (time and money)

BRAFO
Stephane Vidry
15 April 2010, Iceland



Reference scenario	No fortification
Alternative scenario	Fortification of bread with folic acid at 70 µg/100 g
Target population	Dutch population

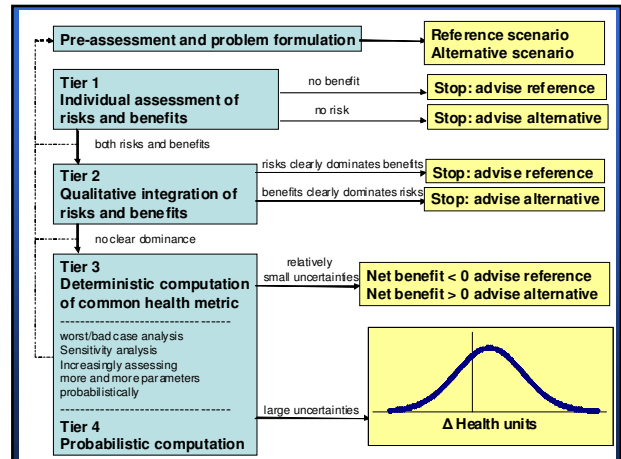
Pre assessment and problem formulation:

The potential benefits are:

- A reduced incidence of neural tube defects
- A reduced incidence of megaloblastic anaemia
- A reduced incidence of stroke in people without a history of the disease

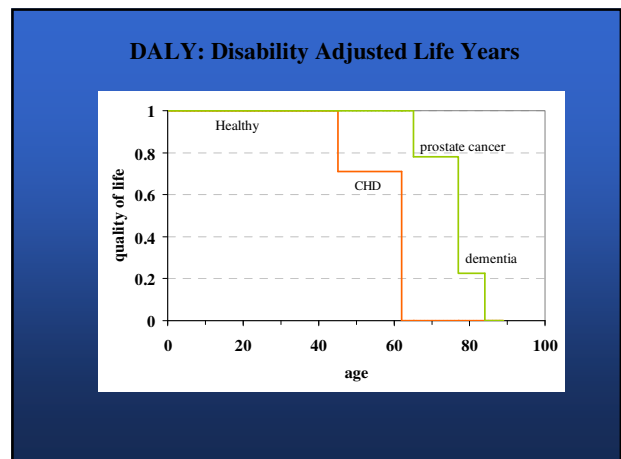
The potential risks are:

- An increased incidence of neurological damage due to masking of vitamin B₁₂
- An increase in the incidence of colorectal cancer
- An accelerated progression of colorectal cancer



In tier 1: it is concluded that the alternative scenario versus the reference scenario involves potential health benefits as well as potential health risks.

In tier 2: no definite answer can be given whether or not the alternative scenario dominates the reference scenario or vice versa.



BRAFO
Stephane Vidry
15 April 2010, Iceland

In tier 1: it is concluded that the alternative scenario versus the reference scenario involves potential health benefits as well as potential health risks.

In tier 2: no definite answer can be given whether or not the alternative scenario dominates the reference scenario or vice versa.

In tier 3: the overall DALY value indicates an overall reduction of 7000 DALY's.

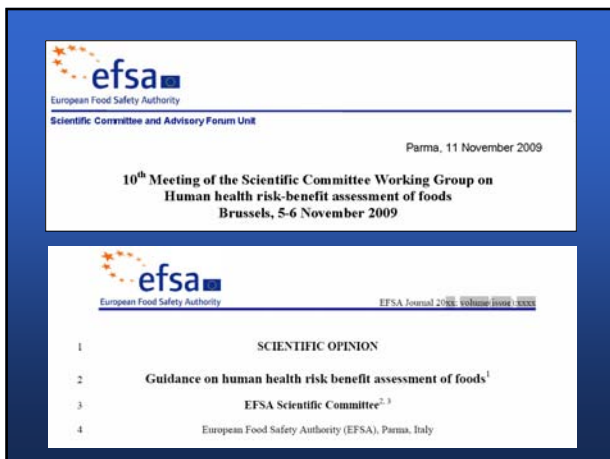
Conclusions: the overall effect of fortification of bread with folic acid at 70 ug/100g is a significant benefit.



The poster features a top section with a salmon fillet and a bottom section with french fries. The BRAFO logo is in the top right. Text on the poster includes: 'The health benefit and risk of the fortification of bread with folic acid...'. A small text block on the right side reads: 'As the burden of health risks within society increases due to longer lifespan, overall balanced nutrition can play an important role in disease prevention. There is considerable disparity in the way healthy and risky diets are consumed for populations found in food, raising strong concerns on subjective judgement. This presents unique challenges for scientists and policy makers. This project will provide a comprehensive policy to consumers. It is expected that this will be a valuable tool for the health impact of chemicals in food to be assessed and quantified, in a manner analogous to the current assessment of risk.'

SIXTH FRAMEWORK PROGRAMME

www.BRAFO.org



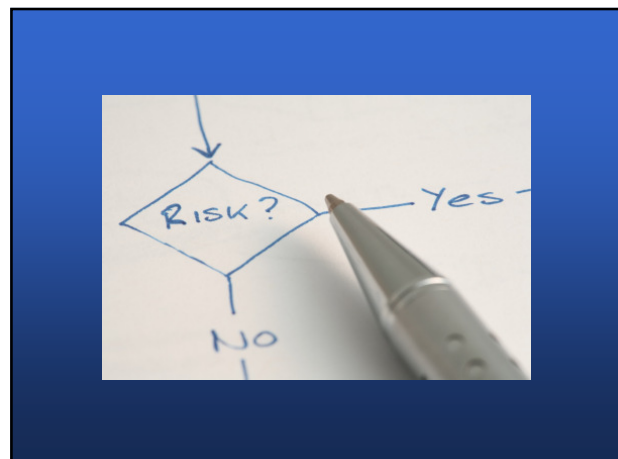
efsa
European Food Safety Authority
Scientific Committee and Advisory Forum Unit

Parma, 11 November 2009

10th Meeting of the Scientific Committee Working Group on Human health risk-benefit assessment of foods
Brussels, 5-6 November 2009

efsa
European Food Safety Authority
EFSA Journal 2010, Volume 7(10), 1935-1944

1 SCIENTIFIC OPINION
2 Guidance on human health risk benefit assessment of foods¹
3 EFSA Scientific Committee^{2,3}
4 European Food Safety Authority (EFSA), Parma, Italy





Working Groups: *Identification of Similarities and Differences in Benefit-Risk Assessment between disciplines*

Q1: What are the similarities between the various benefit-risk approaches?

A1:

- (sub)populations considered
- Structure steps/phases
- Medicine food microbiology: health only
- Others broader
- Data constraints except medicine
- Probabilities/likelyhoods not certainties
- Risks and benefits are common in all dispiplines
- Value risks and benefits (utility, importance)



Working Groups: *Identification of Similarities and Differences in Benefit-Risk Assessment between disciplines*

Q2: What are the differences between the various benefit-risk approaches?

A2:

- health only
- Policy implementation
- Different methodology and modelling approaches
- Medicine, pharmacovigilance on safety only, high level of data requirements and documentation
- Health claims, health benefits data requirements for scientific substantiation
- Voluntarily risks, individual perception of risks
- Food, medicine separation between assessment and decision - making; environment involvement stakeholders
- Maturity of disciplines differ



Working Groups: *Identification of Similarities and Differences in Benefit-Risk Assessment between disciplines*

Q3: How can the experiences from the other approaches be used to improve benefit-risk assessment of food and nutrition?

A3:

- Interdisciplinary research (natural and social sciences beta,gamma)
- Common language and definitions, assessors, managers, consumers
- How involve other stakeholders (environment)
- Think about consumer. Not only health conscious etc..
- Beware of communication aspect, transparency, focus on special groups
- Microbiology coincide, similar to nutrition/toxicology
- Phasewise approach from medicine



Working Groups: *Identification of Similarities and Differences in Benefit-Risk Assessment between disciplines*

Q4: What are good steps to convey to the consensus group?

A4:

- Need information about legal issues
- Constraints and possibilities, private public law
- Precautionary principle , article 14 GFL
- Position benefits as reduction of risk: to allow RB under the precautionary principle
- More contact between partners, teleconf..
- Focus on case study for all groups



Working Groups: *Identification of Similarities and Differences in Benefit-Risk Assessment between disciplines*

Q5: Other suggestions?

A5:

- risk vs benefits can be reffered to also as risk-risk net health impact
- Benefit is reduction of risk or additional health benefit
- Difference between Hedonic Benefits (taste) and Utilitarian Benefits (price)



Working Groups: *Identification of Similarities and Differences in Benefit-Risk Assessment between disciplines*

Q1: What are the similarities between the various benefit-risk approaches?

A1:

- They all tried to weigh or explain RB
- Most had a quantitative approach and qualitative evaluation
- Most approaches focus on risks. Particularly environment.
- Food is most evolved having a quantitative approach followed by pharma.
- Assessment by hard data. Analysis includes evaluation, putting the assessment data into a context.
- DALY's used in several of the approaches. Food, microbiology, environmental.
- There were some economic similarities, but the approach differed from industry point of view to public health.



Working Groups: *Identification of Similarities and Differences in Benefit-Risk Assessment between disciplines*

Q2: What are the differences between the various benefit-risk approaches?

A2:

- There were some economic consequences, but the approach differed from industry point of view to public health.
- In food economic consequences are concerned with optimal health. In economics the market got the consequences.
- **In food you will not accept risks (related to food safety), but in pharma and environmental you can (have to) accept risks.**
- The role of risks and benefits is different in the various approaches.



Working Groups: *Identification of Similarities and Differences in Benefit-Risk Assessment between disciplines*

Q3: How can the experiences from the other approaches be used to improve benefit-risk assessment of food and nutrition?

A3:

If you take the larger perspective, a food in a bigger context such as over a longer period of time, a certain risk can be accepted (related to health).
 "It's easier to do risk-benefit analysis (the scoping) in food because it is doable."



Working Groups: *Identification of Similarities and Differences in Benefit-Risk Assessment between disciplines*

Q4: What are good steps to convey to the consensus group?

A4:

- Strength of evidence, clearly defined steps includes steps on post-market monitoring (from pharma).
- Identification of critical points (from microbiology)
- Several organisations and agencies have established guidelines, regulations and approaches to evaluate risks; political decision making (from environment)
- People buy hope (from marketing).
- Consider the context, whole diet and substitution possibilities (from consumer).



Working Groups: *Identification of Similarities and Differences in Benefit-Risk Assessment between disciplines*

Q5: Other suggestions?

A5:

- Regulations to influence behaviour (management).
- Reevaluate the role of the risk manager.
- Risks and benefits are in totally different areas, ie. Environmental: chlorine which leads to cancer as well as less microbes. Transportation have pollution consequences but also convenience issues.



Working Groups: *Identification of Similarities and Differences in Benefit-Risk Assessment between disciplines*

Q1: What are the similarities between the various benefit-risk approaches?

A1:

- Not much
- Environment & microbiology: in majority of cases only a risk assessment, excludes perception
- Medicine – benefits and risks –limited experiece with quantitative RBA, excludes perception
- Economics- benefits and risks – perception is included
- Consumer science- perception is included
- Food & nutrition: excludes perception



Working Groups: *Identification of Similarities and Differences in Benefit-Risk Assessment between disciplines*

Q2: What are the differences between the various benefit-risk approaches?

A2:

- Many differences- metric differences, availability of data
- Medicine –qualitative – sufficient data both for humans and animals
- Food- animal data for risks and human data for benefits, shortage of data common esp. dose-response data, exposure data limited and uncertain
- Environment ? Which metric ? RBA ?
- Economics & food use mathematical models –others not
- Consumer science
- Microbiology -



Working Groups: *Identification of Similarities and Differences in Benefit-Risk Assessment between disciplines*

Q3: How can the experiences from the other approaches be used to improve benefit-risk assessment of food and nutrition?

A3:

- Widen the scope to include not only human health; carry out the RBA with more than one common currencies i.e. economics (willingness to pay), include environmental/sustainability issues , include consumer & consumer market perception in RBC,
- Learn from medicine how to report on the Benefits & Risks to professionals and consumers (use standardised formats),



Working Groups: *Identification of Similarities and Differences in Benefit-Risk Assessment between disciplines*

Q4: What are good steps to convey to the consensus group?

A4:

- Need a clear definition for each step of the RB-Analysis, which metric , the problem is we do not have the best practice for each step (e.g. RBM, RBC ? –medicine), identify key persons and interview them on best practises as this info isnot available in the literature (medicine, microbiology, environment ?)



Working Groups: *Identification of Similarities and Differences in Benefit-Risk Assessment between disciplines*

Q5: Other suggestions? The focus of the project was best practise

A5:

- Identified best practise for RB Assessment=> can learn from them
 - Medicine
 - Food
 - Economics
 - Microbiology
 - RB Communication can learn from Economics and consumer science
- Need to take next step to interest RB managers in RBA inform and train them about emerging methods and tools