

**4th meeting of the Chairs and secretariats  
of the Commission's and agency's  
Scientific Committees and Panels  
involved in RA**

**November 4, 2008  
Parma, I**

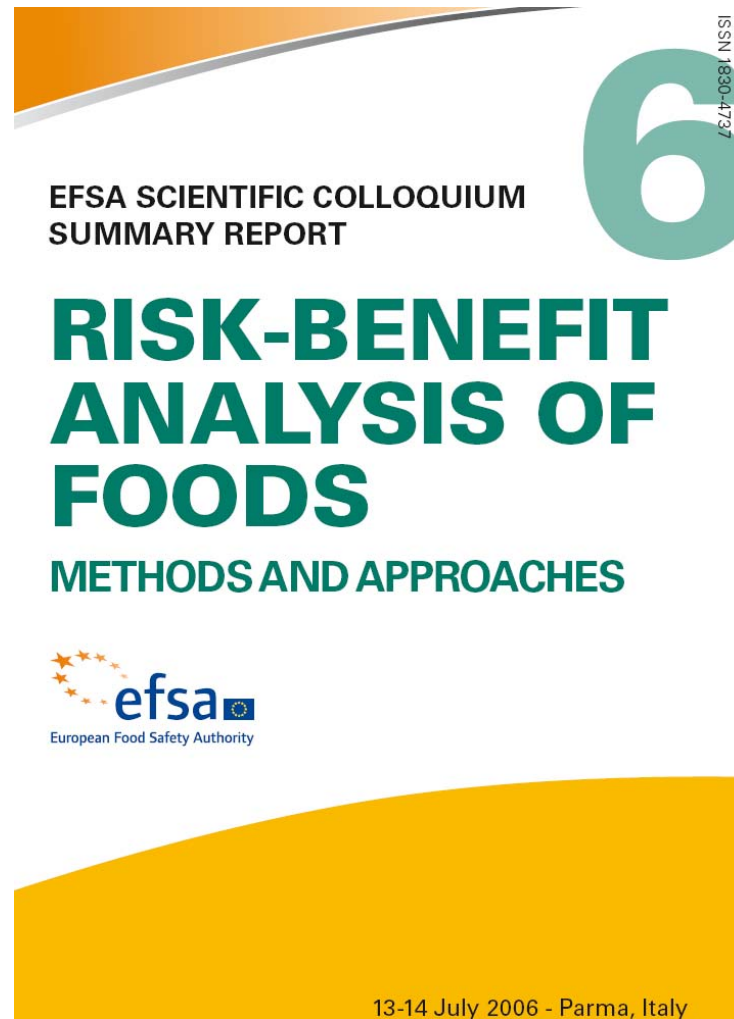
**Risk-Benefit Assessment within the EFSA**

**Josef Schlatter**

- ✓ **History/Background**
- ✓ **Definitions**
- ✓ **The EFSA RBA WG - Bernard Bottex**
- ✓ **Related activities**
- ✓ **Example form the CONTAM Panel (nitrate) - Claudia Heppner**



# EFSA Colloquium on RBA



Schweizerische Eidgenossenschaft  
Confédération suisse  
Confederazione Svizzera  
Confederaziun svizra  
Swiss Confederation

Federal Department of Home Affairs FDHA

**Federal Office of Public Health FOPH**  
Consumer Protection Directorate  
Nutritional and Toxicological Risks Section



**Josef Schlatter**  
**SC Chairs meeting**  
**Parma 4.11.2008**

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# EFSA Colloquium on RBA

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*“When a food or food substance is associated with **both potential health risks and benefits**, and particularly when the **levels of intake** associated with risk and benefit **are close**, there is a need to define an intake range within which the **balance of risk and benefit is acceptable** for risk management purposes.”*

*EFSA Scientific Colloquium Summary Report 6: Risk-Benefit Analysis of Foods – Methods and Approaches, 2006*



# Recommendations from the Colloquium

## Guidance document to be developed by EFSA to address:

- Problem formulation
- Definitions and language to be used
- Conversion of animal data to human situation
- Methods and approaches
- Potential pitfalls

## Spring 2007: the EFSA SC established a WG on Human Health Risk-Benefit Assessment of Foods (WG RBA) EFSA-Q-2007-043

- To prepare a guidance document for performing risk-benefit assessments of food related to human health risks and human health benefits
- Guidance to be adopted by end 2009
- Draft for public consultation by summer 2009



# EFSA Working Group on RBA

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## Terms of Reference:

- ✓ Scope and objective, harmonised language
- ✓ **Situations for which RBA may be appropriate**
- ✓ Guidance on problem formulation guidance on problem formulation
- ✓ Consideration of methods and approaches needed to assess risks and benefits and how to compare them (**common scale of measurement**)
- ✓ Usefulness of toxicological, nutritional and epidemiological data to assess risks and benefits
- ✓ Extrapolation of animal and other data to the human situation
- ✓ Identification of potential limitations of any RBA
- ✓ **Review of ongoing activities**
- ✓ Recommendations on future initiatives to overcome current limitations

***The Working Group is composed of 11 Experts + observers from EC***



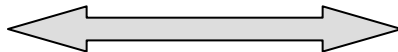
# Definitions

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**Risk:** The probability of an adverse effect in an organism, system, or (sub)population in reaction to exposure to an agent (IPCS, 2004).

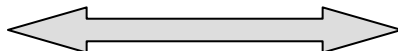
**Benefit:** Probability of a positive health effect and/or the probability of a reduction of an adverse health effect in a group of individuals in reaction to exposure to an agent.

**Risk**



**Benefit** (probability of a pos. health effect)

**Hazard**



**Positive health effect**



# Risk-Benefit Analysis

## Risk Assessment

Hazard Identification

Hazard Characterisation

Exposure Assessment



Risk Characterisation

## Benefit Assessment

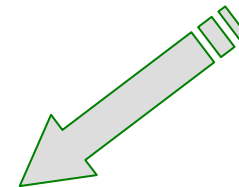
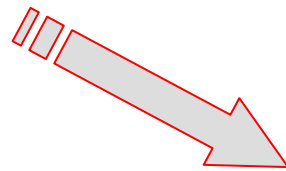
(+) health effect Identification

(+) health effect Characterisation

Exposure Assessment



Benefit Characterisation



## Risk-Benefit Assessment

## Risk-Benefit Comparison

**(Assumptions and uncertainties should be clearly addressed)**

(Also: Risk-Benefit Management and Risk-Benefit Communication)



# When to perform a RBA ?

- ❖ **Narrow margin between the dose for the claimed beneficial effect and the dose showing risks**  
(e.g. nitrates in vegetables → CONTAM/NDA)
- ❖ **Benefits and risks occur in different population groups**  
(e.g. folic acid → ANS/NDA)
- ❖ **Nutritional and dietary advice to the population to be revised**  
(e.g. fish consumption → CONTAM/NDA)  
see: SAFETY ASSESSMENT OF WILD AND FARMED FISH - EFSA-Q-2004-22  
[http://www.efsa.europa.eu/cs/BlobServer/Scientific\\_Opinion/contam\\_opinion\\_ej236\\_swaff\\_v2\\_en1.pdf?ssbinary=true](http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/contam_opinion_ej236_swaff_v2_en1.pdf?ssbinary=true)
- ❖ **Significant change of dietary consumption**  
(e.g. substitution of sugar by low-calory sweeteners → ANS/NDA)
- ❖ **Before implementing new measures**  
(e.g. addition of nutrients to food – maximum levels → ANS/NDA)
- ❖ **New knowledge emerges triggering the need for RBA**  
(e.g. meat consumption → CONTAM/NDA)



# EFSA Expert Participation

**EFSA experts are also involved in the following projects:**

- **QALIBRA** (<http://qalibra.eu>)

“To develop methods that can take account of multiple risks, benefits and uncertainties and implement them in web-based software for assessing and communicating net health impacts”.

- **BRAFO** (<http://europe.ilsil.org/activities/ecprojects/BRAFO/default.htm>)

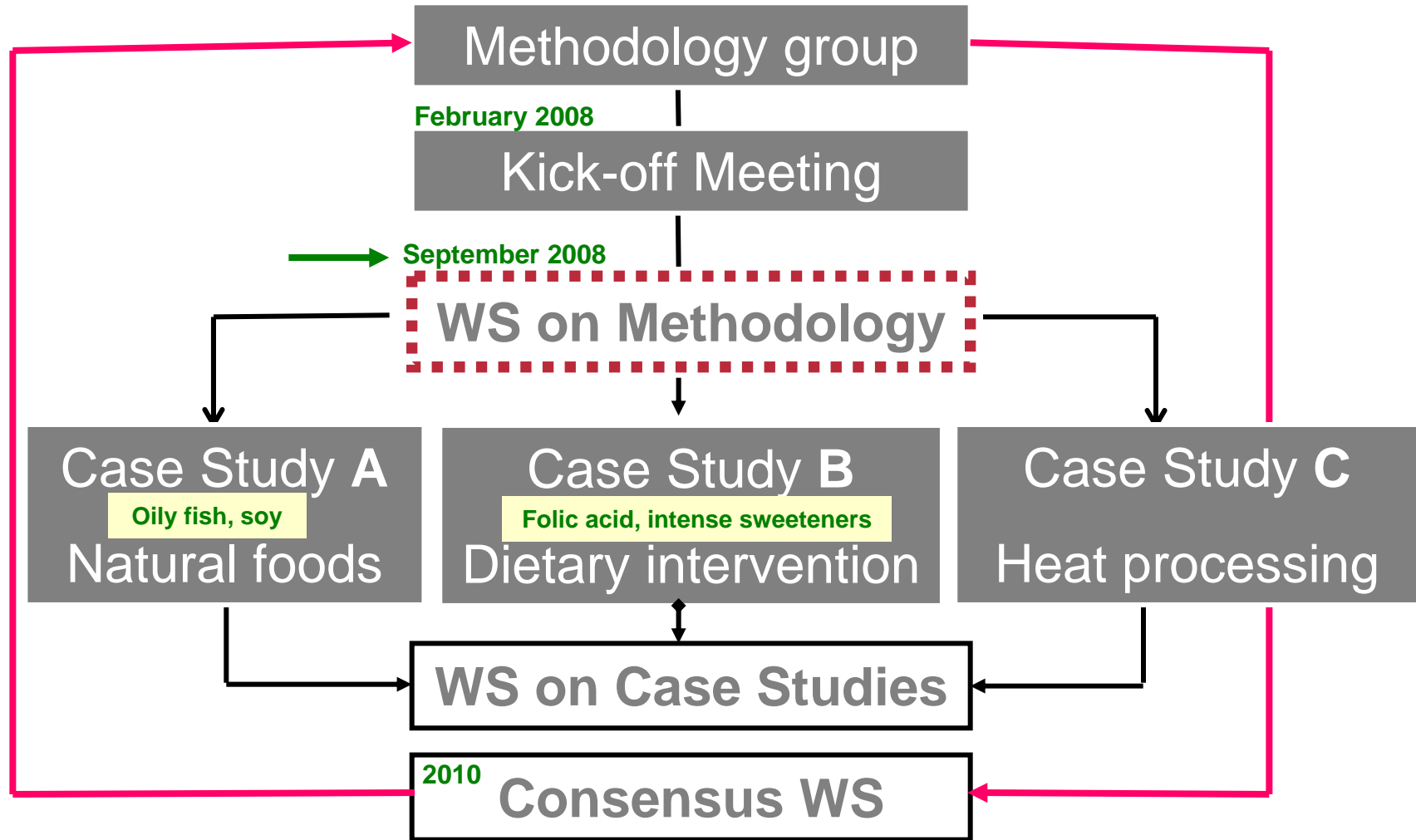
(Observer status of EFSA)



- [ **BENERIS** (<http://www.beneris.eu/>)

“Concept of “Open Risk Assessment” The risk assessment work is based on the principle of mass collaboration (Wiki system) ]





e.g. "no one eats fish"

e.g. "everyone eats 100g fish/day"

**Pre-assessment and problem formulation**

**Reference scenario**  
**Alternative scenario**

**Tier 1**  
**Identification and screening**

**Stop**  
**Perform either**  
**Risk or**  
**Benefit assessment**

Genuine RB question  
yes

no

**Tier 2**  
**Qualitative evaluation**

risks clearly dominates benefits

**Stop; advise reference**

benefits clearly dominates risks

**Stop: advise alternative**

no clear dominance

**Tier 3**  
**Deterministic computation**  
**of common health metric**

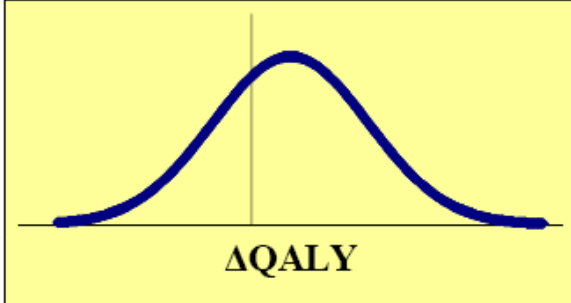
relatively  
small uncertainties

**Net benefit < 0 advise reference**  
**Net benefit > 0 advise alternative**

-----  
worst/bad case analysis  
Sensitivity analysis  
Increasingly assessing  
more and more parameters  
probabilistically  
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**Tier 4**  
**Probabilistic computation**

large uncertainties



# Opinion of the CONTAM Panel

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**Nitrate in vegetables (question No. EFSA-Q-2006-071) is available at:**

[http://www.efsa.europa.eu/EFSA/Scientific\\_Opinion/contam\\_ej\\_689\\_nitrate\\_en.pdf](http://www.efsa.europa.eu/EFSA/Scientific_Opinion/contam_ej_689_nitrate_en.pdf)

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*“ ..provide a scientific risk assessment for the longer term strategy for managing the risk from nitrate in vegetables.”*

*“..to assess the risks to consumers from nitrate in vegetables. The assessment should take into account the amounts of nitrate found in vegetables as consumed and **any relevant considerations on the possible balance between risks and beneficial health effects**”.*



# On the one hand.....




**FOOD STANDARDS AGENCY**
**Eat well, be well** Helping you make healthier choices
Cymraeg


Home
Healthy diet
Ages and stages
Health issues
Keeping food safe
Food labels

Search

### Healthy diet

- ▶ 8 tips for eating well
- ▶ The eatwell plate
- ▶ Nutrition essentials
  - **Fruit and veg**
  - Starchy foods
  - Fish and shellfish
  - Eggs and pulses
  - Meat
  - Milk and dairy
  - Fats, sugars, salt
  - Drinks
  - Vitamins and minerals
- ▶ Healthy weight
- ▶ Food for sport
- ▶ Food myths debunked
- ▶ Eating out healthily
- ▶ Vegetarian and vegan
- ▶ Seasons and celebrations

### Fruit and veg



Most people know that we should be eating more fruit and veg. But most of us aren't eating enough.

Did you know that we should be eating at least five portions of fruit and veg every day?

You can choose from fresh, frozen, tinned, dried or juiced. But remember that potatoes don't count because they're a starchy food.

#### On this page

- ▶ How much fruit and veg should I be eating?
- ▶ Getting your five portions a day
- ▶ Getting the most out of fruit and veg
- ▶ Why it's important
- ▶ Recommendations

#### How much fruit and veg should I be eating?



Lots! Fruit and veg should make up about a third of the food you eat each day. And it's also important to eat a variety. Five-a-day is a good, achievable target. If you count your portions each


#### Ask Sam...

"Can I get all my daily fruit and veg portions from juice?"

- ▶ Answer
- ▶ More questions on Fruit and veg



#### eatwell on film




Healthy eating tips from Lorraine Kelly and dietitian Nigel Denby...

▶  Find out more...

#### I'd like to know about...

- ▶ Fibre
- ▶ How to be a healthy weight
- ▶ Healthy heart
- ▶ Summer veg

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 Tell a friend  
 Printer friendly  
 ABC Text only

## Vegetables are part of a healthy diet



# What are the impacts of eating vegetables?

## Vegetables are good for your health

400g fruit and vegetables/day recommended by WHO, 2003

Prevention of non-communicable diseases e.g.:

- cardiovascular

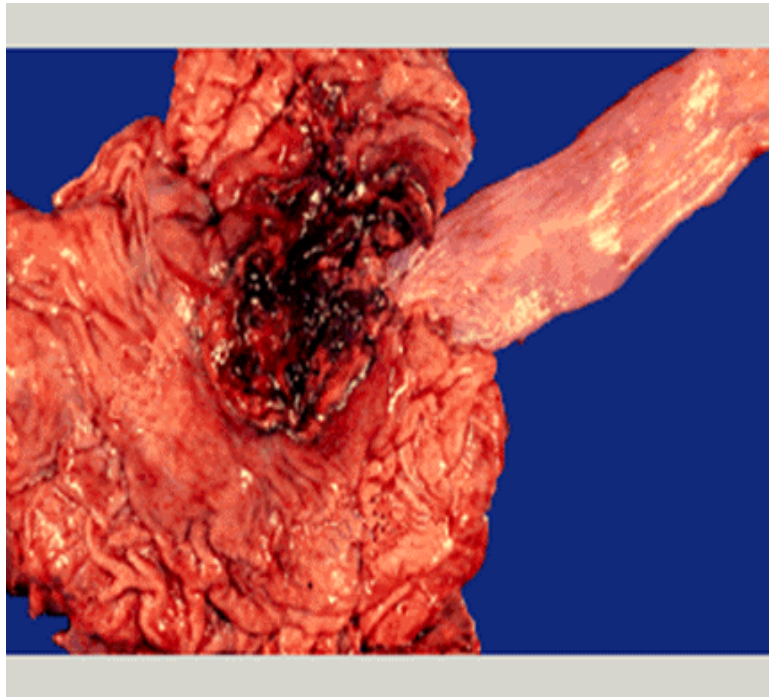
- cancer
- obesity
- type 2 diabetes



# On the other hand.....

## Nitrate via nitrite may lead to adverse health outcomes

**Gastric Carcinoma**

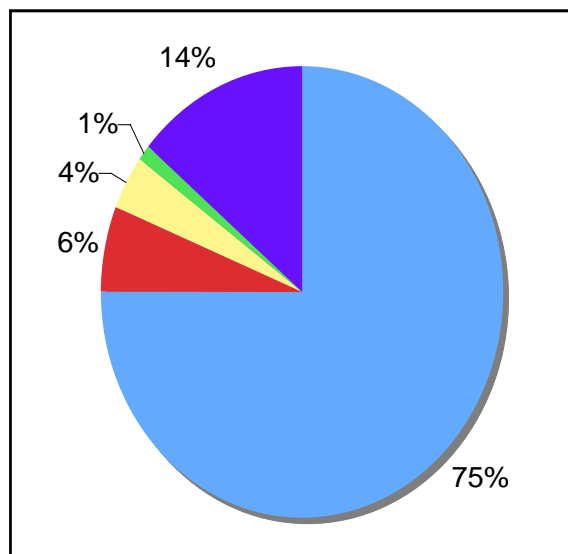


**Blue Baby Syndrome**

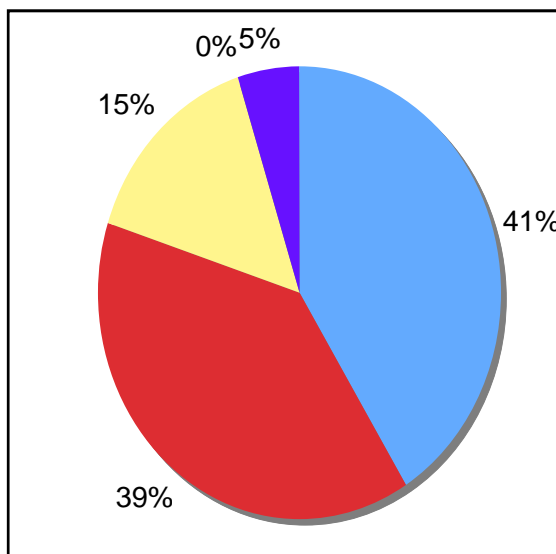


# Dietary exposure in France:

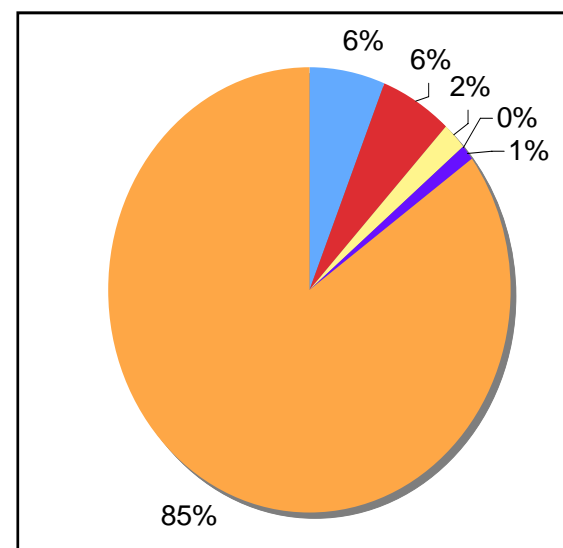
■ Vegetables and fruit ■ Animal-based products ■ Other foods ■ Beer ■ Water ■ Conversion of nitrate



**Nitrate:** 141 mg/person/day



**Nitrite:** 2.0 mg/person/day

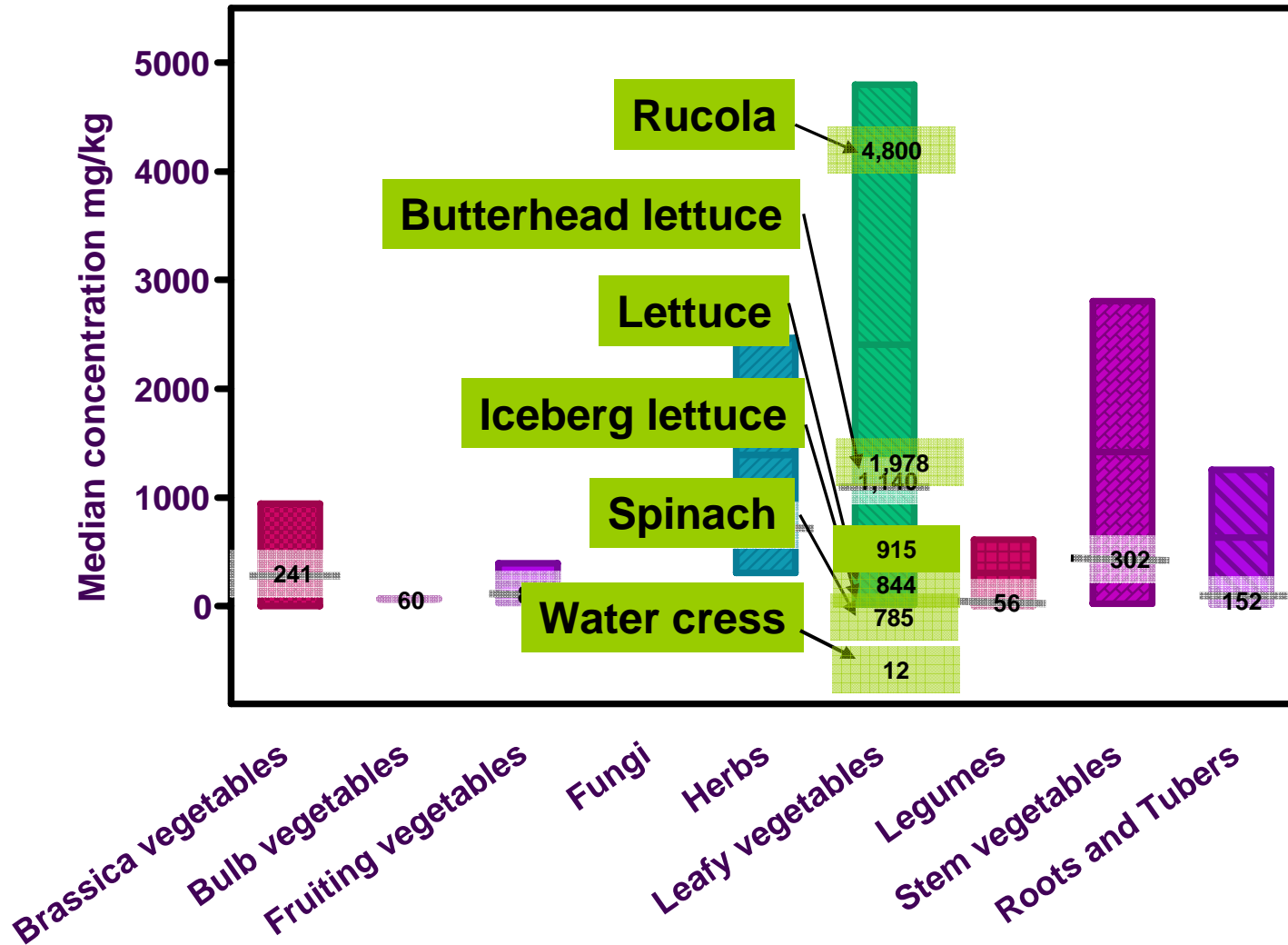


**Total nitrite** 11.3 mg/person/day

- **41'969 nitrate occurrence data from 20 Member States and Norway on 59 vegetable varieties**
- **Large range median nitrate concentration: 1 – 4,800 mg/kg**



# Nitrate levels in vegetable groups



# Vegetable consumption is variable in Europe

- No typical consumer
- Estimates of WHO GEMS Food Consumption Cluster Diets database: **mean 372 g**
- Data from 11 Member States & Norway: 97.5th percentile **393 g**
- WHO recommendation: **400g/person/day** fruit and vegetables
- CONTAM selected **400 g/person/day** as a conservative figure

**ASSUMED ALL CONSUMED AS VEGETABLES**

- Tested impact of different “high consumer” scenarios, e.g.,  
**771g potatoes/day Ireland and 133g/day leafy vegetables in Spain**








# Acceptable daily intake (ADI) - nitrate

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- Former SCF and the JECFA derived an ADI of 3.7 mg/kg b.w.
- The ADI equates to 222 mg/day for an 60 kg adult.
- No new data were identified by the CONTAM Panel to revise this ADI.



# Exposure scenarios vs. ADI

Scenarios	Vegetable consumption (g/person/day)	Exposure (mg NO <sub>3</sub> /person/day *)	% of ADI
S1 	400 (mix, except potatoes)	201	91
S2 	771 (potatoes)	126	57
S3 (A/B/C) 	133 (spinach/ lettuce/ 1/3 rucola 2/3 lettuce)	148/222/374	67/100/168
S4 	133 (spinach/lettuce)/ 267 (mix)	253/327	114/147
S5 	133 (spinach/lettuce)/ 267 (mix) regional	381/501	172/226

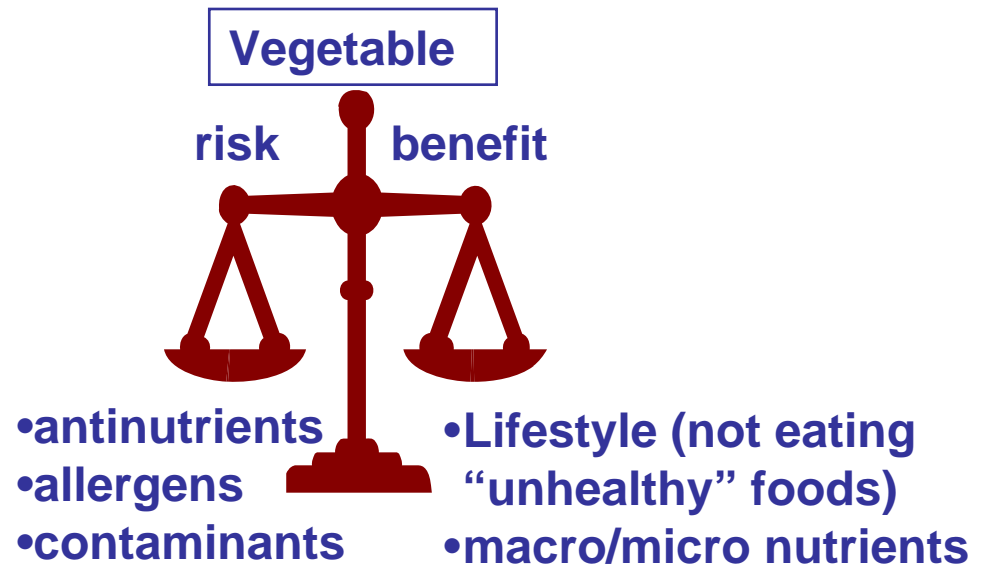
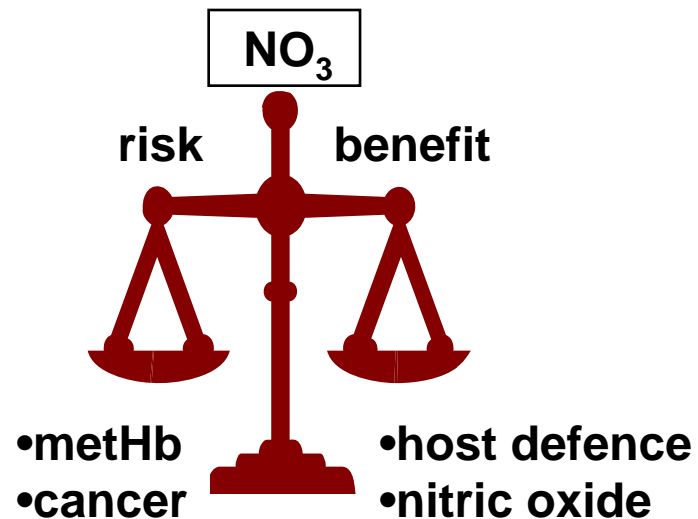
\*) inc. background exposure from other sources 44 mg/person/day

**Exposure normally below the ADI, but can be exceeded for certain consumers**

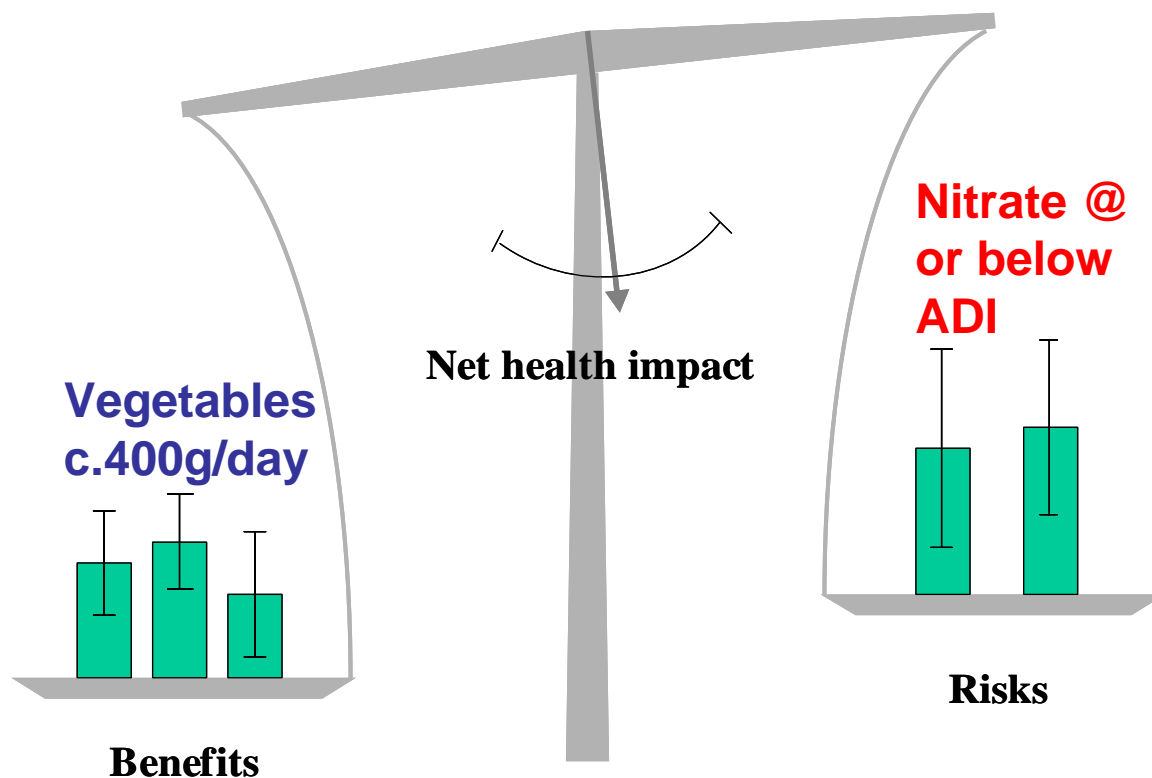


# Balancing risk and benefit

Pros and cons of exposure to nitrate  
Pros and cons of eating vegetables



# Weighing risks and benefits



**Overall the estimated exposures to nitrate from vegetables are unlikely to result in appreciable health effects.**

**The beneficial effects of eating vegetables prevail.**





Thank you for your attention !!!



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Josef Schlatter  
*SC Chairs meeting*  
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