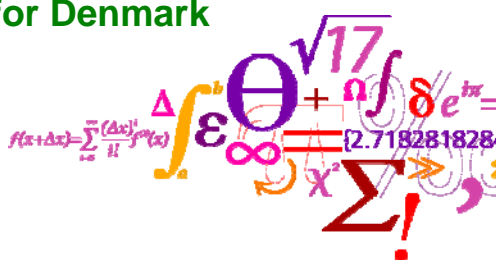




"The principle of risk assessment in use of analytical results"

Arne Büchert
Chief Consultant
EFSA Focal Point for Denmark



DTU Food
National Food Institute



ARNE BÜCHERT

- Scientific background as analytical chemist – mass spectrometry, organic food contaminants like dioxins
- Member of the EFSA scientific panel for Plant Protection Products (2006 – 2009)
- Technical assessor for DANAK and SWEDAC since 1992
- Presently Chief Consultant with responsibility for:
 - Coordination of cooperation with the Danish Food Administration
 - Management of EFSA Focal Point for Denmark



Presentation

- Short introduction to EFSA – the European Food Safety Authority
- Principles of risk assessment of food
- The need for analytical data
- The influence of analytical data on the reliability of risk assessments
- Risk assessment of cumulative exposure to triazoles - an example

National Food Institute, Technical University of Denmark



The European Food Safety Authority



- EFSA is an independent European agency funded by the EU budget
- EFSA operates separately from the Commission, the Parliament and the Member States
- EFSA was founded in 2002 with the aim of separating risk assessment from risk management
- EFSA is located in Parma and has approx. 450 staff members

National Food Institute, Technical University of Denmark



EFSA – Organisation

Management Board

Advisory Forum



Scientific Committee

Scientific Panels

National Food Institute, Technical University of Denmark



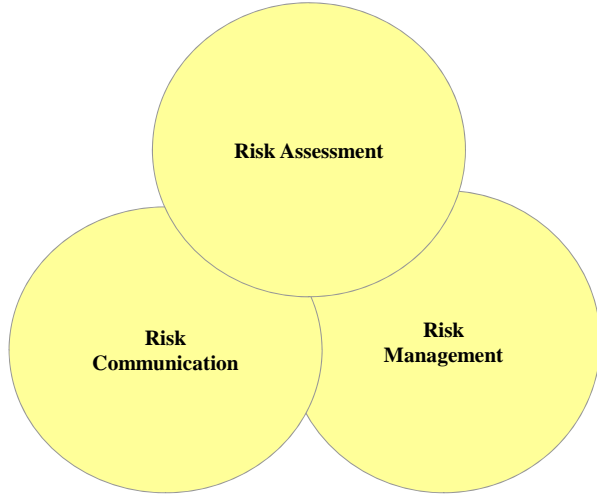
The European Food Safety Authority

- The main objectives of EFSA is to do **risk assessments** on request from the EU Commission, the Parliament and/or Member States
- EFSA risk assessments are prepared by scientific panels
- EFSA has 10 different scientific panels
- Approx. 700 opinions were adopted in 2009

National Food Institute, Technical University of Denmark



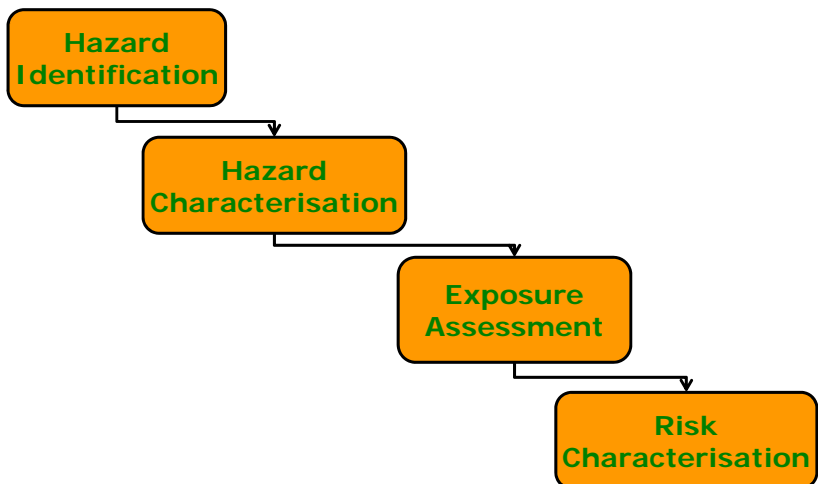
Risk assessment



National Food Institute, Technical University of Denmark



Risk Assessment



National Food Institute, Technical University of Denmark

Hazard Identification



First step of the Risk Assessment process

- The identification of the type and nature of adverse effects that an agent has as inherent capacity to cause in an organism, system or (sub) population.
- Hazard identification is the first stage in hazard assessment and the

Only limited need for analytical data

National Food Institute, Technical University of Denmark

Hazard Characterisation



Second step of the Risk Assessment process

- The qualitative and, wherever possible, quantitative description of the inherent properties of an agent or situation having the potential to cause adverse effects. This should, where possible, include a dose-response assessment and its attendant uncertainties.

Major need for analytical data

National Food Institute, Technical University of Denmark

Exposure estimation

Third step in the Risk Assessment process



- Evaluation of the exposure of an organism, system or (sub) population to an agent (and its derivatives)

Major need for analytical data

National Food Institute, Technical University of Denmark

Risk Characterisation

Fourth step in the Risk Assessment process



- The qualitative and, wherever possible, quantitative determination, including attendant uncertainties, of the probability of occurrence of known and potential adverse effects of an agent in a given organism, system or (sub)population, under defined exposure conditions.

Only limited need for analytical data

National Food Institute, Technical University of Denmark



Hazard Characterisation

Major need for analytical data to determine and control:

- Doses and levels in animal experiments
- Quality of feed mixtures

National Food Institute, Technical University of Denmark



Exposure estimation

Major need for analytical data to determine the level of chemicals in food and food products

- Analytical data from monitoring and control programmes are the typical basis for exposure estimation
- Monitoring data are quite often below detection limit

National Food Institute, Technical University of Denmark



Quality of analytical data

- The reliability of exposure estimations and the risk characterisation depends highly on the quality of the analytical data (and the consumption data)
- The quality of monitoring data is considered higher to day than previously. This is most probably due to:
 - ❑ The demand for ISO17025 accreditation for public control laboratories and
 - ❑ The development of national and community reference laboratories.

National Food Institute, Technical University of Denmark



Quality of analytical data

- Analytical data will always be defective
- Uncertainty will increase when sampling uncertainty is included in the expanded uncertainty
- Any risk assessment can't be more reliable than prescribed by the uncertainty of the analytical data

An evaluation of the uncertainty and the uncertainty factors should be included in the risk assessment

National Food Institute, Technical University of Denmark



Quality of analytical data

➤ Other factors that can influence the reliability of the risk assessment:

- Sampling strategy (time, geography etc.)
- Monitoring strategy (target or random)
- Extrapolation from crop to crop
- Extrapolation from country to country
- Reduction or concentration of residue concentration during storage and preparation of the food
- Handling of monitoring result below detection limit

National Food Institute, Technical University of Denmark



Handling of non-detects (dioxins)

- Monitoring results for dioxins, PCBs and other POPs include several congeners
- Results for dioxins should be reported as upper bound, medium bound or lower bound results.
- Upper bound results are based on the assumption that the level for non-detected congeners are at the detection level!
- Lower bound results are based on the assumption that the level of non-detected congeners are 0!

National Food Institute, Technical University of Denmark

Handling of non-detects (pesticides)



- The major part of EU monitoring results for most pesticides are below detection limit (or reporting level)
- The residue level in a non-treated crop is a true 0
- Information about treatment of specific crops is generally not available
- Should 0, ½DL or DL be assumed as the level in samples without residues?
- It is recommended to make a sensitivity analyses

National Food Institute, Technical University of Denmark

Risk Assessment of "Dietary Cumulative Exposure"



➤ **2008:**

Opinion of the Scientific Panel on Plant Protection products and their Residues to evaluate the suitability of **existing methodologies** and, if appropriate, the identification of new approaches to assess **cumulative and synergistic risks** from pesticides to human health with a view to **set MRLs** for those pesticides in the frame of Regulation (EC) 396/2005

National Food Institute, Technical University of Denmark

Risk Assessment of “Dietary Cumulative Exposure”



➤ 2009:

Opinion of the Scientific Panel on Risk Assessment for a Selected Group of Pesticides from the Triazole Group to test Possible Methodologies to Assess Cumulative Effects from Exposure throughout Food from these Pesticides on Human Health

National Food Institute, Technical University of Denmark

Sensitivity Analysis



Residue	I	II	III	IV	V
Bitertanol	0.0186	0.22	0.42	1.62	3.23
Cyproconazole	0.0004	0.05	0.09	0.80	1.61
Difenoconazol	0.0130	0.62	1.23	1.61	3.21
Diniconazole	0.0002	0.02	0.03	0.32	0.64
Epoxiconazole	0.0008	0.09	0.18	2.01	4.16
Flusillazole	0.0030	0.14	0.29	3.21	6.42
Myclobutanil	0.0012	0.01	0.02	0.04	0.09
Propiconazole	0.0008	0.05	0.10	0.48	0.96
Tebuconazole	0.0024	0.03	0.08	0.08	0.17
Triadimefon	0.0030	0.02	0.04	0.08	0.16
Triadimenol	0.0286	0.15	0.27	0.34	0.66
Cumulativ	0.072	1.4	2.74	10.61	21.32
%ADI	0.36	7.01	13.71	53.07	106.61

National Food Institute, Technical University of Denmark

Thank you for your attention



and

**Good luck with your future
Analytical Chemistry and
Risk Assessments Activities**

