The German Federal Institute for Risk Assessment (BfR): general risk assessment scheme

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German Federal Institute for Risk Assessment, Department of Exposure
History of the BfR

1876-1919 Imperial Office of Public Health
1919-1945 Reich Office of Public Health
1952-1994 Federal Health Agency
1994-2002 Federal Institute for Health Protection of Consumers and Veterinary Medicine

Law on the reorganisation of consumer health protection and food safety
1.11.2002

Risk Management
Risk Assessment

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
Bundesinstitut für Risikobewertung

Stephanie Beyvers, 10/12/2018, Rome
German Federal Institute for Risk Assessment (BfR)

Set up on 1\textsuperscript{st} November 2002 as an independent departmental research facility under the authority of the Federal Ministry of Food and Agriculture (BMEL – formerly BMELV).

**Overall goal:**
Strengthening consumer health protection

**Tasks:**
- Assessment of health risks posed by foods, products or chemicals
- Research to deepen the knowledge on which the assessments are built
- Risk communication
Concept

Separation between
• Risk assessment, risk communication (BfR)
• Risk management (BVL)

Objective
Qualified scientific assessment, free from influence from politics, business and society

Expected results
• Clear responsibility regarding decisions and conflicts
• Control of dissonance between interdisciplinary expert systems
• Orientation information from a neutral party and structured procedures
BfR mode of operation

The institute is **independent** in
- its scientific assessments
- its research
- its risk communication

NEW: members of "mirror"-panels invited to join

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Scientific expertise of employees

Scientific knowledge from other sources

Advice of external experts (BfR committees)

Risk Communication
- Political consulting
- General public
- Authorities…

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Stephanie Beyvers, 10/12/2018, Rome
Food Safety Network

- EFSA: European Food Safety Authority
- DG SANTE: Directorate General
- FVO: Food and Veterinary Office
- BfR: German Federal Institute for Risk Assessment
- BMEL: Federal Ministry of Food and Agriculture
- BVL: Federal Office of Consumer Protection and Food Safety
- Federal research institutes
- 16 State ministries, LAV
- Working groups and committees of the federal government and the states

Official food surveillance, monitoring in the 16 states

Food business operators
Experimental toxicology

Food safety

Biological safety

Healthy animals

Healthy food

Healthy people

Safety of substances and preparations

Safety of consumer products

Risk communication

Quelle: Fotolia, C Taylor
Department “Exposure”: one pillar of risk assessment paradigm

9 units (recently restructured)

- MEAL Study Centre, National Total Diet Study
- Chemical Exposure and Transport of Dangerous Goods
- Exposure Assessment of Dangerous Products
- Epidemiology, Statistics and Exposure Modelling
- Dietary Exposure and Overall Assessment
- Information and Communication Technologies
- GLP Federal Bureau and Quality Management
- National Monitoring of Poisonings
- Junior Research Group „Toxicokinetic Modeling“
Research in the context of risk assessment

Department „Exposure“

We generate the necessary data

We create new insights by linking information in the fields of

One Health

Exposure to chemical agents

- Orion (H2020/EJP)
- COHESIVE (H2020/EJP)
- RADAR (H2020/EJP)

- Prediction of food and feed supply chains (ExpoPredict/BfR)
- Total exposure via different paths (Total Exposure/BfR)
- External & internal exposure (Toxicokinetics/BfR)
- Exposure assessment via HBM data (HBM4EU)

Risk-benefit

Network analysis of food and feed supply chains (IntelliNet/BfR)

- Focus on global food chains
- Junior Research Group Toxicokinetic Modelling planned

Pilot study consumer products (BMUB)

Contents & origin (ExpoTrace/BfR)

Expo & HBM (NVS III/BMEL)

Pilot study National Monitoring of Poisonings (BMU)

EuroCigua (EFSA)

LiquidTabs (EU KOM)

Stephanie Beyvers, 10/12/2018, Rome
Exposure: one pillar of the risk assessment paradigm

- Hazard is an unchangeable dimension
- Exposure depends on actual circumstances and can be mitigated

**Hazard**

- Activities to improve the distance
- Ensure a safe distance

**Exposure**

- Account for variance in the distance
  - Which differences in intake between different subpopulations exist?
- Which risk management options can be derived?

**Exposure estimate**

\[
\text{[µg /kg bw/day]}
\]
The data base for dietary exposure in Germany

- **Data to assess dietary exposure in Germany**
  - **Food consumption**
    - **VELS (2002)**
      - University Paderborn
      - Age 0.5-4 Years
    - **ESKIMO (2006)**
      - Robert Koch-Institut (RKI)
      - Age 6-17 Years
    - **NVS II (2006)**
      - Max Rubner-Institut
      - Age 14-80 Years
- **Concentration data in Food**
  - **Food Monitoring**
    - **Food composition table for nutrients (BLS)**
      - Max Rubner-Institut
Mahlzeiten für die Expositionsschätzung und Analytik von Lebensmitteln

[Meals for Exposure assessment and Analytics in food]
BfR MEAL Study: modular structure and steps

![Diagram showing modular structure and steps]

- **Core Module**
  - Elements and environmental contaminants
  - Plant protection product residues
  - Perfluorated surfactants
  - Mycotoxins
  - Nutrients
  - Pharmacologically active substances

- **Authorisation**
  - Process contaminants
  - Food contact materials
  - Food packaging
  - Food additives

**Authorisation**

**CORE MODULE**

**Elements and environmental contaminants**

- Plant protection product residues
- Perfluorated surfactants
- Mycotoxins
- Nutrients
- Pharmacologically active substances
BfR MEAL Study: modular structure and steps

CORE MODULE
Elements and environmental contaminants

- Plant protection product residues
- Perfluorated surfactants
- Mycotoxines
- Nutrients
- Pharmacologically active substances

Process contaminants
- Food additives
- Food contact materials
- Food packaging
- Processing

Authorisation

unique structure!
BfR MEAL Study: modular structure and steps

CORE MODULE
Elements and environmental contaminants
- Plant protection product residues
- Perfluorated surfactants
- Mycotoxines
- Nutrients
- Pharmacologically active substances

- Process contaminants
- Food contact materials
- Food packaging
- Authorisation
- Processing
- Food additives

Step 1
Selection of foods

Step 2
Shopping on national level

Step 3
Preparation and processing

Step 4
Pooling and homogenisation

Step 5
Analysis

Step 6
Evaluation and exposure assessment
Scientific Community

Core Module
- Elements & environmental contaminants
- Perfluorated surfactants

Expert group
- Mycotoxines

Process contaminants

Expert group
- Nutrients

Pharmacological active substances

Expert group
- Food contact materials

Additives

Intl. Advisory Board

Chemical investigation offices
## BfR MEAL Study: time scheme

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**Legend:**
- Orange: 2015
- Yellow: 2016
- Green: 2017
- Blue: 2018
- Light Blue: 2019
- Gray: 2020
- Dark Gray: 2021
Current case examples

Entry links for BfR‘s current opinions


and annual reports:

https://www.bfr.bund.de/en/publication/annual_reports-62595.html
Despite clear standards...

- Codex Alimentarius Commission (1999)
- IPCS (2009a)
- IPCS (2009b)

... each risk assessment is different and depends upon various factors and pre-conditions, like

- regulatory framework
- the data base
- the food or product affected
- especially vulnerable groups

Dealing with uncertainties:

- Conservative assumptions
- Concise and understandable communication of all assumptions made
- Demonstrate the effect of uncertainties
Maximum consumer protection without raising unnecessary public concern requires a combination of risk assessment, uncertainty analysis and risk communication.

…realised at the BfR by in close exchange with

- Research & data generation for risk assessment
- In-house risk communication expertise
- Cooperations (internal and external)
- Risk management (BVL)
Joint EFSA/BfR International Conference on Uncertainty in Risk Analysis (20-22 Feb 2019)

Measuring and Communicating the Unknown in the fields of

- food safety
- environmental health
- occupational health
- animal health
- plant health

https://www.bfr-akademie.de/english/events/uncertainty-conference.html
Thank you for your attention
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Food Monitoring in Germany

**Systematic Monitoring**
- ca. 20-40 foods per year from a pre-defined food basket
- Food basket
  - Derived from consumption surveys
  - Minimum of 90% of mean consumption
  - Each food item is analysed every 3 to 6 years
- Analysis of raw or processed foods (“as purchased”)

**Project Monitoring**
- Focus on specific questions
- Annual selection based on proposals of federal states, ministries, BVL* and BfR
- ca. 200 samples per project
- Possibility to analyse diverse substances, e.g. currently tropane alkaloids in baby food; antibiotics in veal meat.

* BVL: Federal Office of Consumer Protection and Food Safety

**Most important limitations:**
I. Mainly substances with maximum levels
II. Mainly foods with maximum levels
III. Mainly foods at raw agricultural commodity level
IV. LOD/LOQ as low as needed
V. Only partly representative