The Federal Institute for Risk Assessment and its risk-based approach

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Federal Institute for Risk Assessment (BfR)

- founded in November 2002
- within the portfolio of the Federal Ministry of Nutrition, Agriculture & Consumer Protection (BMELV)
- main tasks: risk assessment and risk communication
- independent in its scientific risk assessments
- independent in its research
- Independent in its risk communication
BfR Mandate: Scientific Risk Assessment

Main work areas

- Health assessment of **biological** and **material-chemical** safety of foods
- Health assessment of **safety** of **substances** (chemicals, pesticides, biocides) and selected products (consumer products e.g. textiles, food packaging, cosmetics and tobacco products)
- Risk assessment of **genetically modified organisms** in food, feed, plants and animals

**Risk communication**

- Development and validation of **alternatives** to **animal experiments**
- Development of methods and **validation activities** of **National Reference Laboratories** (NRL)
Science as a Basis for Decisions

Scientific Risk Assessments especially serve as scientific basis for:

- **Decisions** regarding the **authorisation** of products
- **Decisions** regarding **action** of those **authorities** that control food, chemical or product legislation,
- **Court decisions** regarding food, chemical or product safety
- **Actions** by the **national** or **EU legislative body** or other political authority
- **Different scientific views** on a point critical to the result are to be indicated **transparently**
- **Divergences** between different **national** authorities or **EU authorities**, are to be described precisely
Example for the national level - Germany

Typical structural elements:
- independent risk assessment
- independent regional level

Food Safety Authorities in Germany

Ministries and subordinate public authorities in the 16 federal states

Simplified depiction of the authority structure
Risk versus Hazard

**Hazard** means the potential of a substance or situation to cause an adverse health effect

**Risk** means the likelihood of an adverse effect in an organism, system or a (sub) population on exposure to hazardous substances
„Philosophy“ of Risk Assessment

- Identify potentially **hazardous** situations
- Estimate the **uncertainty** associated with the analysis
- Provide alternative options to **reduce** a possible risk
- Estimate the **adequateness** of those options

**Application of the precautionary principle:**
Even when scientific knowledge is incomplete, consumer protection measures are frequently admissible and sometimes have to be taken very quickly!
Risk Assessment

Problem Formulation

Exposure Assessment
- levels of substance in food and diet
- amounts of food consumed
- intake in individuals (max/min, regularly/occasionally)
- intake in special population groups

Risk Characterisation

Hazard Identification
- identification of adverse health effects (potential and nature)
  - human studies
  - animal-based toxicology studies
  - in vitro toxicology studies
  - structure-activity considerations

Hazard Characterisation
- kinetic and dynamic variability
- mode/mechanism of action
- dose-response for critical effect
- identification of starting point
- selection of critical data set, qualitative/quantitative
Consumer Protection Measures

The following consumer protection measures may be considered:

- Restrictions on distribution/sale or commercial use;
- Limit values / standards for tolerable exposure, e.g. maximum levels in foods when placed on the market;
- Labelling, warnings, recommendations and restrictions on use;
- Measures to avoid or reduce contamination with and multiplication of microbial agents, the reduction of such agents in the food chain by producers/manufacturers, retailers and consumers;
- Action against misleading advertising claims, and increased information and education of consumers
Communicating Risk and Hazard: BfR Risk Profile

<table>
<thead>
<tr>
<th>A</th>
<th><strong>Affected</strong> Persons</th>
<th>General Public (Example)</th>
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<tbody>
<tr>
<td>B</td>
<td><strong>Probability</strong> of impaired health</td>
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**BfR Risk Profile:** Example (Opinion No.)

- **A** Affected Persons: General Public (Example)
- **B** Probability of impaired health:
  - Practically impossible
  - Improbable
  - Possible
  - Probable
  - Certain
- **C** Severity of health impairment:
  - No impairment
  - Slight impairment
  - Moderate impairment
  - Severe impairment
- **D** Validity of available Data:
  - High: The most important data are available and there are no contradictions
  - Medium: Several important data are missing or contradictory
  - Low: Numerous important data are missing or contradictory
- **E** Controllability by the consumer:
  - Control not necessary
  - Controllable through precautionary measures
  - Controllable through avoidance
  - Not controllable

**Risk Profile (since 2013):** intended to visualise the risk described in BfR opinions
Ongoing Challenges – Dynamic Reality

• New technologies and new products (novel foods)
• New contaminants
• Product piracy and food fraud
• Packaging materials
• New substances, additives, technical aids (pesticides, veterinary drugs, flavour compounds etc.)
• Process contaminants (acrylamide, 3-MCPD, furan, glycidol fatty esters etc.)
• Higher standards in using alternative methods of animal experiments
Predictable Trends – Emerging Challenges

- Climatic change, global warming
- Increasing world population
- Globalization in production, trade and consumption
- New markets
- Demographic trend
- New energy policies
Risk Assessment: What is needed

- New analytical strategies are needed
- Global harmonization of standards, methods, and data interpretation
- Science-based approach
- Harmonization of risk assessment procedures (assessment criteria, uniform terminology)
- Joint risk assessment with acceptance in Europe and further countries
Consequences of Global Trends

• New strategies for agricultural production
• New technologies (nanotechnology, genetic engineering…)
• Traceability to fight fraud and product piracy
• Problems from recycling processes
• Increase of aquaculture production
• Active packaging
• Import controls
• Bioethanol production
• New feeding stuffs
Global Conclusions

• New analytical strategies

• Global harmonization of standards, methods, and data interpretation.

• Global quality assurance and traceability systems.

• Harmonization of risk assessment procedures

• Joint risk assessment with acceptation in Europe and further countries

• Transparent and target group oriented risk communication that integrates public‘s risk perception
Thank you for your attention

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