

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



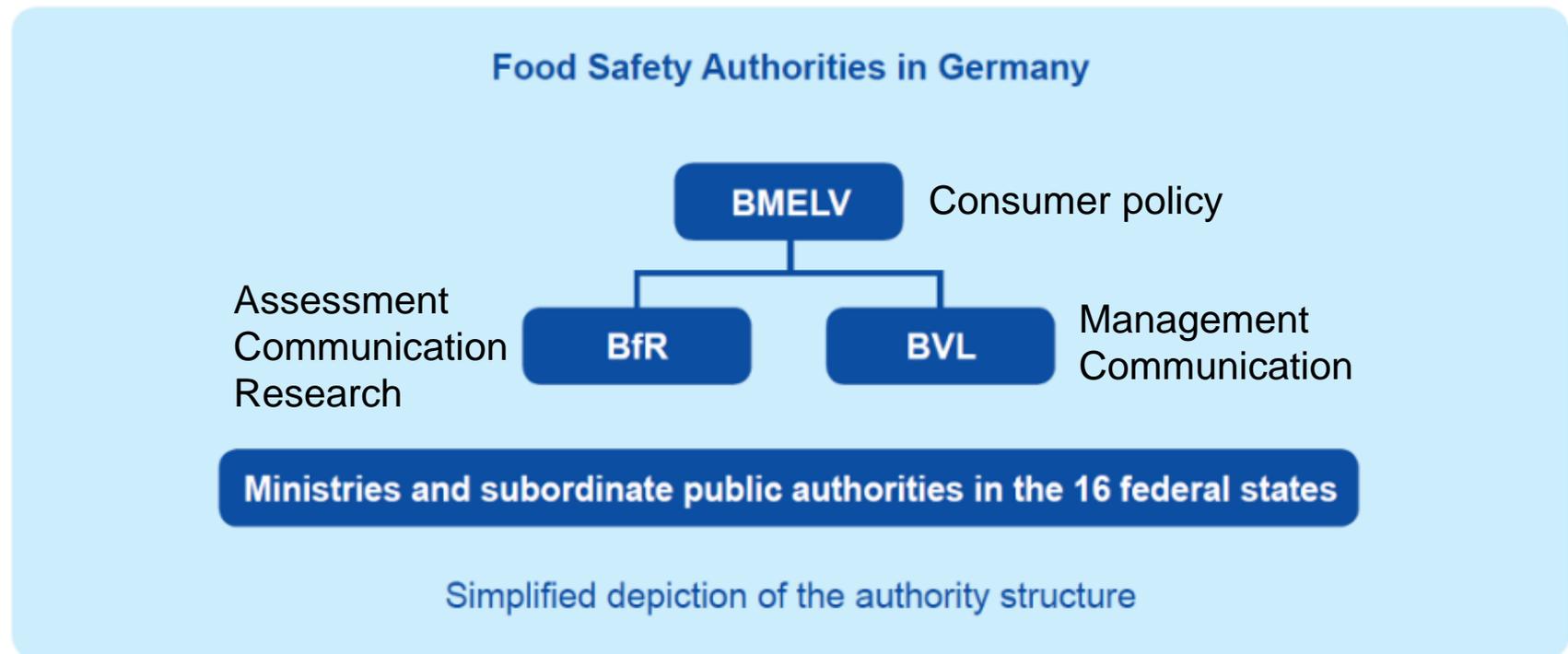
Scientific Risk Assessments especially serve as **scientific basis** for:

- **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



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

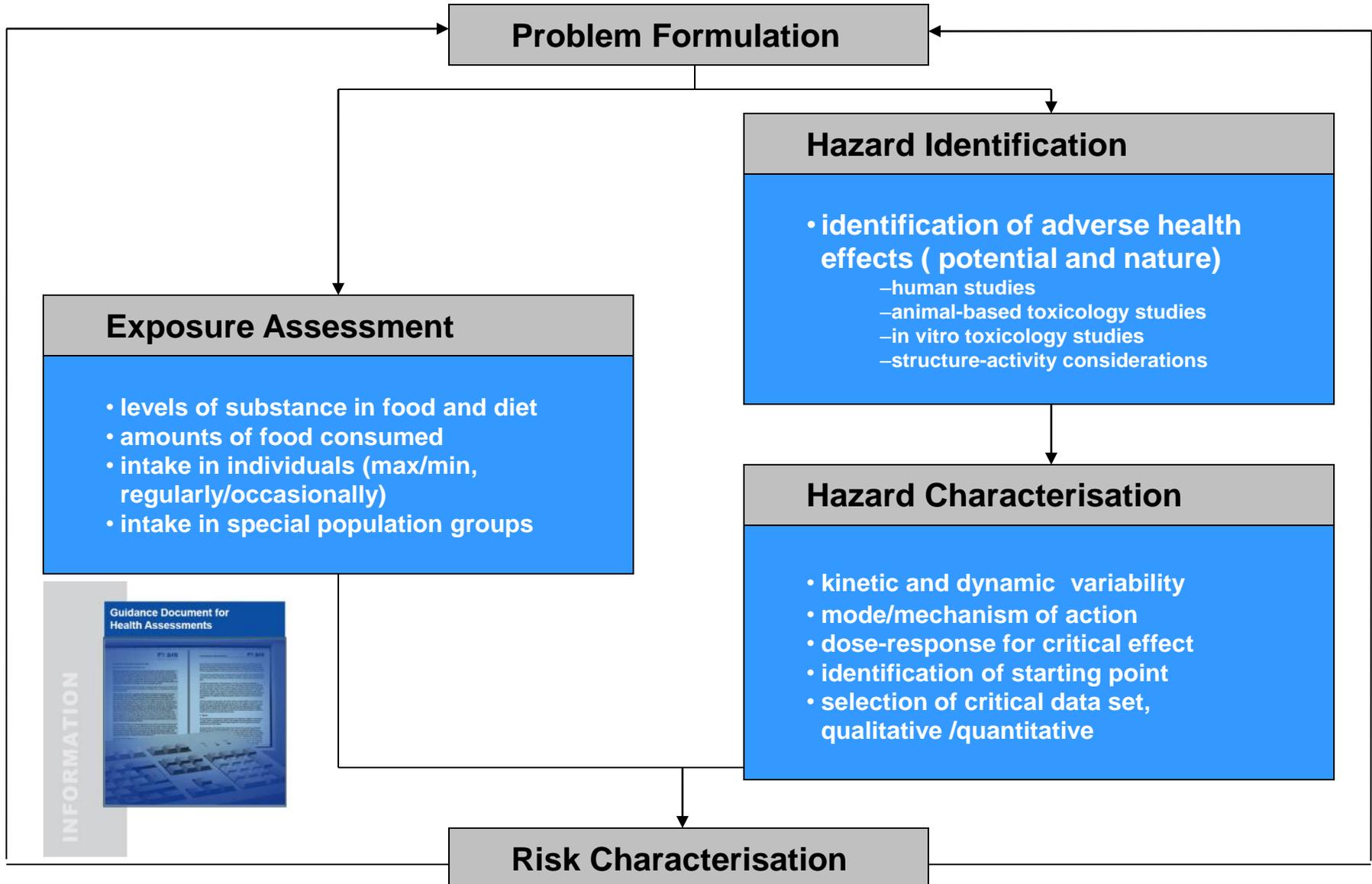
- Identify potentially **hazardous** situations
- Estimate the **uncertainty** associated with the analysis
- Provide alternative options to **reduce** a possible risk
- Estimate the **adequateness** of those options

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



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

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 acceptance in Europe and further countries
- Transparent and target group oriented risk communication that integrates public's risk perception



Bundesinstitut für Risikobewertung

**Thank you for your
attention**

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