

***Risk Assessment in Food and Feed Safety:
nice to have or need to have? –
The Role of the European Union Member States***

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- Who is regulating it?
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 - Europe - EU
 - EU Member States
 - Germany

Part 3

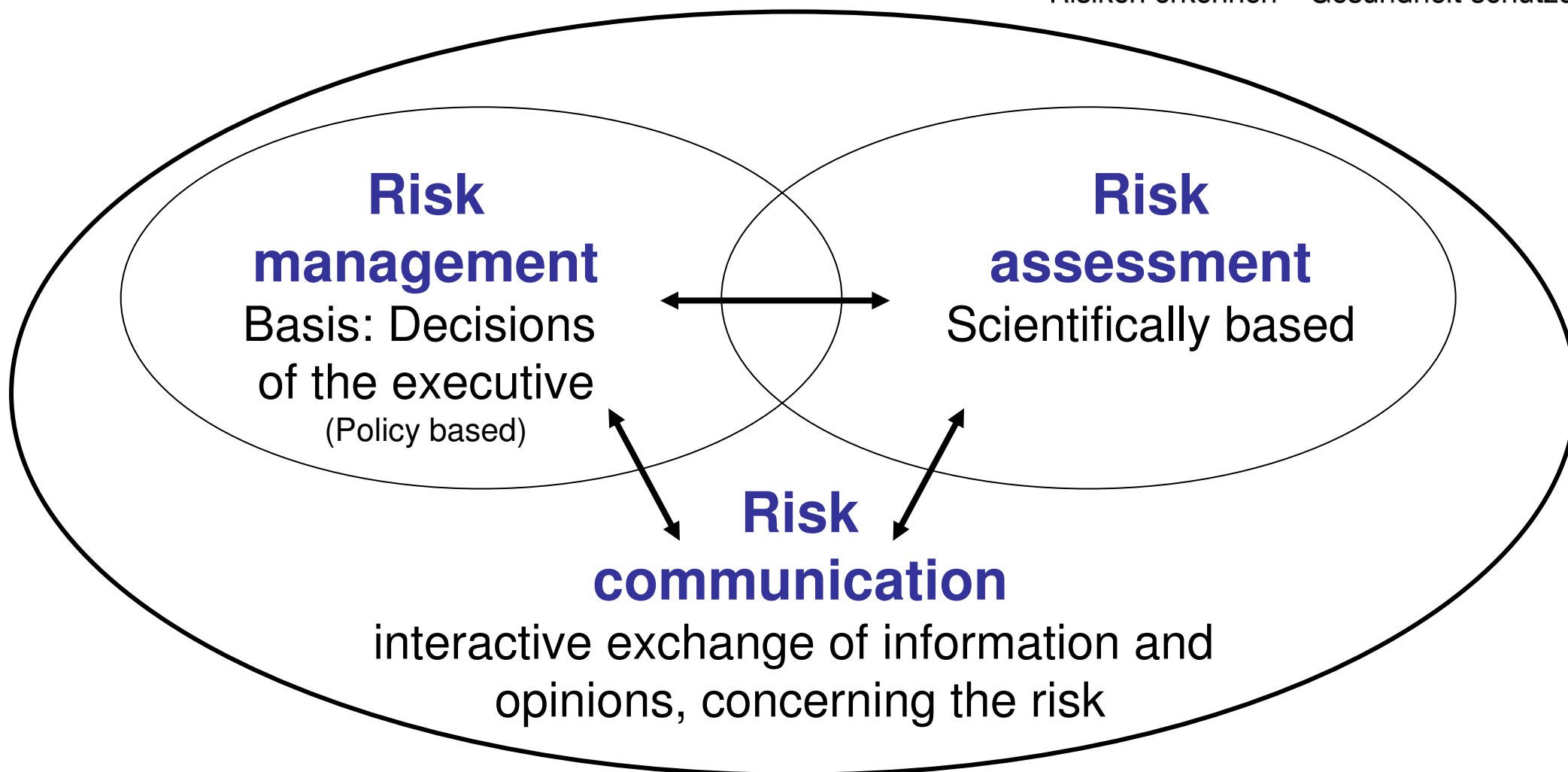
- International cooperation
- Support to candidate, potential candidate and third countries

What is Risk assessment?

Definitions in REGULATION (EC) No 178/2002, Article 3 - Other definitions

9. **‘risk’** means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard;
10. **‘risk analysis’** means a process consisting of three interconnected components: **risk assessment, risk management and risk communication**;
11. **‘risk assessment’ means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation**;
12. **‘risk management’** means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options;
13. **‘risk communication’** means the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions;

Risk analysis framework



Who is regulating it?

GLOBAL WORLD TRADE
ORGANIZATION



The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (“**SPS Agreement**”), Article 5: Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

1. Members shall ensure that their sanitary or phytosanitary **measures** are **based on** an **assessment**, as appropriate to the circumstances, **of the risks to human, animal or plant life or health**, taking into account **risk assessment** techniques developed by the relevant international organizations.

Signed by all member states

International WTO reference organizations are:



CODEX (Joint FAO/WHO Food Standards Program)

IPPC



International Plant Protection Convention
Protecting the world's plant resources from pests



OIE (World Organization for Animal Health setting standards relating to animal health and zoonoses)

Who is regulating it?



European Commission
Application of EU law



REGULATION (EC) No 178/2002, Article 6 - Risk analysis

1. In order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.
2. **Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.**
3. Risk management shall take into account the results of risk assessment, and in particular, the opinions of the Authority referred to in Article 22, other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 7 (1) are relevant, in order to achieve the general objectives of food law established in Article 5.

An EU regulation is similar to a national law with the difference that it is applicable in all EU countries.

What for it is regulated?

(Health) Risk Assessment

Food chain

Commodities

Environment

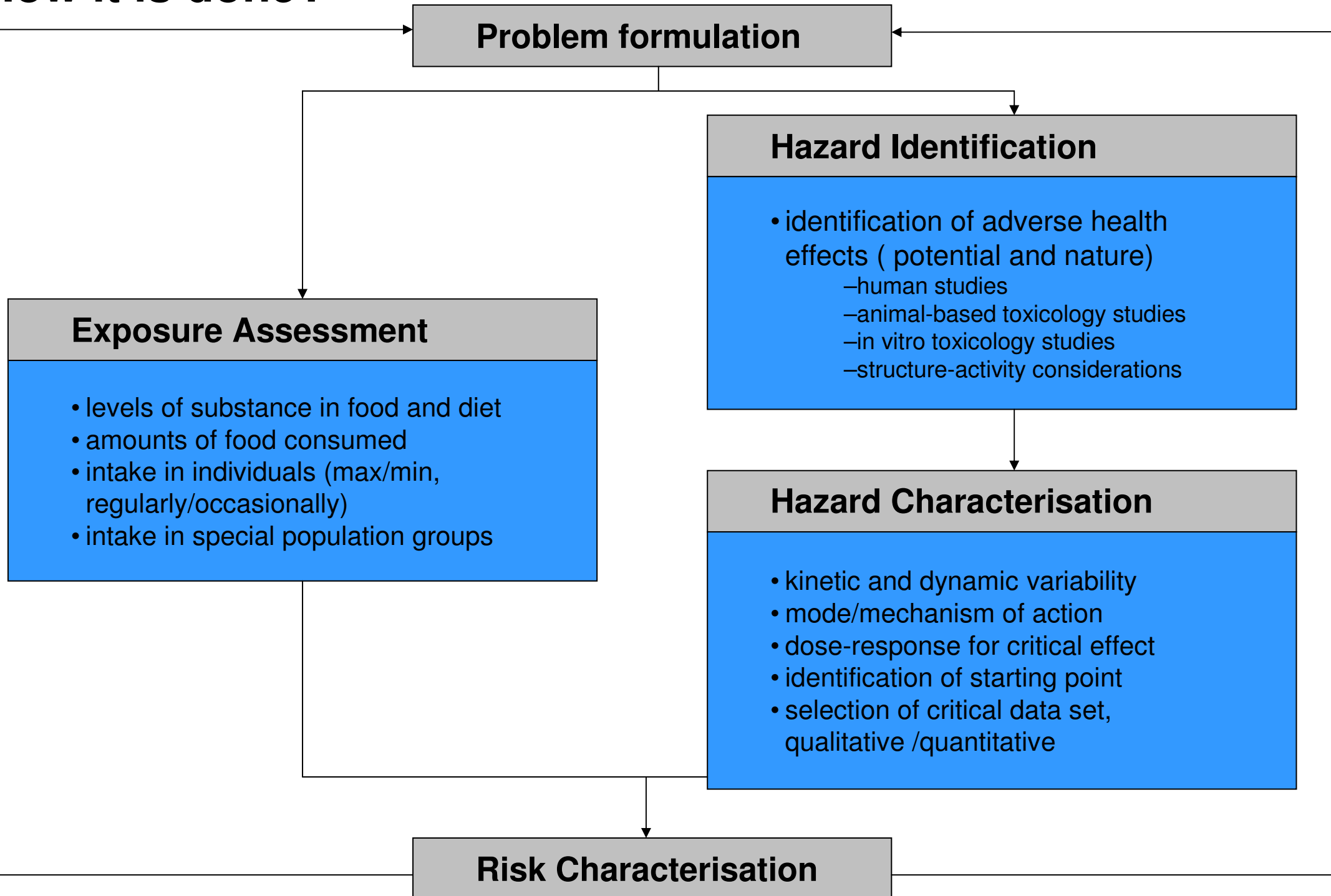
Authorization of

- Chemicals
- Pesticides
- Veterinary medicine
- Human medicine



With similar scientific techniques and special expertise

How it is done?



Nice to have or need to have?

Risk Assessment



Hazard Identification
Hazard Characterization



Nice to have

If values are established once,
they have general validity for all countries



Exposure Assessment
Risk Characterization



Need to have,

As values can vary from country to country

Minimum requirements to transform existing risk assessments for the specific needs of one country:

Specialists in Pharmacology/Toxicology/Pathology, Epidemiology, Biostatistics, Exposure Assessment, Scientific Data Bases, Bacteriology, Virology, Molecular Biology/Gene Technology and Antimicrobial Resistance

Who is doing what?



GLOBAL

Food Safety Risk Assessment - International Scientific Panels - Joint FAO/WHO Expert Committees

- Food Additives and Contaminants (JECFA)
- Pesticide Residues (JMPR)
- Ad hoc expert consultations on specific issues
- Microbiological contamination of foods (JEMRA)
- GM Food Risk Assessment

Who is doing what?

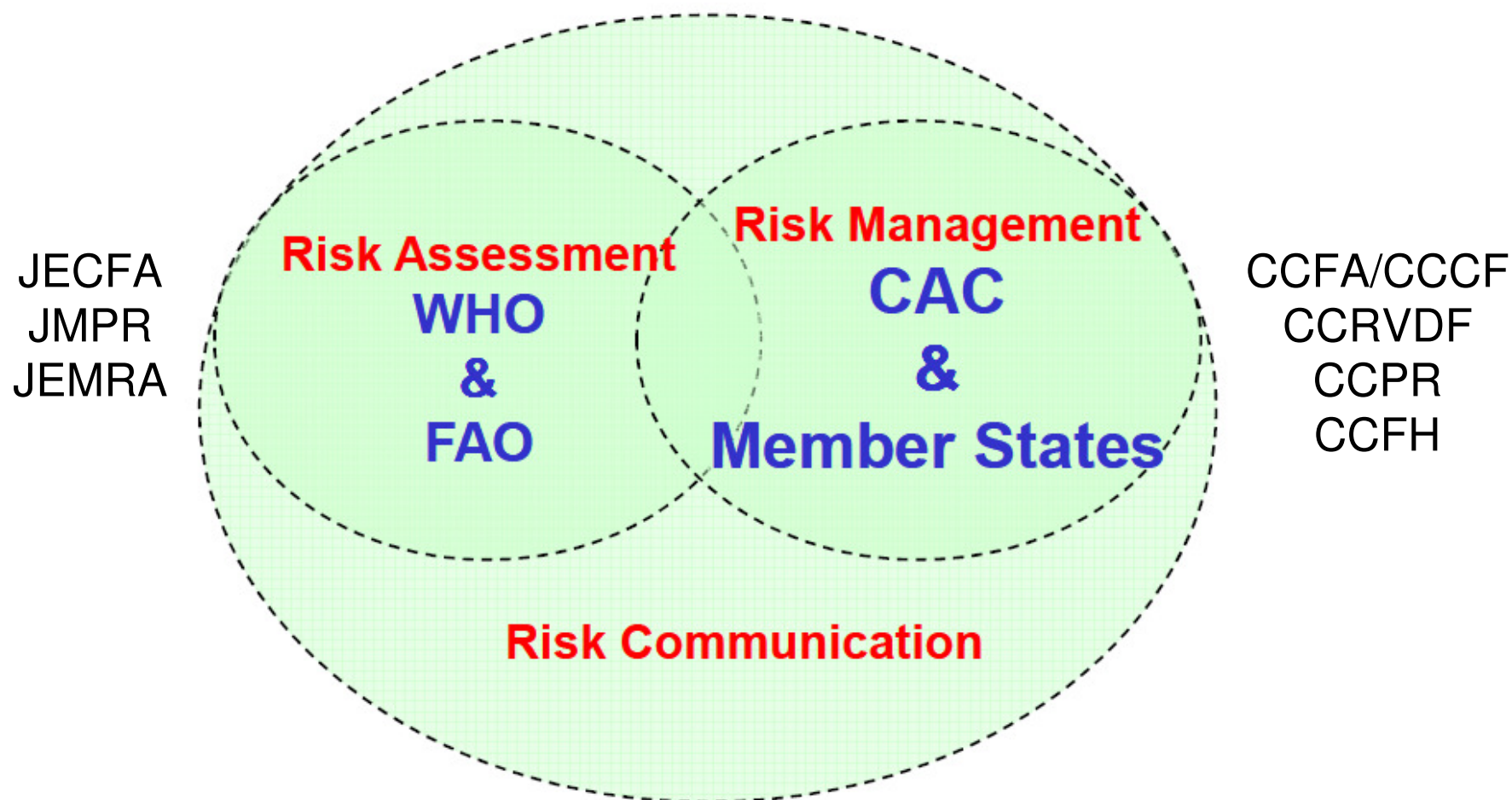
GLOBAL



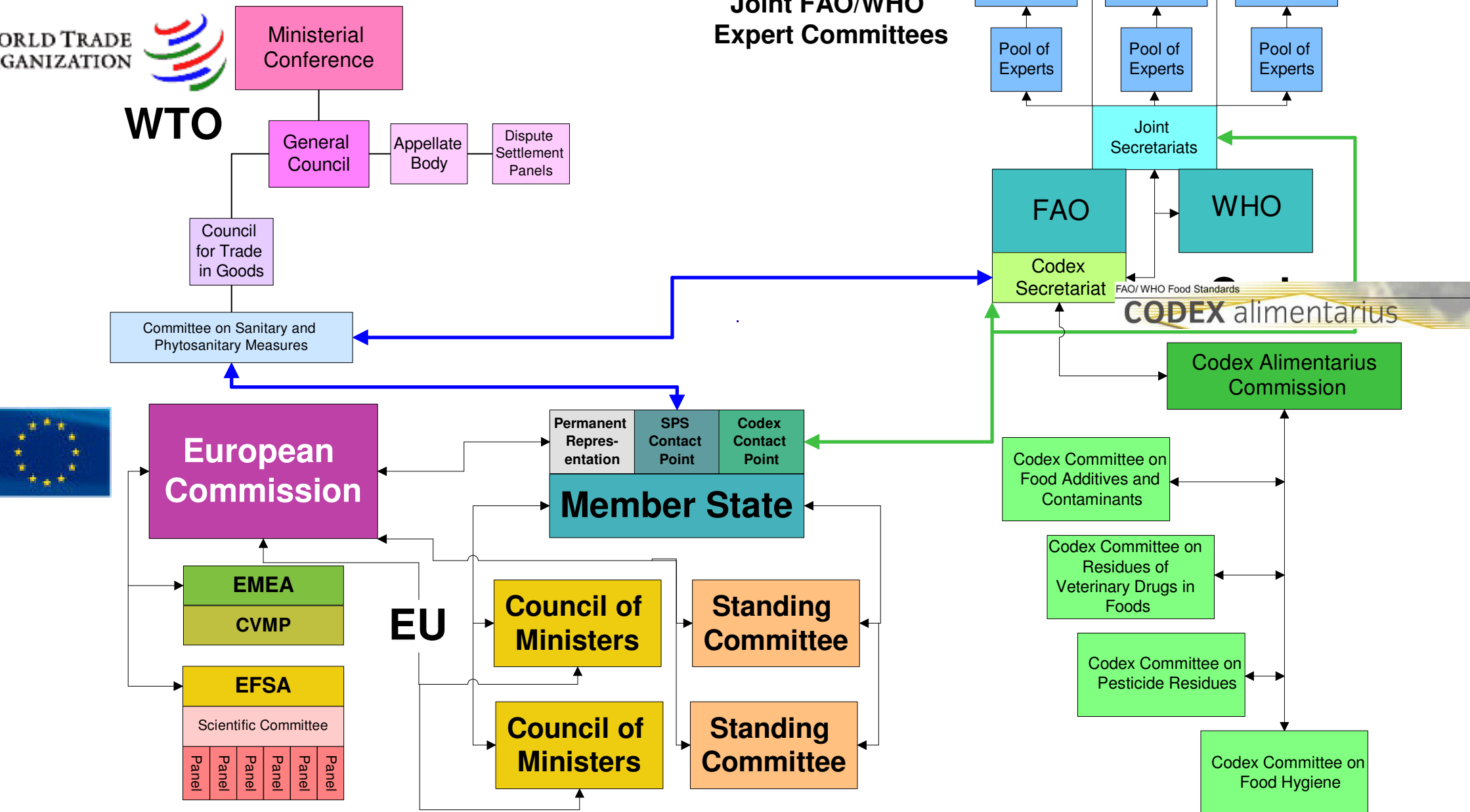
Food and Agriculture Organization
of the United Nations



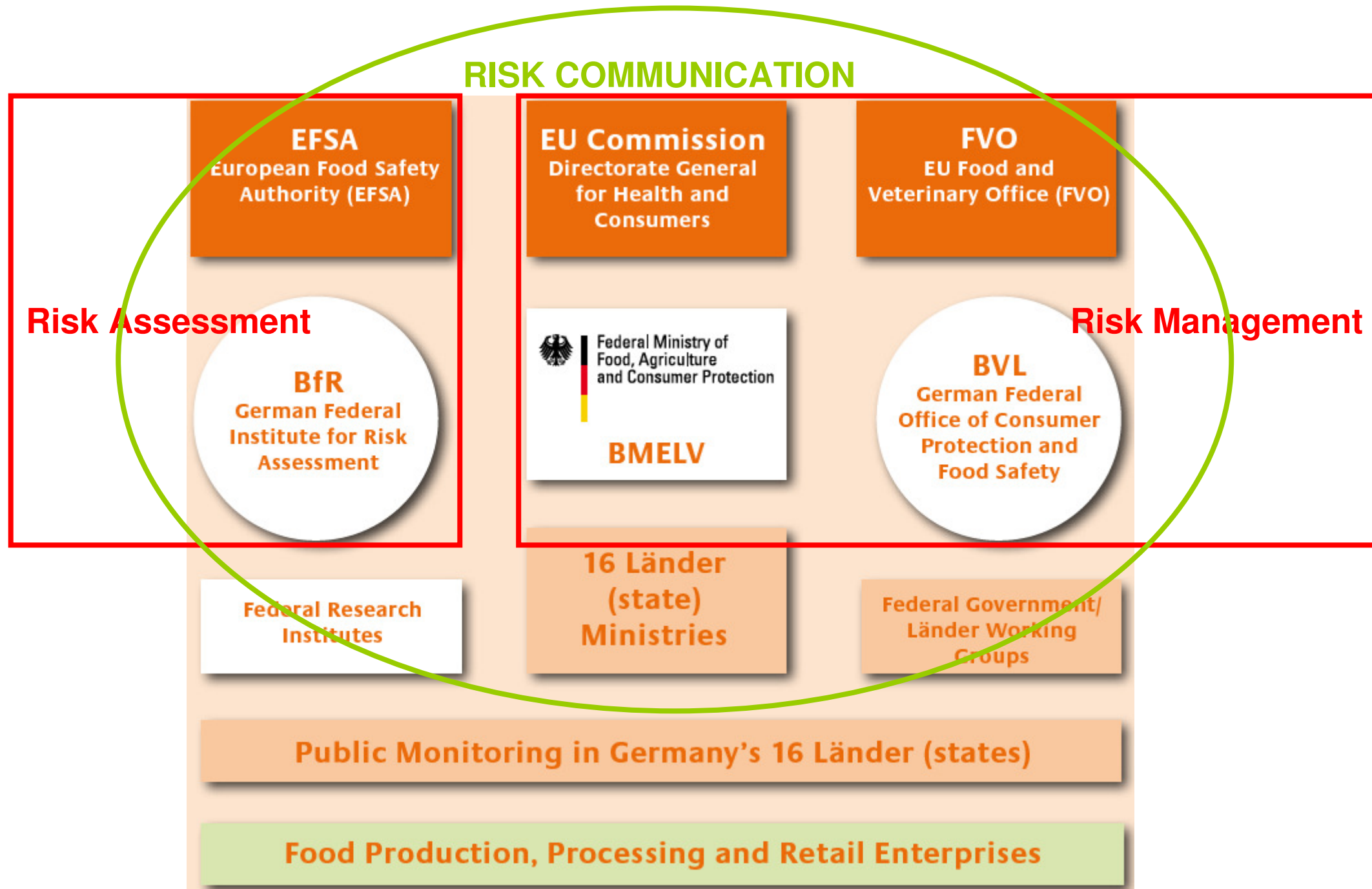
World Health
Organization



Who is doing what?



Europe and the German food safety network



Who is doing what?



in EUROPE

EFSA's Scientific Panels at Risk Assessment Directorate

AHAW	Animal health and welfare
ANS	Food additives and nutrient sources added to food
BIOHAZ	Biological hazards
CEF	Food contact materials, enzymes, flavourings and processing aids
CONTAM	Contaminants in the food chain
FEEDAP	Additives and products or substances used in animal feed
GMO	Genetically Modified Organisms
NDA	Dietetic products, nutrition and allergies
PLH	Plant health
PPR	Plant protection products and their residues
SC	Scientific Committee
AFC	Former Panel on additives, flavorings, processing aids and materials in contact with food

Who is doing what?

30 (different) legal structures in the EU Member States:

EU Food Safety Almanac (2009)

Overview of **public authorities & structures** of
food and feed safety in the
European Union and its
Member States

Overview from the **angle of public law**

Priority area: **risk assessment**

to achieve:

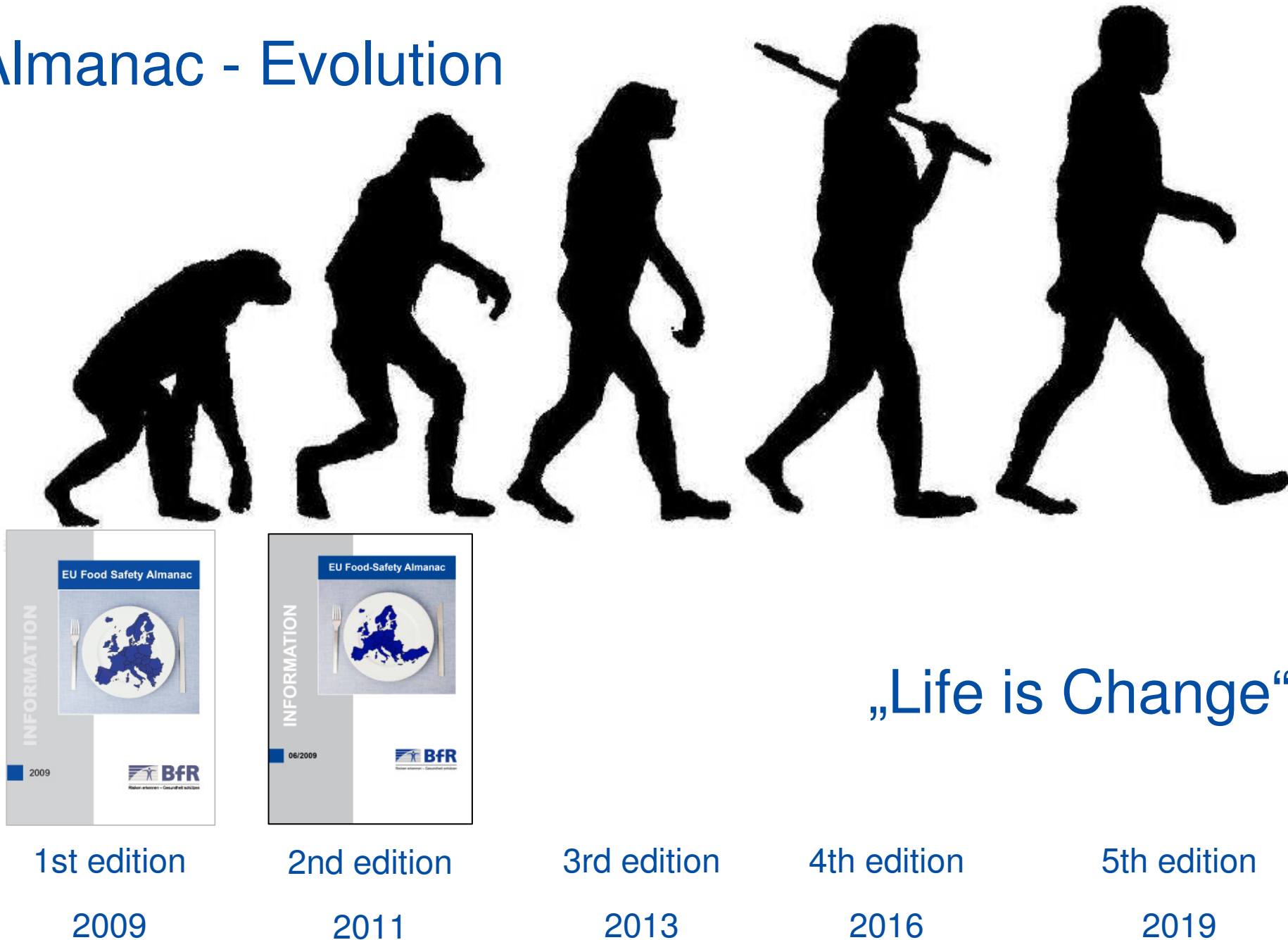
- **Transparency of organizational structures in Member States**
- **Facilitate and enable contact and collaboration**



www.bfr.bund.de

Who is doing what?

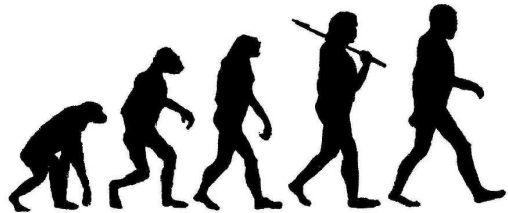
Almanac - Evolution



„Life is Change“

Who is doing what?

Changes in 2nd edition



– Turkey and Cyprus are on the plate



- 3 additional countries (now: “27 + 6”)
 - Croatia
 - Former Yugoslav Republic of Macedonia
 - Turkey
- Updates from all countries are included
- Text editing: clear language & clear message
- Additional icon: contaminants
- Glossary



Separation of risk assessment and risk management – a German model as best practice?

Example: Dioxin



**BERLINER
KURIER**

**AGRARMINISTER
FORDERT**
Knast für die Dioxin-
Panscher!

Berliner Zeitung

Die stille Gefahr
LEBENSMITTEL - DER SKANDAL UM
DIOXINBELASTETES TIERFUTTER
SCHLÄGT HOHE WELLEN.

Frankfurter Allgemeine
FAZ.NET

Landwirtschaft - der Dioxin-Skandal
Gift im Fleisch,
Streit in der Politik



Dioxin-Gipfel
So soll unser Essen
giftfrei werden

Bild.de



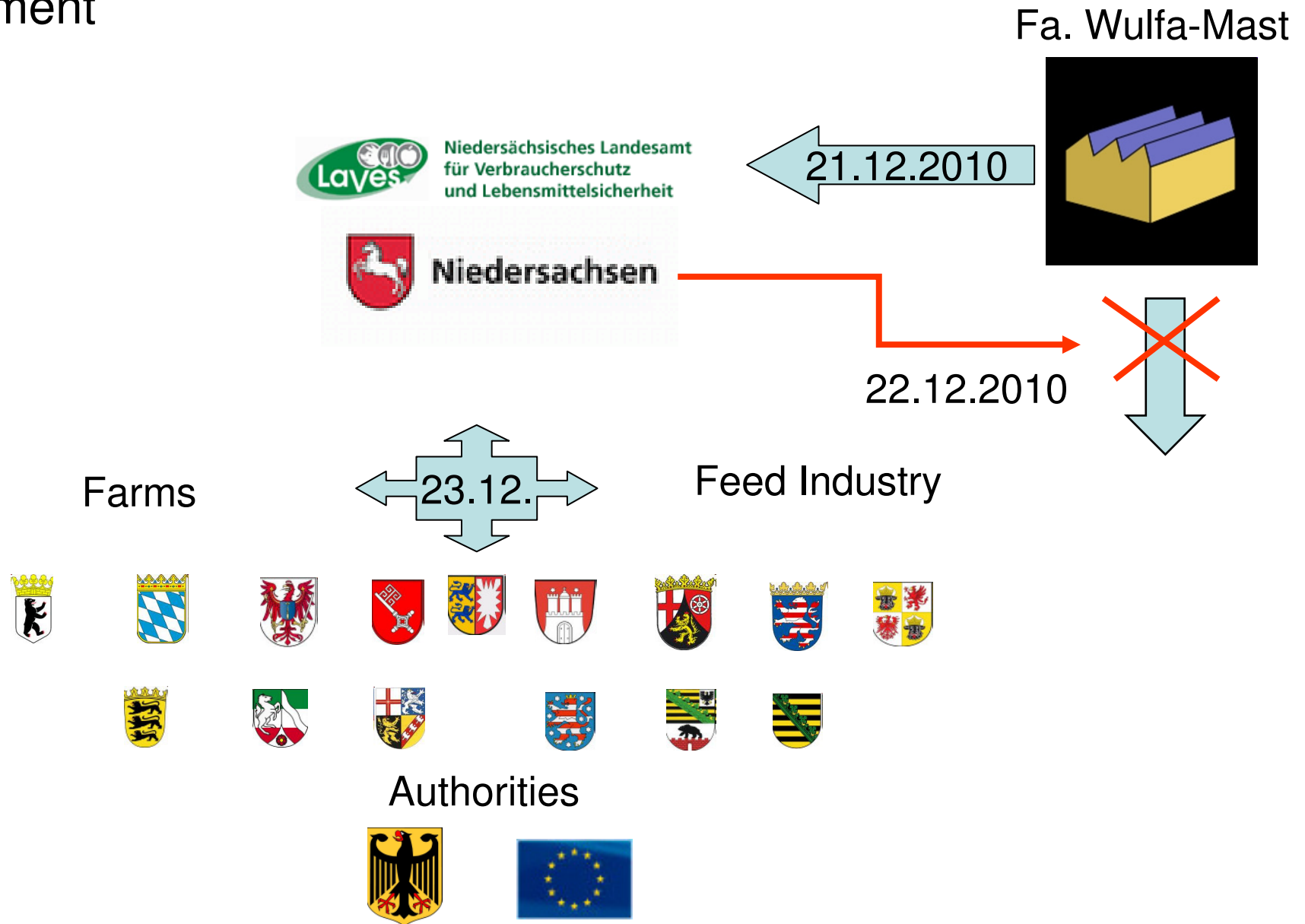
DIE ZEIT

Lebensmittel
Mehr als 1000 Bauernhöfe
wegen Dioxin-Funden
gesperrt



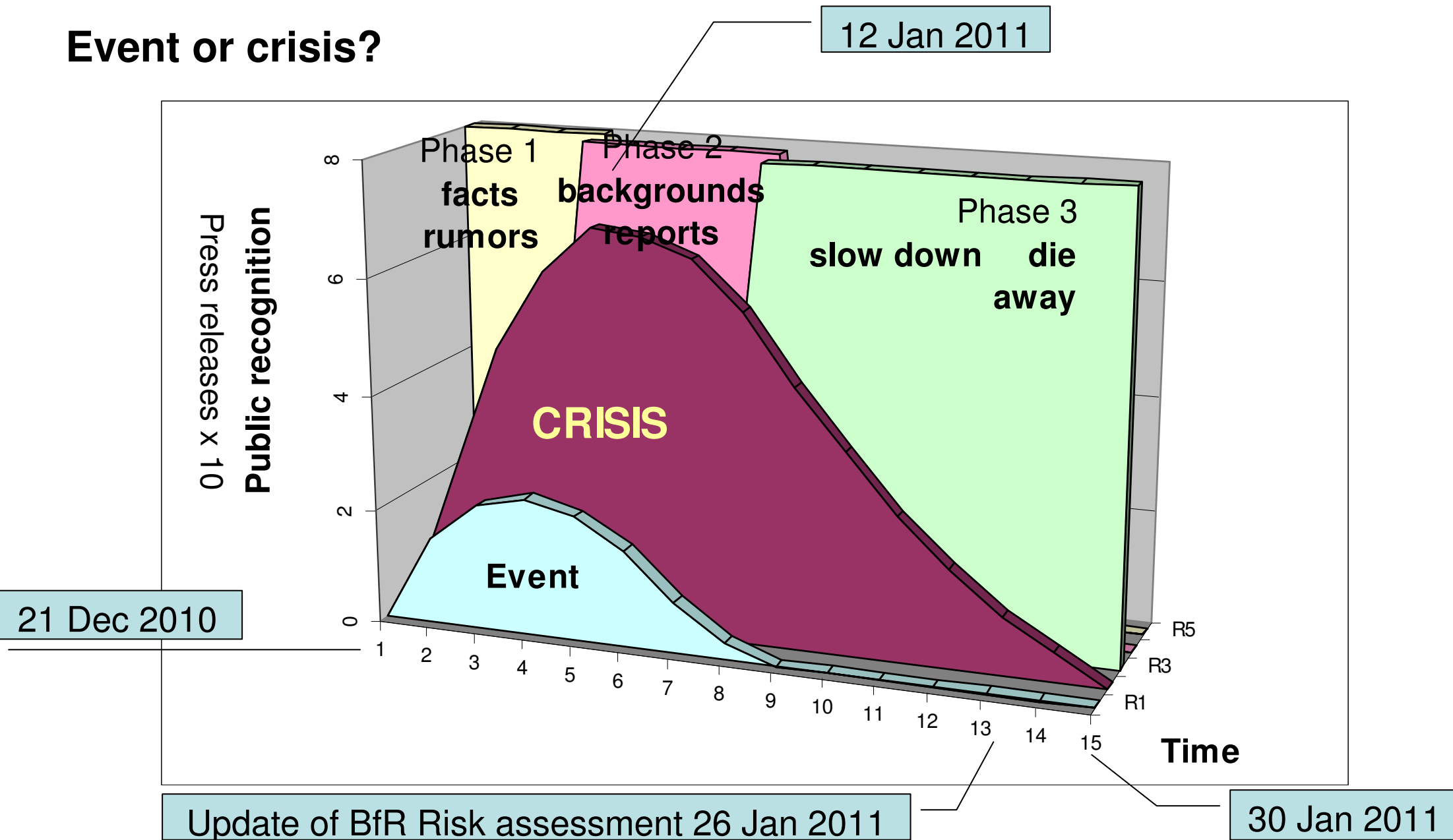
Example: Dioxin

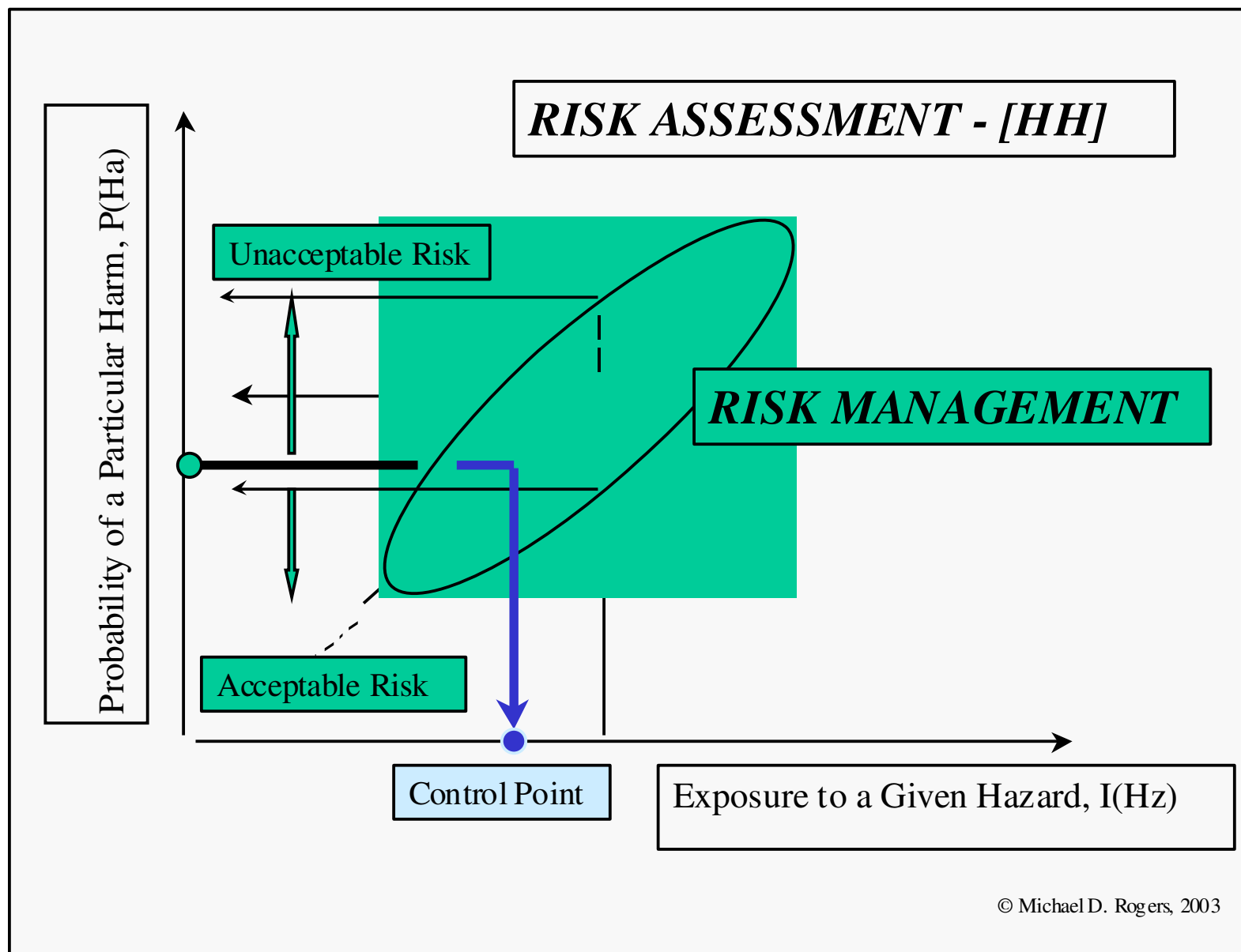
Risk Management



Example: Dioxin

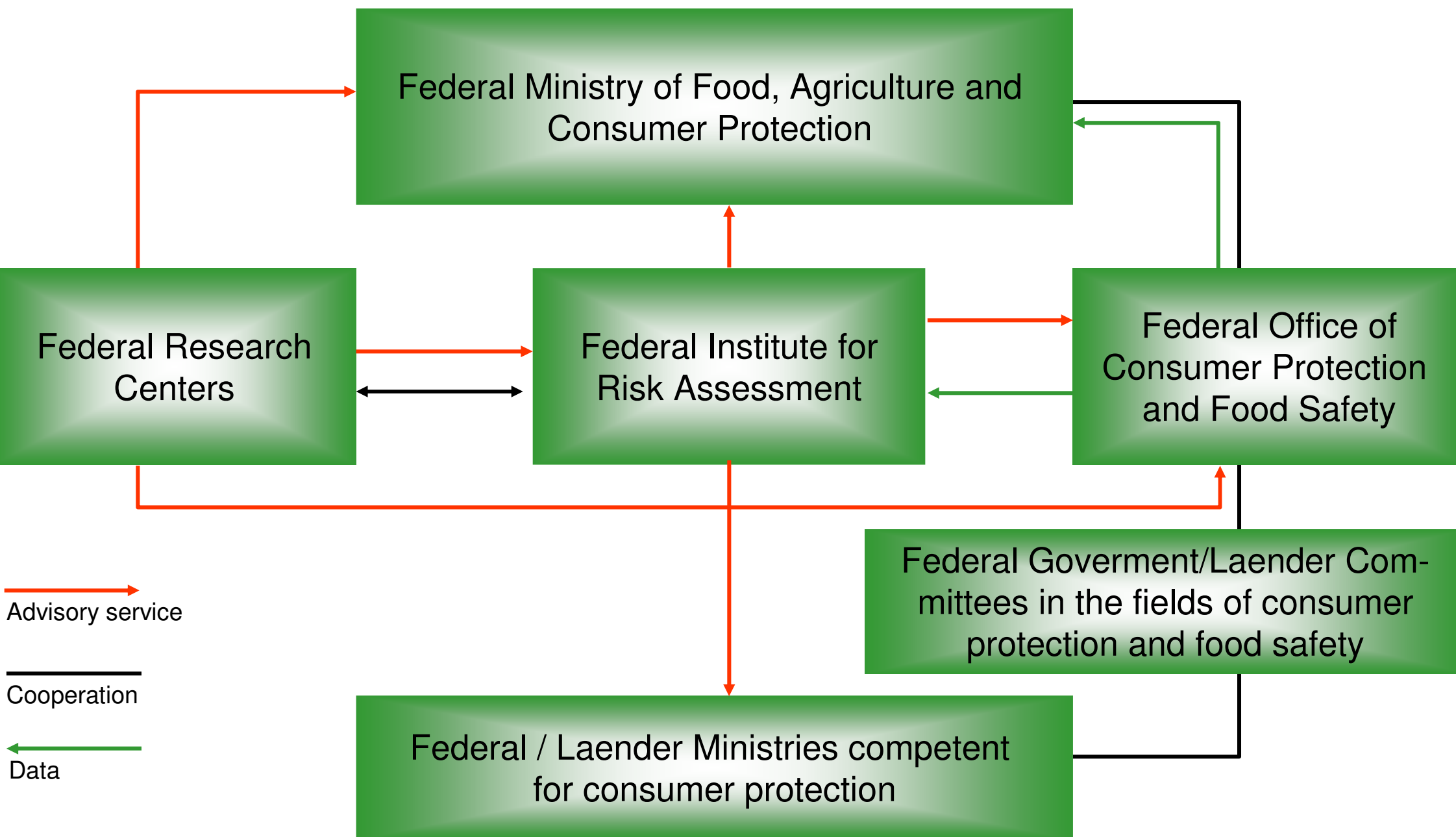
Event or crisis?





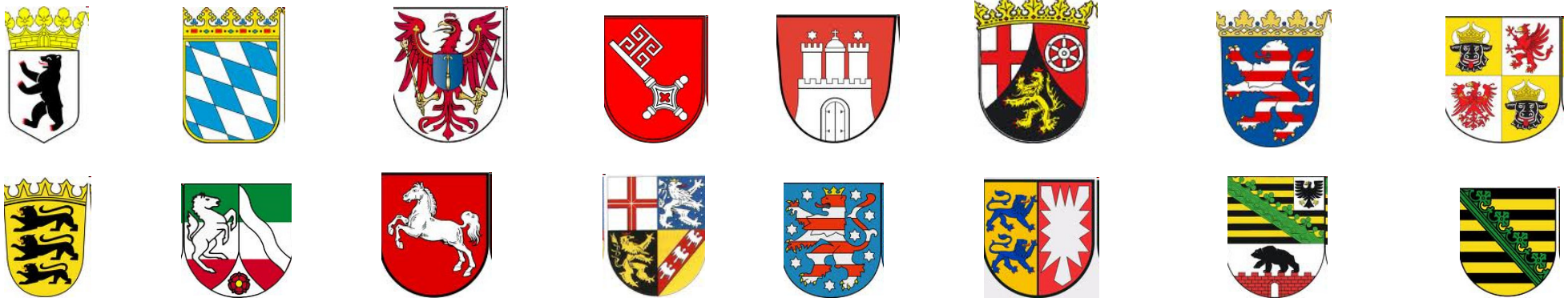
Who is doing what?

Structure of Consumer Health Protection in Germany
independent risk assessment; independent regional level



Burden sharing in Germany

➤ The daily task of inspection / monitoring / surveillance is within the responsibility of the 16 federal states (regional and local level). Their ministries and subordinate authorities act on their own responsibility.



➤ The 16 federal states coordinate their work in working groups and invite the national authorities to contribute and cooperate. Risk assessment and risk management are not divided as on the national level.

➤ The national level is being involved in matters including risk assessments of principal impact.

Concepts of food safety

From static legal concepts...

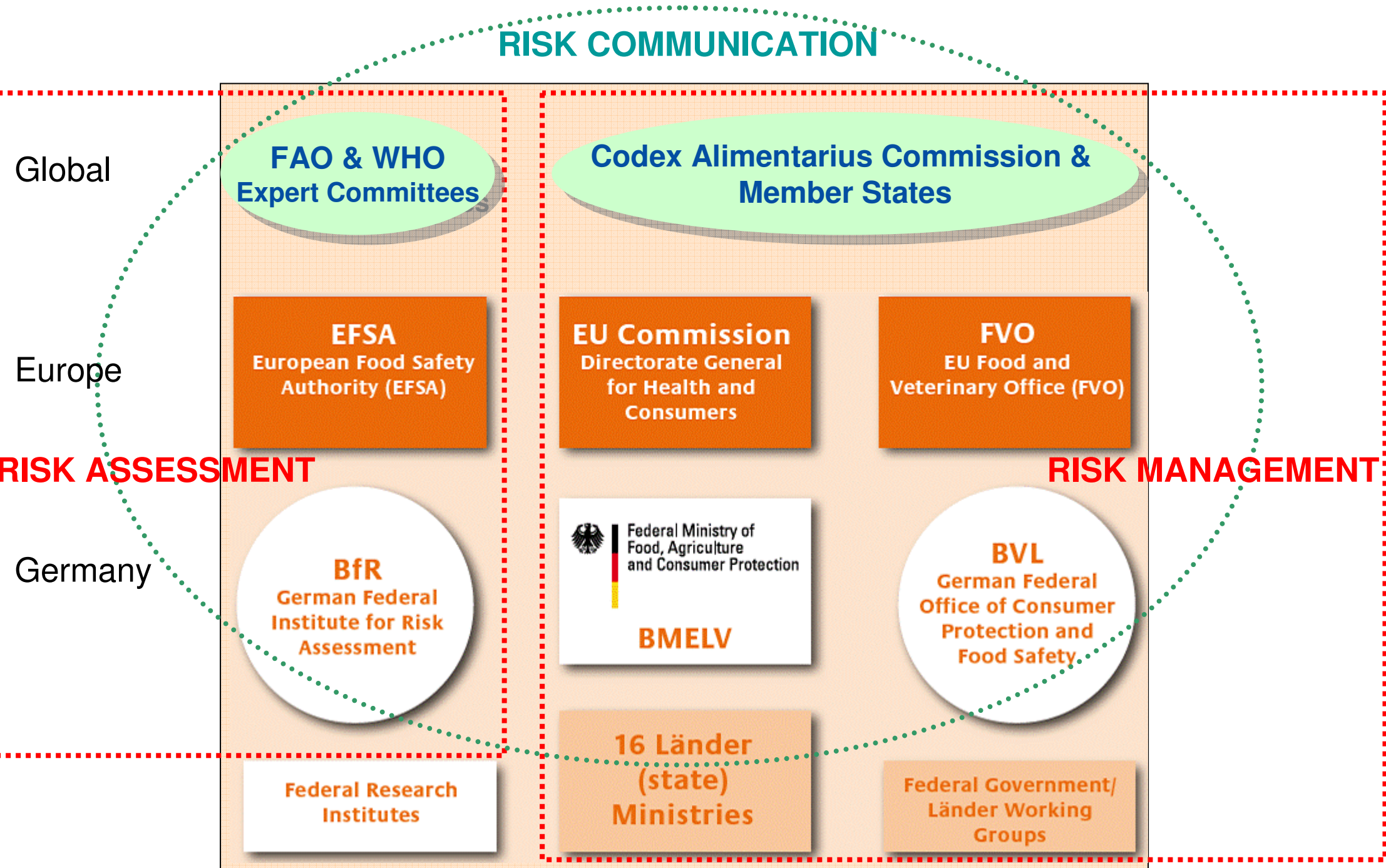
- Building and business requirements e.g. for food facilities
- Final product controls through random sampling
- Systematic border controls of all foreign imports

... to more dynamic legal concepts.

- Priority of process controls over final product controls
- Incorporation of primary production (“from farm to fork”)
- Control of in-house monitoring by official control authorities

Basis of risk management:
risk assessment and risk communication !

Germany within the Global food safety network



Federal Institute for Risk Assessment (BfR)



Risiken erkennen – Gesundheit schützen

Established

- on 1 November 2002
- as a body under public law
- in the area of responsibility of the Federal Ministry of Food, Agriculture and Consumer Protection

independent

- in its scientific assessments and
- in its research

Human resources Headcount: 740

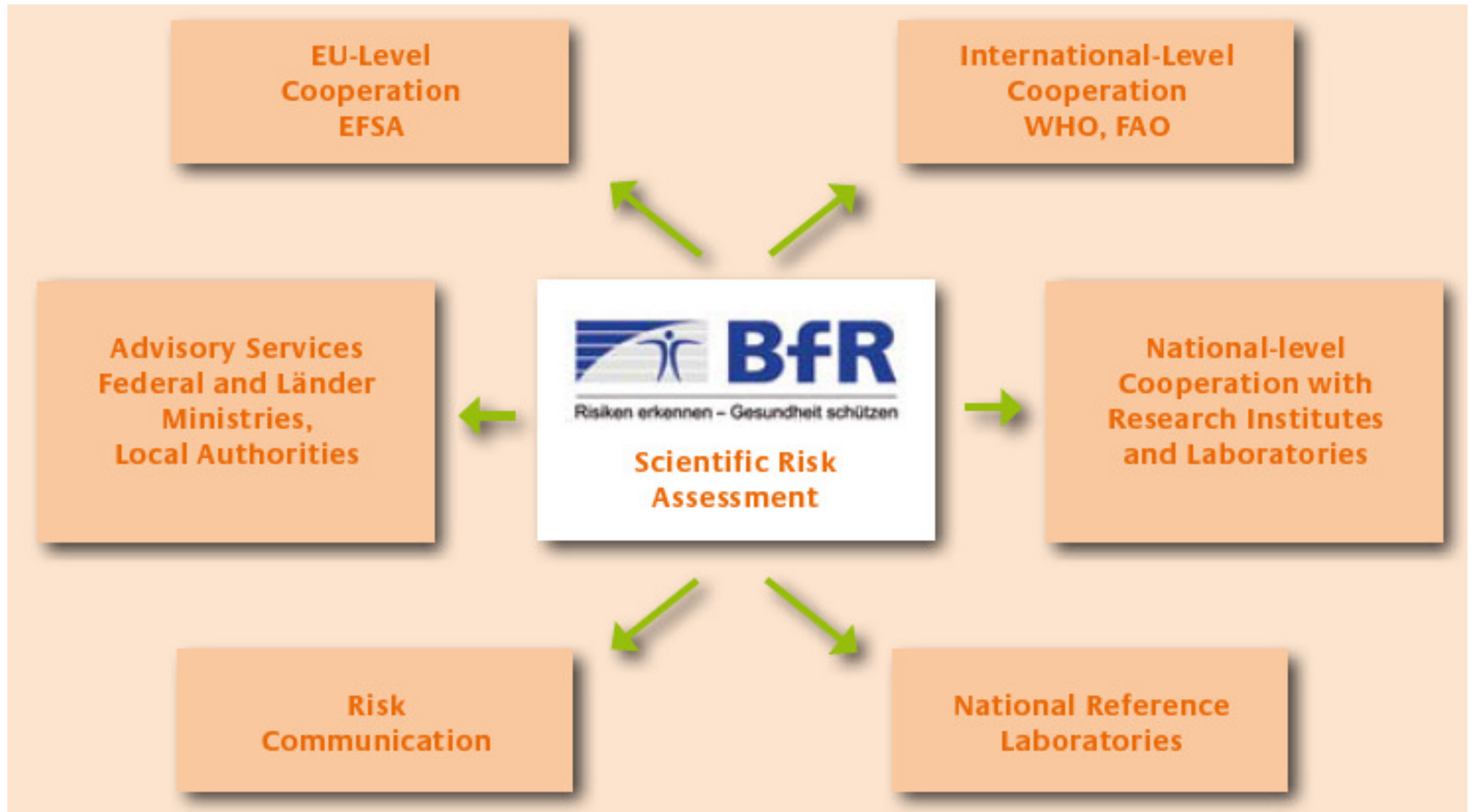
- Scientists: 281
- Trainees: 36

Budget

For its statutory tasks in 2009, BfR had a budget of € 53.13 million including third-party funding of € 2.62 million

Food Safety Strategies in Germany

BfR mandate



Concept of BfR

Separation of risk assessment + risk communication from risk management

Objective: qualified scientific assessment, free from (even authorised) influence from political, business and social circles

Expected results

- clear responsibility regarding decisions and conflicts
- control of "dissonance" between interdisciplinary expert systems
- orientation information from a neutral party and structured procedures

2 350 expert opinions in 2009

The Expert Opinions include:

• Assessments in marketing authorization procedures for pesticides	765
• Expert opinions for supervising federal ministries	330
• Assessments pursuant to biocides legislation	170
• Assessments of intoxication cases pursuant to Chemicals Act	140
• Opinions on chemicals pursuant to chemicals legislation (REACH)	80
• Assessments of chemical substances / international procedures	80
• Opinions in procedures under feedstuff law	45

Expectations of BfR

Place to go when there is cause for concern

- Screening body for risks and early detection
- Harmonisation and coordination of risk assessment
- Forum for risk research
- Forum for risk communication
- Efficient application processing in consumer protection administrative procedures

Professional risk assessment – a rational factor in consumer safety

- Less subjectivity - more objectivity
- Less undercover influence of stakeholders, more transparency
- Less prejudices, scientific and other,
- **Better reasons and arguments**
 - for interpreting existing law, e.g. Art. 14 Reg 178/2002.
target groups: authorities, food businesses, law courts
 - for changing / not changing existing law.
target groups: politicians, associations, parliament

Conflict of interests in consumer safety

- Producer interests
- Competitor interests
- Consumer interests
- Dramatization interests
- Media interests
- Research interests
- Interests of other scientific disciplines
- Personal interests

Communication about products

Companies:

- Sale of safe (unsafe?) products
- Admissible (misleading?) advertising
- Warnings

Public authorities:

- Approvals, sales constraints
- Information, official recommendations
- Warnings

Health risks and risks of deception

**... and in the case of
divergence and crises:**



Food / feed scandals

- a consequence of poor risk assessment and communication -

Overreacting authorities

⇒ damage for industry,
commerce and competitors

⇒ example: Birkel-noodle scandal

soothing/hesitating authorities

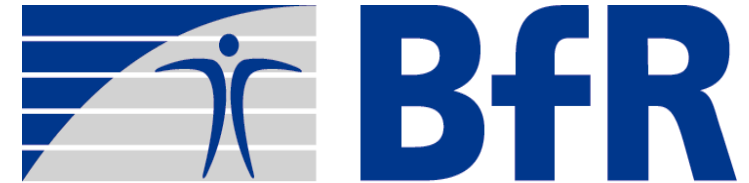
⇒ damage and deception for
consumers;
„Angst“ in the population

⇒ example: BSE-crisis

Resulting in = political and financial consequences, loss of confidence...

Structure of scientific opinions / BfR

1. Title
2. Subject of the assessment
3. Result
4. Reasons



Risiken erkennen – Gesundheit schützen

- ***Risk assessment***

- Possible risk source*

- Hazard potential*

- Exposure*

- Risk characterisation*

- Discussion*

- ***Scope for action, management options***

5. References

A guidance document of the BfR for risk assessment opinions



Official communication and food crises

- Ordered recall (in case the manufacturer has not done so)
- Public warning (in case the manufacturer has not done so)
- Warning to inform other public authorities (RASFF)
- Press: right to information
- Citizens: freedom of information
- Courts: compensation for damages, penal procedures

Quality parameters of risk communication

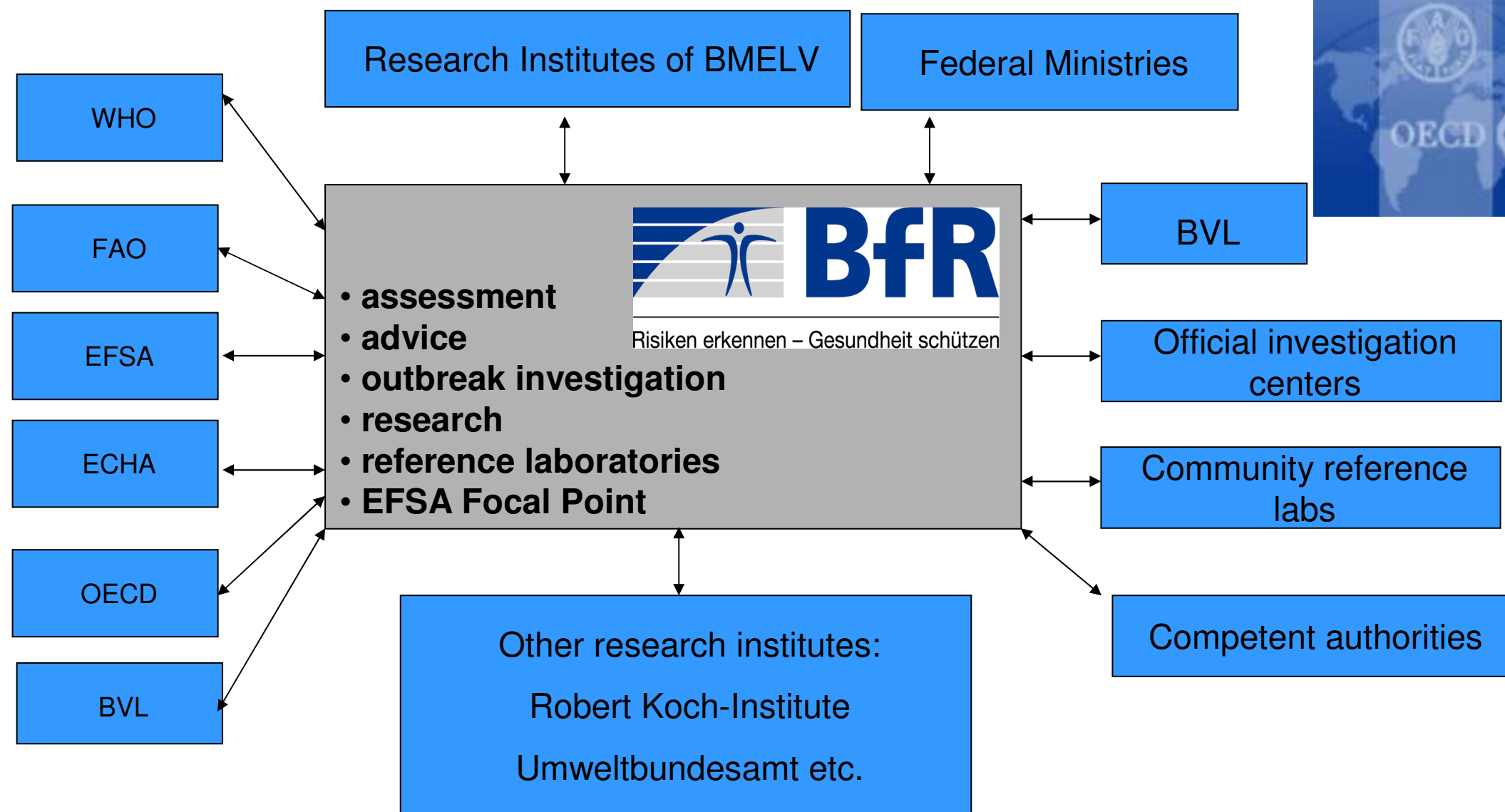
- > focus: autonomy and health of consumers
- > levels of responsibility:
 1. the industry / food / feed businesses
 2. the consumers
 3. the authorities
- > fairness and transparency of the process
(for consumers, industry, sciences, law courts, politics)
- > trustworthiness of the message
(for consumers, industry, sciences, law courts, politics)

Conclusion: what knowledge is necessary?

- Institutional structure - who is responsible for what?
- Legal provisions of consumer safety - what is prescribed by law?
- Relevant operation procedures
 - how to get quickly to the best results -
- Reproduction of the relevant „state of sciences“
 - fair conclusion of scientific knowledge -
- Routine in interdisciplinary cooperation
 - observance of different ways of thinking and talking –

and finally : excellence in science!!!

Cooperation and support



Cooperation and support

National

Federal Panels	41
Bund-Laender-Panels	29
Panel of BVL	20
Panel of other facilities	67

European level

European commission	45
EFSA	34
Other European organizations	13

World wide

Codex Alimentarius (WHO/FAO)	12
Other Panels (WHO/FAO)	5
OECD-Panels	16
Other world wide panels	17

Panels – Total	299 (2008)
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International Projects – Support sources



International trade in food

The SPS Agreement (WTO) contains provisions on **technical assistance** and special and differential treatment to help **developing and least-developed countries** implement and take advantage of the Agreement.



UNDP (United Nations Development Programme)



OECD (Organization for Economic Co-operation and Development) + World Bank



US Aid (United States Agency for International Development)



Europe Aid

Cooperation and support - Europe

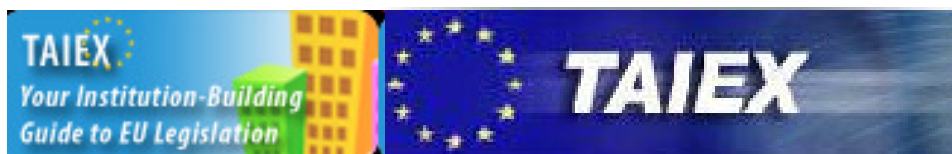


Main Instruments

pre-accession

Instrument for pre-accession assistance (IPA)

European Neighborhood and Partnership Instrument (ENPI)



pre-accession

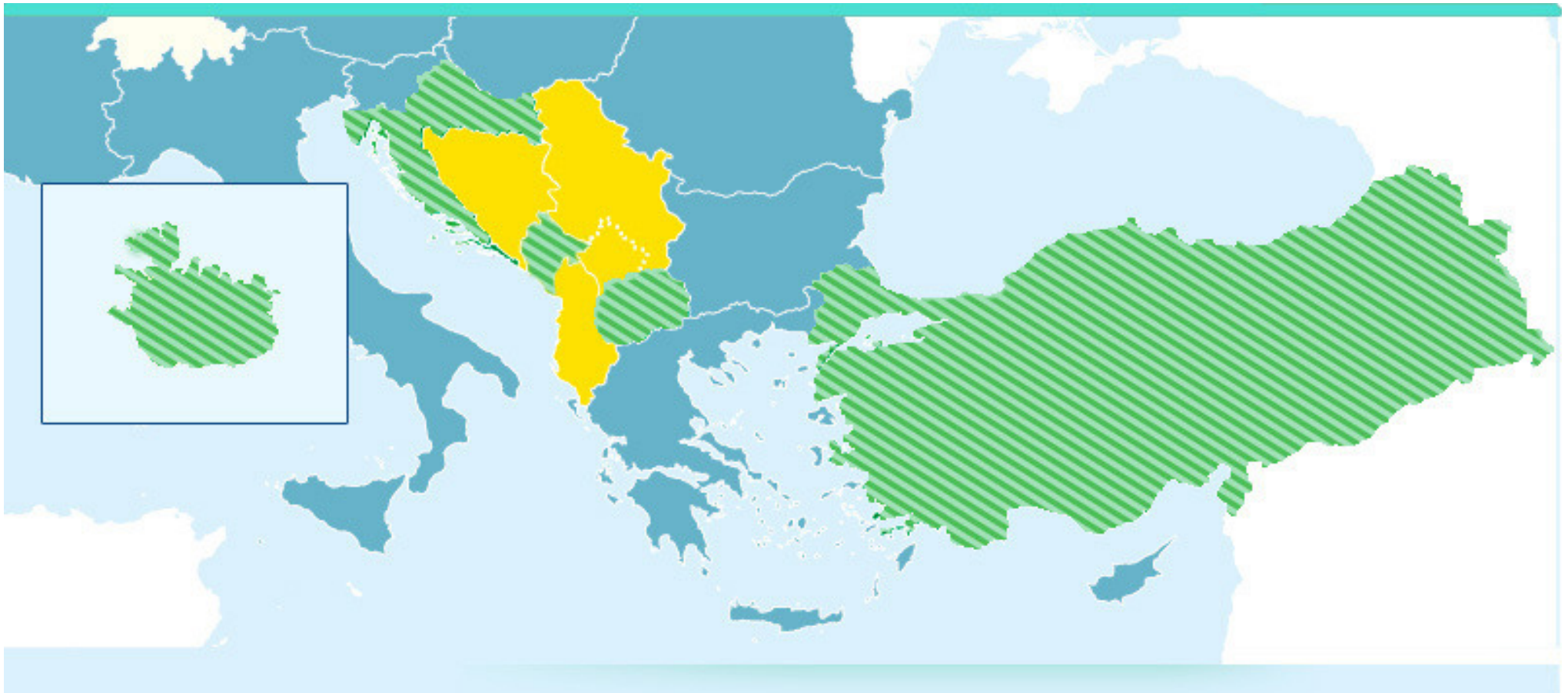
Technical Assistance and Information Exchange instrument (TAIEX)



pre- + after accession

Better Training for Safer Food initiative (BTSSF)

Cooperation and support IPA (Instrument for pre-accession assistance)



Candidate countries

- * Croatia
- * Iceland
- * The former Yugoslav Republic of Macedonia
- * Montenegro
- * Turkey

Potential candidates

- * Albania
- * Bosnia and Herzegovina
- * Kosovo under UN Security Council Resolution 1244
- * Serbia

Cooperation and support **ENPI** (European Neighborhood and Partnership Instrument)





KEY FEATURES OF TWINNING

- Projects are built around jointly agreed EU policy objectives
- Beneficiary Country retains ownership of project
- Projects yield concrete operational results linked to EU acquis adoption
- Projects involve a peer-to-peer exchange of hands-on public sector expertise and experience
- Projects are a genuine partnership fostering close co-operation
- Clear tasks and responsibilities

http://ec.europa.eu/enlargement/pdf/twinning_brochure_2005_en.pdf

http://ec.europa.eu/europeaid/where/neighbourhood/overview/twinning_en.htm

http://ec.europa.eu/enlargement/how-does-it-work/technical-assistance/twinning_en.htm

‘Twinning Light’ projects



- Financial ceiling at € 250.000
- Maximum duration for Twinning activities limited to 6 months; (exceptional extended to 8 months; supplemented by 3 months foreseen for inception and reporting)
- No Consortia of MS partners
- No vocational presentation of proposal
- Absence of a jointly designed work plan (absence of reimbursement of preparatory costs)
- Absence of a Resident Twinning Advisor (RTA)
- No project assistants
- No purchase of equipment or private sector services

TAIEX (Technical Assistance and Information Exchange) =

Short term technical assistance and advice on the transposition of EU legislation and on the subsequent administration, implementation and enforcement

- Short term assistance (max. 5 days)
- Conferences and seminars (max. 2 days)
- Study visits (max. 5 days for 3 officials)

Request by the Beneficiary country (Candidate countries and potential candidates)

Financial support by TAIEX

Logistical matters are managed by delegated entity (GTZ)

TAIEX Special (Turkish Cypriot community, Iceland)



http://ec.europa.eu/enlargement/taieux/index_en.htm

"Better Training for Safer Food"

Training program on initiative of the European Commission in the areas of food law, feed law, animal health and animal welfare rules, as well as plant health rules for member states and third countries.

Legal Base: Article 51 of Regulation (EC) No 882/2004 on official controls

To ensure

- High level of consumer protection and of animal health, animal welfare and plant health;
- Harmonized approach to the operation of Community and national control systems;
- Equal level playing field for all food businesses;
- Enhancing trade of safe food;
- Ensuring fair trade with third countries and in particular developing countries.

Cooperation and support

Twinning BfR Projects

Country	Number	Year	Issue
Slovakia	1	2000/2001	Harmonization of the milk and milk quality control system and establishment of the National Accredited Laboratory
Poland	1	2002/2003	Ensuring food safety and control of foodstuffs
Hungary	3	2003 2004/2005 2005	- Food Safety Office - Establishment of Food Safety Office - Development of a Strategy for Laboratory Infrastructure in Food Safety
Latvia	1	2005	Food Control: Drinking Water and Beverages
Lithuania	1	2007/2008	Strengthening of control on bacterial zoonoses and poultry viral diseases

Cooperation and support

Twinning projects

BfR attendance

Country	Number	Year	Issue
Lithuania	2	2005/2006 2006	- Strengthening of official control of food safety and residues in food in the Republic of Lithuania - Strengthening of risk assessment, risk management, risk communication, quality assurance and residue analysis in official food control in the Republic of Lithuania
Turkey	1	2006/2007	Restructuring and strengthening of the food safety and control system in Turkey

Short term experts to following issues: Wine, Pesticides, Contaminants, GMO's, Aquaculture also in other countries

Cooperation and support direct

Bilateral by Germany, some examples

Azerbaijan	Food Safety: Preparation for WTO accession
China	Quality Assurance of Agricultural Products - Food Safety

Institutional by BfR experts

Saudi-Arabia	Expert training
Tajikistan	Laboratory equipment and training

International Cooperation Agreements

Food and Consumer
Product Safety Authority (VWA)

Netherland



Österreichischen Agentur für Gesundheit und
Ernährungssicherheit GmbH (AGES)

Austria

State Food and Veterinary Service

Latvia



State Food and Veterinary Service
Lithuanian Veterinary Academy

Lithuania
Lithuania



Universität Zürich VETSUISSE Fakultät
Veterinärpharmakologie und Toxikologie

Suisse



Joint Research Center

Italy



Central Food Research Institute

Hungary



The Croatian Food Agency

Croatia



International Cooperation Agreements

Institute of Nutrition of the Russian
Academy of Medical Science and
Federal Centre of Hygiene and Epidemiology

Chinese Academy for Inspection and Quarantine

State General Laboratory of Cyprus (SGL)

National Institute of Food and Drug Safety Evaluation

French Food Safety Agency (ANSES)

Danish National Food Institute (DTU)

Icelandic Food and Veterinary Authority (in preparation) Iceland

Matís - Icelandic Food and Biotech R&D (in preparation) Iceland



ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗАЩИТЫ
ПРАВ ПОТРЕБИТЕЛЕЙ И БЛАГОПОЛУЧИЯ ЧЕЛОВЕКА

Russian Federation



China



Cyprus



South Korea

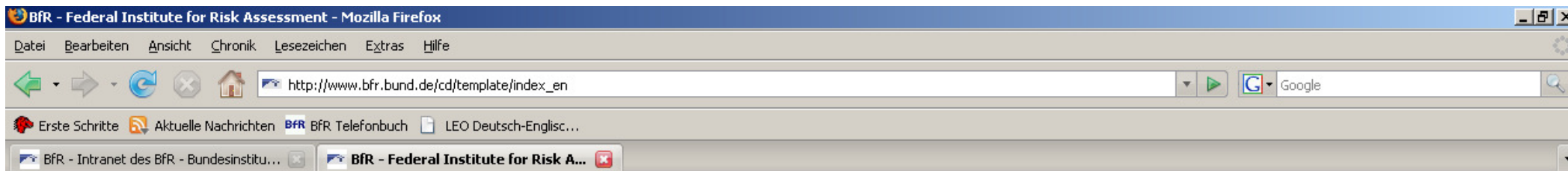
NIFDS



France

Denmark





Federal Institute for Risk Assessment

Risiken erkennen – Gesundheit schützen

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Biological Safety >>>



Food Safety >>>



Safety of substances >>>



Product Safety >>>

Risky delicacy: Pink duck breast



Campylobacter infections in humans are frequently caused by poultry meat, including duck breast. *Campylobacter* bacteria are heat-sensitive and die when meat is cooked through. As duck breast in traditional recipes is often not cooked through ("pink duck breast"), its consumption can lead to unpleasant gastrointestinal disorders caused by *Campylobacter* bacteria. This risk can be completely ruled out when the internal temperature of the meat during preparation on the stove or in the oven is 74 degrees Celsius or higher for more than 10 minutes. The Federal Institute for Risk Assessment (BfR), points out that this rule also applies to other germs present in meat. All common pathogens in food, both bacteria like *Salmonella*, *Listeria* and *Campylobacter* as well as noroviruses and hepatitis viruses, are destroyed when exposed to high temperatures for long enough. [more >>>](#)

Frequently Asked Questions about 3-monochloropropane-1,2-diol (3-MCPD)

The substance 3-monochloropropane-1,2-diol (3-MCPD) may be formed when fat-containing foods that also contain salt are exposed to high temperatures during production. It has been detected in numerous heated foods, for instance in dark brown toast. During the production of fats and oils, 3-MCPD fatty acid esters may be formed from 3-monochloropropane-1,2-diol when the fats and oils are heated to high temperatures. Significant amounts of 3-MCPD fatty acid esters have now been detected by food control authorities in numerous edible fats and fat-containing foods, for instance in infant formula and follow-up formula. The Federal Institute for Risk Assessment (BfR) has assessed the detected levels from the health angle and recommended that concerted action be taken to lower the levels of 3-MCPD esters in infant formula and follow-up formula. The Institute recommends that mothers who are unable to breastfeed their infants and give them infant formula should continue to do so. BfR responds to Frequently Asked Questions about 3-MCPD below. [more >>>](#)

More important information

- ▶ [Hyperactivity and Additives - Is there an association? \(PDF-File, 166.1 KB\)](#)
- ▶ [Isolated isoflavones are not without risk \(PDF-File, 277.7 KB\)](#)
- ▶ [Infant formula made from soy protein is no substitute for cow's milk products](#)
- ▶ [Detergent and cleaning agent formulations must be notified to BfR](#)



Intake of coumarin from cosmetics

The natural flavouring, coumarin, can cause liver damage in highly sensitive individuals. However, the effect can be reversed once coumarin intake is halted. This plant ingredient is found in woodruff and sweet clover and there are higher levels in cassia cinnamon, too. Consumers mainly ingest coumarin from food containing high levels of cassia cinnamon. [more >>>](#)

Consumers view the

Thank you for your attention

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President

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