

The legal and institutional background of food safety in Europe – The role of BfR in Germany

Reiner WITTKOWSKI

EU food law

Originally, food safety was not dealt with at the EU level.

Problem: Diverse national food safety provisions blocked free movement of goods.

EU was increasingly forced to deal with food safety issues on an *ad hoc* basis.

Regulation (EC) No 178/2002 of the European Parliament and of the Council



- 28.1.2002
- Laying down the general principles and requirements of food law
- Establishing the European Food Safety Authority (EFSA)
- Laying down procedures in matters of food safety



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Introduction to EU law

EU is responsible for nearly all important food safety legislation in its member states.

Member states have transferred competences to the EU

- Exclusive → EU
- Shared → EU, member states
- Supplementary → Member states (EU supplements)

Laid down in the EU treaties

- Treaty on European Union (TEU)
- Treaty on the Functioning of the European Union (TFEU)

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Introduction to EU law

EU food law is based on several shared competences

- Internal market → Article 114 TFEU
- Public health → Article 168 TFEU
- Consumer protection → Article 169 TFEU

Based on these competences laid down in the treaties, the EU can adopt legislation (e. g. directives, regulation, decisions).

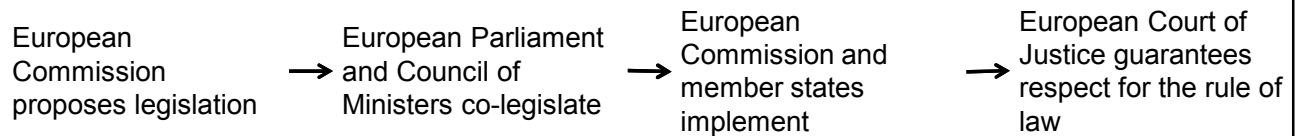
- If EU **has not** legislated: national law is applicable.
- If EU **has** legislated: EU law is applicable. → **Primacy of EU law over national law**



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Community method



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Structural reform of EU food safety: A response to BSE crisis

Bovine spongiform encephalopathy (BSE), progressive neurological disorder

Transmissible to humans, variant of Creutzfeldt-Jakob disease

Outbreak in UK end of 1980s (180.000 confirmed infected cattle; 1.000 new cases per week in January 1993; 177 death until June 2014)

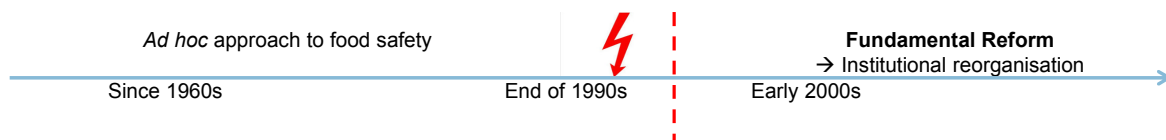
Spread to other European countries, e. g. Ireland, Switzerland, France, Liechtenstein, Luxembourg, Netherlands, Portugal and Denmark

Outbreak of BSE in 1996

Criticism: Blurred relationship between scientific and political decisions

Public distrust

Consequence: Reorganisation of food safety in the EU and in Germany



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General Food Law of 2002

Regulation 178/2002

- Established a new legal framework for EU food safety regulation: From farm to fork
- Three overarching principles
 1. Risk analysis
 2. Precaution
 3. Transparency
- Two basic requirements
 1. Responsibility of food business operator: "food shall not be placed on the market if it is unsafe" (Article 17)
 2. Traceability: "ability to trace and follow food, feed and ingredients through all stages of production, processing and distribution" (Article 18)



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EU food law

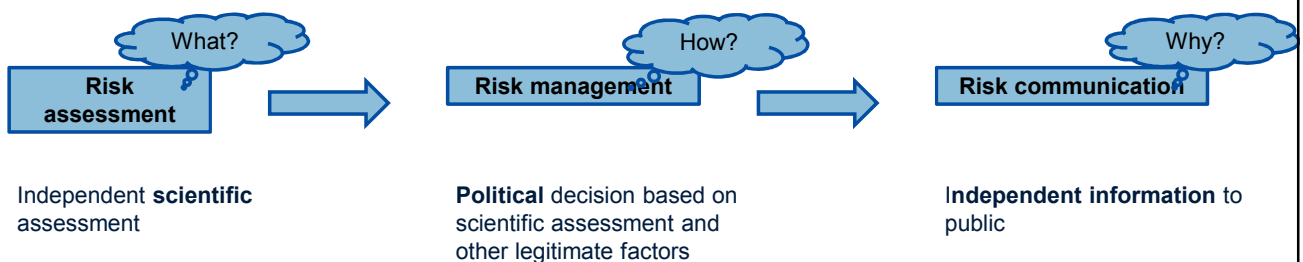
General Food Law

- Regulation (EC) No. 178/2002 of 28.1.2002 laying down **the general principles and requirements of food law**, establishing the European Food Safety Authority (EFSA) and laying down procedures in matters of food safety

Specific EU Food Law (pre-market approval systems)

- Regulation (EC) No 1935/2004 of 27.10.2004 on **materials and articles intended to come into contact with food**
- Regulation (EC) No 1829/2003 of 22.9.2003 on **genetically modified food and feed**
- Regulation (EC) No 258/97 of 27.1.1997 concerning **novel foods** and novel food ingredients
- Regulation (EC) No 1333/2008 I of 16.12.2008 on **food additives**

Principle of risk analysis: A clear separation of tasks



Rationale: Increase transparency and guarantee independence of scientists from political influence

Risk assessment, Independent scientific advice

- General Food Law creates **European Food Safety Authority (EFSA)** at EU level = Cornerstone of the system
- Task: **Independent scientific advice** to Commission, Parliament & member states
- **Network**



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Transparency

Public consultations

- http://ec.europa.eu/yourvoice/consultations/index_en.htm

Public information

- Independent communication about about risks to allow public to make informed decisions, incl. publication of scientific opinions
- Access to documents held by EFSA, Commission, Council and European Parliament

31.5.2001	EN	Official Journal of the European Communities	L 145/43
REGULATION (EC) No 1049/2001 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 May 2001 regarding public access to European Parliament, Council and Commission documents			
THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,		this Regulation as regards documents concerning the activities covered by those two Treaties.	
Having regard to the Treaty establishing the European Community, and in particular Article 255(2) thereof,		(6)	Wider access should be granted to documents in cases where the institutions are acting in their legislative capacity, including under delegated powers, while at the same time preserving the effectiveness of the institutions' decision-making process. Such documents should be made directly accessible to the greatest possible extent.
Having regard to the proposal from the Commission (1),			
Acting in accordance with the procedure referred to in Article 251 of the Treaty (2),			

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- **Since 2008**
- **Consisting of EU member states, associated countries and candidate countries**
- **Contact points**
- **Exchange of information**



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Risk management, Politics

Weighing of policy alternatives, taking into account EFSA's scientific assessment and other legitimate factors (social, cultural, ethical, political, environmental)

Actors: European Commission (DG SANTE) and Standing Committees composed of Member State representatives

Risk management options

- No action needed
- Legislation for certain products
- Ban of a dangerous product
- Consumption recommendation
- Raising awareness

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Precautionary principle

Idea

“Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost effective measures to prevent environmental degradation.”

Principle 15 of the 1992 UN Rio Declaration on Environment and Development

Conditions in the General Food Law

- Assessment of available scientific data
- Possibility of harmful effects on health identified
- Risk assessment is inconclusive = Existence of scientific uncertainty

Legal structures of agencies

- 130 public authorities to work on food safety
- Who does what in Europe?

EU Food Safety Almanac



www.bfr.bund.de/en/publication/eu_almanac-192693.html

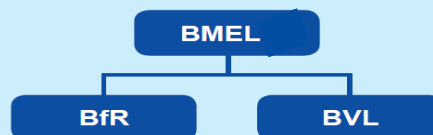
Present situation in Europe in food safety



- Member States have undertaken numerous reforms of their structures to bring their systems in line with the EU legislation.
- This has led to a network of public authorities and institutions linking the national and European levels.
- Smaller countries have difficulties in building up institutionally separate risk assessment units.

Food safety regulation in Germany

Food Safety Authorities in Germany



Ministries and subordinate public authorities in the 16 federal states

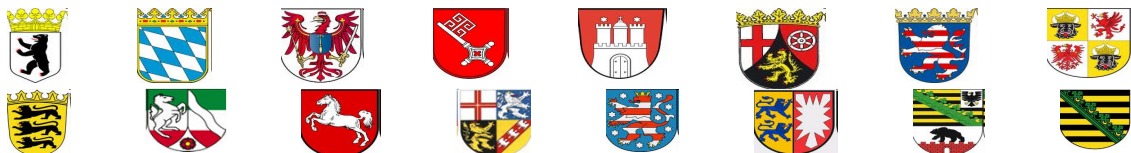
Simplified depiction of the authority structure



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 **federal** authorities to contribute and cooperate.
- Risk assessment and risk management are not divided as on national level.

Encouraging self-regulatory mechanisms

- Norms and standards, **not** made by parliament or ministries, e. g. EN/ISO, OECD
- Associations, trade partners, enterprises become motivated by government and authorities to fulfil the requirements
- Strengthening competition
- Risk communication and participation

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Thank you for your attention

Reiner WITTKOWSKI

German Federal Institute for Risk Assessment
Max-Dohrn-Strasse 8-10 • 10589 Berlin • Germany
Phone +49 / 30 / 184 12 - 0
bfr@bfr.bund.de • www.bfr.bund.de/en