



The SAFE FOODS project:

**Promoting Food Safety through a New
Integrated Risk Analysis Approach for Foods**

Workpackage 5 Presentation



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Institutional re-arrangements in European food safety governance – A comparative analysis



Mandate

Analysis of how the six cases - Sweden, the UK, France, Hungary, Germany and the EU-level - differ with respect to:

- The **intensity** of structural and procedural reform
- The **challenges** which the reforms mainly seek to address
- The respective underlying **key rationale**

Focus of comparative account on three governance aspects

How do the reform efforts relate to:

- The allocation of **responsibilities** for risk assessment and risk management
- The resort to **democratic procedural norms** such as transparency and public and stakeholder involvement
- The dealing with **scientific uncertainties** associated with food risks

Intensity and key rationale of reform

Food safety systems	Reform features	Intensity of reform efforts	Key rationale underlying reform
EU		High	Restoring of trust
UK		High	Restoring of trust
France		High	Improving effectiveness of food safety system
Germany		High	Restoring of trust
Sweden		Low	Adaptation to EU-risk policy approach
Hungary		High	Transposition of the EU's acquis on food safety into national legislation and adaptation to EU-risk policy approach

On the design of the science and policy interplay

Food safety systems	Reform features	Formal organisation of relationship between RA and RM
EU		Institutional segregation of responsibilities Declared aim: Ensuring RA independence
UK		Functional segregation of activities
France		Institutional segregation of responsibilities Declared aim: Ensuring RA independence
Germany		Institutional segregation of responsibilities Declared aim: Ensuring RA independence
Sweden		Intra-organisational (dept.) segregation of responsibilities
Hungary		Overlapping responsibilities and activities

EU, France, Germany: Division of RA and RM activities between separate institutions

- Underlying idea:

Separation at the institutional level shall:

- Ensure **independence of RA** from non-scientific judgements and that way restore expert credibility and authority
 - Strengthen political accountability by leaving RM to directly accountable political authorities
- Theoretically, problematic concept of separability
 - Empirically: model does not represent real decision-making processes



Between science and policy: blurring of boundaries in RA

Empirical indicators that RA does not stay within the boundaries of “pure science” and scientific descriptions:

- Expert consultation continues to take the form of **policy advice** rather than scientific commentaries and hence continues to intrude into the political area
- This advice is to guide political action, rather than simply choice-facilitating as it is typically confined to **one action option**
 - Assessors prefer to conclude with a recommendation for a particular action option
 - Managers like to have clear guidance from the expert opinions for their decisions
- What is **different** from the past: **Wording** has become a sensitive issue:
 - Assessors are expected to avoid authoritative formulations which would encroach upon the managers’ room for manoeuvre and decision power



Interaction with RM rather than “splendid isolation”

Also in the systems of institutional divide assessors and managers don't do their job in strict separation and sequence:

- **Interfaces** exist and **interaction** occurs and is deemed necessary
- Few formal structural devices for coordination (e.g., unit 5 of DG Sanco at EU-level)
- In contrast with previous practice, where informal and pragmatic interactions were taken for granted, communication and cooperation of today is **more focused** and subjected to **restriction** and **scrutiny** (e.g. provisions for involvement of risk managers in the assessment process)
 - Formal structure and real working activities seem to have a loose coupling
 - Reflects tensions between public legitimisation needs (insulating science from policy) and practical action requirements



Experiencing of critical interfaces

Practical experience has increasingly shown that there is a specific **need** for communication and cooperation at **specific points** in the risk analysis process:

- **Formulation of referrals** (introduction of quality procedures in referral handling in France)
 - Performance of **evaluative judgements** at the interface between RA and RM (expressed need for „best practices in evaluation“ in Germany)
 - **Communication of food risks** and assessment results to the public (informal agreements on timely information and consultation of managers about publication of RA opinions and related press announcements at EU-level and in Germany)
- Interactions are deemed esp. important at the **beginning** of the risk handling process – when the questions and tasks are defined – and at the **intermediary** stage – when scientific advice needs to be communicated and translated into management proposals



On the incorporation of democratic norms in the risk analysis process

Resort to three major modes to strengthen procedural legitimacy at the EU-level, in the UK, France and Germany (where trust-building is *the* or one reform objective):

- By making the risk analysis process, including RA, more transparent through public documentation and free access to information
- By providing more opportunities for the involvement of economic and civil society actors, in both RM and RA activities
- By offering comprehensible and process-oriented information on risk to the public at large, specifically addressing major consumer concerns



On public documentation and participation

	Public documentation	Participation
EU	New focus on both: outcomes <i>and</i> procedures of RM <i>and</i> RA	More <i>emphasis on stakeholder consultation</i> in <i>both</i> RA and RM; more <i>open</i> and <i>regular</i>
UK	New focus on both: outcomes <i>and</i> procedures of RM <i>and</i> RA	Permanent <i>consumer advisory body</i> ; <i>stakeholder participation in RA</i> ; more <i>emphasis on stakeholder consultation</i> , more <i>open</i> and <i>regular</i> involvement
France	New focus on outcomes of RM <i>and</i> RA; access to information about <i>RA procedures only upon request</i>	<i>Stakeholder consultation</i> continues to be focussed on <i>RM</i> ; typically <i>ad-hoc</i> and <i>exclusive</i>
Germany	New focus on outcomes of RM <i>and</i> RA	More <i>emphasis on stakeholder consultation</i> : focussed on RM with first initiatives to <i>extend</i> it to RA; typically <i>ad-hoc</i> and <i>exclusive</i>
Sweden	Continues to be confined to <i>outcomes</i> of RA and RM and occurs only upon <i>request</i>	<i>Stakeholder consultation</i> continues to be restricted to <i>RM</i> ; typically <i>ad-hoc</i> and <i>exclusive</i>
Hungary	Continues to be <i>minor</i>	<i>Stakeholder consultation</i> continues to be <i>minor</i> ; typically <i>ad-hoc</i> and <i>exclusive</i>



On public documentation: Transparency in RA

- In the UK, France, Germany and at EU-level: The effort to enhance transparency via documentation includes the RA phase; it is primarily in this respect that this effort is innovative
- In the UK, France and at EU-level: publication of the main RA outcome *and* (online) information about the procedures which have led to the expert opinions
 - Much more information about the basis of particular RAs is provided
- Assumptions and uncertainties inherent in the experts' conclusions are *not* fully documented – despite growing expectations in this respect in the UK, Germany and at EU-level
- What remains generally undocumented, is the way in which the management and policy making decisions refer to and take up risk assessments
- Transparency in RA is not a settled issue but one on which guidance is being sought and developed against the background of concerns to unduly trigger confusion or distrust in the experts' competencies on the side of the audiences



On participation

- Food safety authorities in the UK, Germany, at EU-level (and the French authorities less) **proclaim commitment** to addressing the outside world in an interactive and dialogue-based manner
- In practice, participation typically takes the form of **stakeholder consultation**, which varies in terms of institutionalisation, formalisation, and deliberative philosophy
- **Empowerment** to influence decision-making in risk analysis is the **exception** (UK: RA advisory committees all involve representatives of consumers, industry and/or the public as members with equal rights: co-determination in RA)



On participation

Changes from the *status quo ante* in stakeholder consultation:

- Greater importance is attached to representation of **consumer concerns** (cp. FSA's Consumer Committee, right to referral to Afssa, EFSA's Consultative Stakeholder Platform)
- Informal exchanges are increasingly performed also in **more open settings** (cp. EFSA's Annual Colloque or FSA's Stakeholder Forums)
- Stakeholder consultation and representation is being extended to the **early phases of RA** (cp. EFSA's Consultative Stakeholder Platform)



On stakeholder consultation in RA: Objectives

- The meetings of EFSA's, Afssa's and BfR's scientific experts remain confidential
- **Afssa and BfR:** eliciting of general information on stakeholder specific concerns, knowledge and practices in relation to selected risk issues
- **EFSA:** eliciting views on the Authority's broader policy such as its strategic objectives, its work programme, and its overall approach to stakeholder involvement and consultations on issue-specific approaches to RA (cp. GM food and feed, genotoxic and carcinogenic compounds)
- Growing effort to involve stakeholders already before managers take over should not be equated with a general support of such a practice:
 - Stakeholder involvement during RA is still controversial: necessary? Appropriate ways in which it could/should be organised?



On risk communication

Food safety systems	Reform features	Risk communication
EU		<i>Increased</i> efforts for addressing <i>consumer concerns</i>
UK		<i>Increased</i> efforts for addressing <i>consumer concerns</i>
France		<i>Increased</i> efforts for addressing <i>consumer concerns</i>
Germany		<i>Increased</i> efforts for addressing <i>consumer concerns</i>
Sweden		<i>Continuing</i> efforts for addressing <i>consumer concerns</i>
Hungary		<i>Continues</i> to be <i>minor</i> and <i>hardly targeted</i> to consumer concerns



On risk communication

In comparison with past practice:

- In the **UK, France, Germany, and the EU**: greater efforts to provide information responding to **concrete concerns** of consumers by both RA and RM authorities (cp. FAQs in relation to BSE in goats, avian flue, semicarbazide, safety of wild and farmed fish, BSE in cattle, GM food and feed)
- Much more than in regard to the formal documents, this communication is aimed to provide **easily accessible** and **quickly available** information which is also **comprehensible** and **helpful** and to address **both** the nature of potential health risks and the way in which the responsible authorities act to handle it
- One-way risk communication has become more **pro-active** and is less focused on crisis communication



The contrasting cases: Procedural legitimacy as a non-issue (Sweden) or an emerging issue? (Hungary)

- In **Sweden and Hungary**, where institutional re-arrangements are a response to **external requirements** framed at the supranational level rather than domestic challenges, restructuring is not or hardly connected with specific efforts to (further) open the process of risk analysis to public scrutiny and stakeholder involvement
- **Sweden**: Transparency and openness are deemed a **matter of fact** and sufficiently guaranteed by a referral system and open access to official documents
- **Hungary**: Transparency continues to be low mainly due to a strong tradition of **paternalism** and **scarcity of available funds** for risk communication; a culture of civil society involvement and public awareness about political accountability when it comes to food safety seem to be slowly evolving (cp. red paprika scandal).



Sweden: Taken-for grantedness of transparency in a high-trust regulatory system

A different (traditional) policy of transparency:

- Access to documents is not provided pro-actively (by posting it on the internet) but only upon **concrete request**
- The process of arriving at decisions is not detailed; the right-of-access principle applies only to **official documents**
- Stakeholder involvement is strictly confined to the **RM phase** (referral system)
- There are no major efforts to maintain informal contacts with stakeholder groups also outside the **exclusive meetings** in more open communication settings and events
 - In the absence of major food scares and scandals (in the past decades) and a situation of high-trust, a policy of transparency specific to the food safety area has neither been proclaimed nor practiced
 - Openness continues to be **reactive** rather than proactive, to apply to **outcomes** rather than procedures, and to the **political** rather than the science business.



On the attention to scientific uncertainties

Food safety systems \ Reform features	Endorsement of the Precautionary Principle	Communication on scientific uncertainties
EU	Yes, with increasing emphasis	EFSA Working Group on transparency in RA
UK	Yes, with increasing emphasis	Official, governmental guidelines
France	Yes, with increasing emphasis	No explicit official commitments
Germany	Yes, with increasing emphasis	Official commitments
Sweden	Yes, with unchanging emphasis	No explicit official commitments
Hungary	Only formal acknowledgement	No explicit official commitments

On the attention to scientific uncertainties

- While the **precautionary principle** is generally appreciated as an important RM tool, the concrete interpretation and application of the principle varies across countries and authorities and appears **highly contingent** on the respective regulatory framework, individual cases and the respective case assessors and managers
- Both at **EU-level and Member State level** the approach to identifying, characterising, and communicating scientific uncertainties and handling them on the basis of the PP is **ad-hoc** and **case-specific**, rather than systematic and based on concrete guidelines.
- **Sweden**: PP traditionally of **high importance**; dealing with uncertainty is reserved to the scientific handling of risks, it is **not** connected to issues of transparency and communication as in the UK, Germany and at EU-level
- **Hungary**: **Little attention** is paid to the issue of scientific uncertainties; only formal acknowledgement of the PP; responses to public concern usually refer to certainty or “zero risk”



Some major conclusions: The role of trust

- It is essential to distinguish between **different levels of trust** as one of the major drivers for the nature and intensity of reform that the five countries and the EU have initiated in the recent past
- In the **UK, Germany, France** and at **EU-level**, where rebuilding of public trust is *the* or one reform objective, the reform packages include efforts that address **each** of the three governance aspects at issue
- These reform packages have in common that they involve **both** results-based and procedure-based legitimisation strategies; they are aimed at a governance framework that combines the authority of **scientific expertise** and the authority of **democratic criteria** like transparency, participation, and political accountability (cp. Skogstad 2003 for GMO regulation)



Some major conclusions:

Two-ways-legitimisation strategy in revised food safety governance in the UK, France, Germany and at EU-level

Results-based measures to prove and ensure the appropriateness of risk analysis <i>outcomes</i>	Procedure-based measures to prove and ensure the appropriateness of risk analysis <i>procedures</i> by enhancing their democratic quality
Functional and/ or institutional segregation of responsibilities for RA and RM: shall warrant the independence of RA from non-scientific considerations/ influences	Improved transparency through public documentation and free access to information as regards RA and RM
Endorsement of the Precautionary Principle : shall ensure consideration of inevitable limits of scientific knowledge	More opportunities for stakeholder involvement (mainly in RM, increasingly in RA)
	Risk information for the public at large which addresses major consumer concerns



Some major conclusions

- Focus of two-ways-legitimation strategy: independence of and transparency in risk assessment
- High trust societies such as Sweden do not need external re-affirmation when they respond to public duties (cp. Löfstedt 2005). Trust acts as a substitute for control and public scrutiny. Interested parties are deliberately excluded from the assessment process; delegation of responsibility is coupled with a strong expectation of effectiveness and accountability
- The institutional divide of responsibilities, destined to ensure the independence of RA, increasingly brings to light that RA and RM cannot be fulfilled in isolation but require concrete devices to bridge the divide and facilitate bilateral communication, interaction, and cooperation
- If this integration is not addressed and provided for by specific mechanisms, it will find its own way through in an informal, rather opaque manner, inviting criticism of intransparency and inconsistency



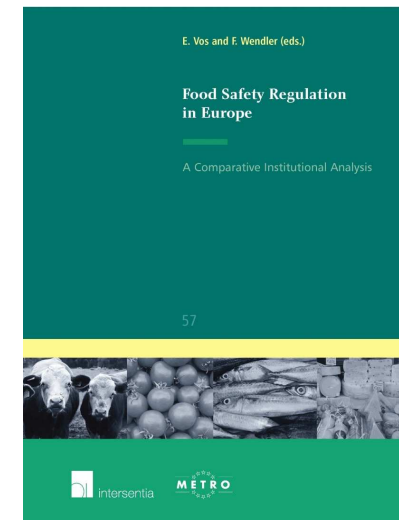
Some suggestions for additional reforms

- To formally organise the framing phase and the evaluation phase:
 - In order to help to ensure that scientific experts address the ,right' questions in the ,right' manner and remove debates on whether assessment authorities overstep from the pure assessment position
- To involve both assessors and managers in the framing and evaluation phases, so that the two phases could operate as mediators between the RA and RM functions and in order to contribute to the policy of transparency
- To better define the function of stakeholder involvement in RA: e.g., how is that compatible with the declared aim of safeguarding the independence of assessment by keeping it separate and free from influences of non-scientific considerations?
- To consider inclusion of the wider public for the handling of conflicts fuelled foremost by conflicting and deeply held value-orientations

Comparative Account of Institutional Re-arrangements

- **Current activities**

Promotion of published results of the institutional analysis in an edited volume entitled “*Food Safety Regulation in Europe: A Comparative Institutional Analysis*”, Publisher: Intersentia Publishing (Ius Commune Series)



- **Upcoming activity**

Publication of key findings in peer reviewed journal

