
**European Risk Governance:
its Science, its Inclusiveness and its Effectiveness**

Workshop Report

CONNEX Network of Excellence

Research Group 6: *The Transformation of the European Policy Space*
co-ordinated by Renaud Dehousse (Foundation Nationale des Science
Politiques, Paris)

Maastricht University, Faculty of Law, Bouillonstraat 1-3, 14-16 June 2007

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DETAILED PROGRAMME

Thursday 14 June 2007

10.00 Registration and coffee

10.30 Welcome, Ellen Vos (University of Maastricht)

*Session 1: European Risk Governance, Its Science and its Procedures
10.45 - 12.30*

Chair: Ellen Vos (University of Maastricht)

10.45 - 11.15 Michelle Everson (Birbeck College, London) and Ellen Vos (University of Maastricht): *European Risk Governance of Food and GMOs: Science, Institutions, Procedures and Participation*

11.15 - 11.45 Marion Dreyer (Dialogik, Stuttgart): *Some Suggestions for a Structured Approach to Participation in Food Safety Governance with Special Emphasis on 'Interface Participation'*

11.45 - 12.00 Discussant Frank Wendler (University of Maastricht)

12.00 - 12.15 Discussion

12.30 - 14.00 Lunch

Session 1 Continued, 14.00 - 17.30

Chair: Michelle Everson (Birkbeck College, London)

14.00 - 14.30 Luis González Vaqué (European Commission): *The Impact of the Precautionary Principle on European Risk Governance*

14.30 - 14.45 Discussant Arnold van der Wielen (Dutch Ministry of Housing, Spatial Planning and the Environment)

14.45 - 15.00 Discussion

15.00 - 15.30 Alberto Alemanno (Luxembourg): *Science and EU Risk Regulation: the Role of Experts in Decision-making and Judicial Review*

15.30 - 15.45 Discussant René Von Schomberg (European Commission)

15.45 - 16.00 Discussion

16.00 - 16.30	Coffee/tea
16.30 - 17.00	Marjan Peeters and Nicole Niessen (University of Maastricht): <i>Beyond Uncertainty in Environmental Decision-making: some Competence Issues</i>
17.00 - 17.15	Discussant Chris Backes (University of Utrecht)
17.15 - 17.30	Discussion
19.00	Dinner (Restaurant Roxy's, Kruisherengang 4)

Friday 15 June 2007

Session 2: European Risk Governance, its Science and its Inclusiveness, 9.00-13.00

Chair:	Ellen Vos (Maastricht University)
8.30 - 9.00	Coffee/tea
9.00 - 9.30	Gilles Hériard Dubreuil (Mutadis, Paris), <i>Stakeholder Involvement in Risk Governance: The TRUSTNET IN ACTION, European Research Project</i>
9.30 - 9.45	Discussant Hubert Noteborn (Dutch Product and Food Safety Authority, The Hague)
9.45 - 10.00	Discussion
10.00 - 10.30	Stijn Smismans (University of Trento): <i>Civil Society and Risk Regulation: New Modes of Governance and the Participatory Myth</i>
10.30 - 10.45	Discussant Damien Chalmers (LSE, London)
10.45 - 11.00	Discussion
11.00 - 11.30	Coffee/tea
11.30 - 12.00	Veerle Heyvaert (LSE, London): <i>Inclusive Governance and the EU Chemicals Policy (REACH)</i>
12.00 - 12.15	Discussant Minna Heikkila (European Commission)
12.15 - 12.30	Discussion
13.00 - 14.30	Lunch (Restaurant De Cuyp, Tongersestraat 30)

Session 3: European Risk Governance and Its Effectiveness: The Role of Private Standards, 14.30 - 18.00

Chair:	Damien Chalmers (LSE, London)
14.30 - 15.00	Frans van Waarden (University of Utrecht): <i>Transnational Private Governance of Risks and its Limits</i>
15.00 - 15.15	Discussant Thomas Conzelmann (Darmstadt U. of Technology)
15.15 - 15.30	Discussion
15.30 - 16.00	Frank Wendler (University of Maastricht): <i>The Public-Private Regulation of Food Safety through HACCP: What does it mean for the Governance Capacity of Public and Private Actors?</i>
16.00 - 16.15	Discussant Thomas Conzelmann (Darmstadt U. of Technology)
16.15 - 16.30	Discussion
16.30 - 17.00	Coffee/tea
17.00 - 17.30	Nicolien van der Grijp (VU University, Amsterdam): <i>The Role of Private Standards in the Agro-food and Environmental Policies of the EU: the Case of Pesticide Use in Fruit and Vegetable Production</i>
17.30 - 17.45	Discussant Han Somsen (Tilburg University)
17.45 - 18.00	Discussion
19.00	Dinner (Restaurant Petit Bonheur, Achter de Molens 2)

Saturday 16 June 2007

8.30 - 9.00 Coffee/tea

Continuation of Session 2: European Risk Governance, its Science and its Inclusiveness, 9.00 - 12.30

Chair: Renaud Dehousse (Science-Po, Paris)

9.00 - 9.30 Renaud Dehousse and Laurie Boussaguet (Science-Po, Paris): *The Role of the Lay People in Risk Governance: the Experience of the First 'Citizen Conference' at the EU level*

9.30 - 9.45 Discussant Ruud Hendriks (University of Maastricht)

9.45 - 10.00 Discussion

Session 4: European Risk Governance and Its Effectiveness: Compliance and Enforcement

10.00 - 10.30 Rob Widdershoven (University of Utrecht): *Compliance and Enforcement of European Risk Regulation*

10.30 - 10.45 Discussant Tetty Havinga (Radboud University Nijmegen)

10.45 - 11.00 Discussion

11.00 - 11.30 Coffee/tea

11.30 - 12.00 Adriaan Schout (EIPA, Maastricht): *Inspecting Air Safety: the Case of EASA*

12.00 - 12.15 Discussant Frans Leeuw (Ministry of Justice/University of Maastricht)

12.15 - 12.30 Discussion

12.30 Closing

**List of participants with institutional affiliation and e-mail address
(alphabetical order)**

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Involvement of Phd students

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All PhD students took actively part in the discussion.

Involvement of practitioners

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Practitioners from European and national authorities participated in this workshop as speakers and discussants and actively contributed to the discussions throughout the whole workshop.

Short description of the activity's goals and objectives

The question of how public authorities should deal with risks and uncertainties has become particularly topical in the aftermath of the 1996 BSE crisis. This crisis put the spotlight on a series of severe institutional shortcomings in EU policies (along with Member States) on risk and triggered a severe crisis of public confidence in both scientific advice and in the management of risks by EU and Member States authorities. It provided a classic illustration of uncertainty in science and of the complex and vital relationship between science and society. Both regulators and the general public have consequently become increasingly aware of the risks that are intrinsic to the food industry, whilst the continuous stretching of the frontiers of science in areas such as biotechnology have raised more anxiety among the public. It thus has become clear that risks must be approached as political issues. All the more since their emergence cannot be dissociated neither from the more important transformations within regulatory regimes (such as food production in the 1980s), nor from the resurgence of contestation and political mobilizations within most European countries (for example, around GMOs). These crises, scandals and controversies have, in turn, shaped the way in which risks are perceived and subsequently managed, with strong implications in terms of political accountability, the role of science and stakeholder participation.

Hence, whilst it is true that innovation may improve the quality of life, and is essential for economic growth, at the same time it raises uncertainties and concerns, and can bring new hazards to human health and environment. Hence, how should regulators react to scientific studies which show the carcinogenic effects of UV-filters in sun creams, presumably disturbing the human hormone balance? And, what should they do with studies indicating that carcinogenic substances (acrylamide) are formed when baking bread or frying potatoes, and thus posing a health risk when consumed or that farmed salmon contains potentially hazardous levels of dioxins and PCBs?

It is clear that risk governance - embracing risk identification, assessment, management and communication - has become a crucial but often highly controversial component of public policy, particularly at the EU level. In the aftermath of the 1996 BSE crisis, reforms have been carried out both at European and national level so as to reinforce scientific advice around principles of excellence, transparency and independence and to allow for more stakeholder participation. Whilst at the European level, a strict separation between science and politics has been introduced in the food area, in other countries a more blurred relationship between science and politics has been admitted. In the BSE aftermath, we moreover witness an increased attention for transparency of science- and decision-making as well as the participation of stakeholders and the public.

Based on experience that can be drawn from risk governance in practice, this workshop discussed the role of institutions, both scientific and regulatory, in European risk governance and the dialogue between risk assessors, risk managers and stakeholders so as to overcome the crisis of confidence. In this manner, it sought to define what lessons have been learnt and put into place more than 10 years after the outbreak of the BSE crisis. Do the principles of transparency and participation truly apply to risk governance, more in particular to risk assessment? What is the impact of the precautionary principle on European decision-making and the role that science and scientific experts/expertise play in risk governance (both in the science- and decision-making and before courts)? And, should scientific advice be strictly separated from regulatory decision-making? In other words: should risk assessment be strictly separated from risk management? What is the role of agencies in this? Importantly what is the role of lay people in the production of scientific advice; does science and scientific advice have to be produced only by the recognised experts or do also citizens or specific stakeholders have a role to play? Should stakeholders and/or the general public participate in science-making? If yes, why, in what form and to what extent? To which extent should stakeholders, civil society and/or the general public participate in decision-making?

The workshop also addressed the intermingling of public and private regulation which is increasingly used as a tool for effective risk governance. The workshop concluded with addressing the issue of enforcement and monitoring of public regulation which is often more a problem than a solution to effective risk regulation, and which is an area in which the Community often lacks competence. Here we asked how the emerging public-private partnerships be understood and whether we need more powers at the EU level to control safety regulation.

Summary of the presentations and discussions, achievements

The interaction between science, institutions, procedures and participation is perfectly illustrated in European food and GMO regulation. Uncertainty in food and GMO issues gives rise to a number of conflicting scientific opinions, values and interests which pose a particular challenge to the balance within European institutional structures. *Michelle Everson* (Birkbeck College, London) and *Ellen Vos* (Maastricht University) concluded from empirical failings and successes in these areas, that future global risk governance should seek to establish its own constitution which not only secures the vital independence and transparency of scientific advice, but also guarantees public participation, whether by stakeholders or a wider public, to ensure that scientific rationality, even as it is used to discipline the potential irrationalities of political debate, is nonetheless not the sole criterion for risk decision-making.

Suggestions for a *structured* approach to participation in food safety were made by *Marion Dreyer* (Dialogik, Stuttgart). She put forward that the loss of trust in European risk governance and lack of social legitimacy may be remedied through both result-based measures (segregation between risk assessment and risk management, the precautionary principle) and procedure-based measures (improved transparency and increased stakeholder involvement). She identified three main problems as regards stakeholder involvement: how to have stakeholder involvement whilst guaranteeing scientific independence; how to avoid 'participatory overkill'; how to improve involvement of social actors beyond the 'Brussels Establishment'?

She suggested following a *'four-stage-approach'* to food safety governance guided by principles of transparency and participation by institutionalization interface participation (by means of an interface committee for framing and evaluating); the installation of a web-based forum for more inclusiveness and the establishment of guidance rules (proceduralisation of decision-making). Discussant *Frank Wendler* (Maastricht University) raised the question whether loss of trust indeed can be remedied through more information and pointed to the problems in consultation and the lack of reflection of its outcome.

The role which the precautionary principle plays in risk assessment, risk management and risk communication was assessed by *Luis Gonzalez Vaqué* (European Commission). Being one of the lessons learnt from the BSE crisis in 1996, the precautionary principle is now a general principle of EU law. Other principles should, however, be taken into consideration whenever the precautionary principle is applied, such as proportionality, legal certainty etc, as laid down in the Commission's Communication on the precautionary principle of 2001. Discussant *Arnold van der Wielen* (Dutch Ministry of Housing, Spatial Planning and the Environment) explained that the precautionary principle has been implemented in the Netherlands as the 'duty of care' article in the Chemical Substances Act, but stressed the difference to REACH, which mentions precautionary principle only in the preamble due to major differences in national legal cultures. He further emphasised the distinction between prevention (based on knowledge) and precaution (based on lack of knowledge) and the strict interpretation of lack of knowledge.

Alberto Alemanno (CFI, Luxembourg) addressed the role which science plays in risk regulation and stressed the increased role of science as an instrument to achieve 'high level of protection' in the EU. He called for more transparency by means of guidance documents and for a strict application of the separation between RA and RM. Further, he stressed the lack of judicial review of scientific opinions (with the exception of one case) and the light standard of judicial review, with the European courts limiting themselves to 'manifest error or misuse of power'. He moreover questioned the desirability of more intrusive scrutiny and pointed to the need to support Courts when reviewing science-

based measures through peer review mechanisms instead of looking for external expert consultation as it is difficult to decide whom to rely on. Discussant *Rene von Schomberg* (European Commission) pointed out that the question is not so much about distinguishing RA and RM, but about determining the reasonable grounds for doubt prior to the risk analysis phase, in the sense of a separate formulating or evaluating step.

Marjan Peeters and *Nicole Niessen* (Maastricht University) discussed decision-making in cases of uncertain *environmental* risks, with a focus on permitting industrial installations. Uncertain activities will be permitted by competent authorities after having regard to the precautionary principle (IPPC-directive). As a consequence of the precautionary principle, the permitting authority is obliged to consider during the permit procedure how to govern the particular risk and to define, to some extent, the responsibility of the permit holder or actual operator for the damage which might occur. The environmental liability directive provides for the general responsibility of the operator, but leaves open the question of the responsibility of the competent authority. It also raises certain questions still to be explored, such as what are the necessary tools for permitting uncertain risks or how much should already be decided on this within the permit. Discussant *Chris Backes* (University of Utrecht) pointed out that the 'polluter pays' principle offers the basic rule in allocating responsibilities. However, the decision who should pay is a political one which should weigh the considerations of environmental protection, victim protection and legal security.

In session 2 on the *inclusiveness* of European risk regulation, *Gilles Hériard Dubreuil* (Mutadis, Paris) presented the Trustnet-in-Action (TIA) project; a project on innovative processes with innovative participatory features of governance. He stressed that today's trend of public participation seldom leads to actual changes of traditional government behaviour. A sustainable influence of citizens thus requires an *actual* transformation of decision-making processes instead of occasional participation. Inclusive governance will thus require a real shift towards 'experimental democracy' and a 'new philosophy of governance'. What is needed is pragmatic governance not based on principles

but open to continuous change and revision according to continuous feedback from society. The TIA urges the European Commission to consider how pluralistic networks of actors engaged in inclusive governance processes can be promoted in the future.

More transparency and participation issues were addressed by *Hubert Noteborn* (Dutch Food and Consumer Product Safety Authority). Even though *Roland Bal* (Erasmus University) could not attend the workshop due to illness, *Hubert Noteborn* discussed his paper and stressed the need for a credible, clear and trustworthy outcome of scientific advice. He pointed out that the success of the Dutch Health Council's co-ordination work between front- and back region (office) depend also on the Dutch consensual political climate. Yet, he expressed some doubts as to whether this is to be considered as a model for other areas of policy-making and pointed to other more open and inclusive models, such as promoted by the SAFE FOODS project. Importantly, for transparency and credibility of scientific advice the five normative principles of European Governance according to the Commission's White Paper need to be taken into account: openness, accountability, effectiveness, coherence and participation.

Stijn Smismans (University of Trento) discussed the issue of participation, in particular the question whether new modes of governance are more 'participatory'. He denied the suggestion that new models of governance *automatically* mean more participation, which is rather to be considered as a 'participatory myth'. In the field of occupational health and safety, which was taken as an example, he concluded that stakeholders are not involved enough, the existing consultation structures are upset or the relevant instruments show inherent limits in this particular field of policy. One should therefore be careful in assessing the participatory character of new modes of governance. Discussant *Damien Chalmers* (LSE, London) focussed on the desirability of participation as such and its sometimes disappointing outcome. In particular, he questioned the problem-solving capability of participation, pointed to possible impediment of the knowledge-base and put the community-building function of participation into perspective.

Veerle Heyvaert (LSE, London) analysed the ways in which REACH EU's new chemicals could be said to represent an inclusive approach to risk governance, and explored some of the limits of this inclusiveness. In particular, she argued that despite there being some scope for the integration of contextual risk factors in the chemical risk identification, assessment and management stages, the risk control process remains sequential and predominantly expert-driven, and that the inclusion of socio-economic considerations chiefly serves as an opportunity to mitigate calculated risks rather than to provide a more comprehensive risk profile, leaving out factors such as risk perception, public dread and anxiety. In terms of stakeholder inclusiveness, civil society is decidedly sidelined in the internal operation of REACH decision-making processes, as exemplified in the authorisation procedure for highly dangerous substances. This view was challenged by discussant *Minna Heikkila* (European Commission) who put forward the view that civil society *is* participating in REACH.

In the following part of the workshop, the focus shifted to *the role of private standards in European risk governance*. Transnational private governance of risks and its limits were addressed by *Frans van Waarden* (University of Utrecht). First, he observed a reversion of the historical trend from private to public regulation which is nowadays the trend towards *private* regulation. This is primarily due to the increasing demand for risk management which cannot be met by the nation-states. Even though such a trend offers a number of advantages (increases trust and legitimacy, ensures various inputs of interests and values, is not bound by territorially confined jurisdictions), it also poses problems such as lack of transparency and accountability in particular. As a possible solution *Frans van Waarden* suggested mutual checks and balances by Peer Review mechanisms and opted for a functional approach to risk instead of territorially confined groups. Discussant *Thomas Conzelmann* (Darmstadt University of Technology) confirmed the trend towards transnational regulation and further discussed the functional approach suggested by the presenter. The discussion centred around the functional approach *versus* territorial representation and the question how the relevant functional groups should be defined.

The role of public and private actors in risk governance was further elaborated by *Frank Wendler* (Maastricht University), who elaborated on public-private regulation of food safety through HACCP (Hazard Analysis Critical Control Points). He pointed to the emergence of firms as partners of public regulators and confirmed the shift of governance to the public-private dimension. He further stressed the transformative effect of public-private partnerships on the structures and conditions of food safety and the possible fragmentation of governance tasks across different levels and actors which this shift of governance capacity implies. Discussant *Thomas Conzelmann* (Darmstadt University of Technology) raised the question in how far the presented example of HACCP can be generalised, which was the focus of further discussion.

The role of private standards in the agro-food and environmental policies of the EU was presented by *Nicolien van der Grijp* (VU University Amsterdam), who assessed the contribution of private standards to the reduction of environmental and human health risks in the area of pesticides. First, she drew a rather pessimistic picture of the effectiveness of the EC legislation on pesticides since an increased occurrence of pesticide residues and more use of illegal pesticide products can be shown. Thus, while governments have difficulties in establishing a coherent and effective law on pesticides, market players are taking over the initiative and create a fragmented pattern of rules with lacking overarching concepts. After outlining both the advantages and disadvantages of such private standards, *Nicolien van der Grijp* suggested a regulatory configuration with better coordination, definition of concepts and procedural criteria (state actors) and multi-stakeholder initiatives (non-state actors). Discussant *Han Somsen* (Tilburg University) confirmed the slow process of EC pesticides regulation, but stressed the problems which private standards imply since such standards reach the rest of the world through processes of globalisation. He further emphasized that self-regulation works where there are asymmetries in information and pleaded for further elaboration of currently vague standards. Further discussion centred around the clash of interests (retailers, small farms etc.) and competition issues relating to self-regulation.

The Saturday morning session of the workshop continued to discuss the issue of *inclusiveness*, with the experience of two first citizen conferences (CCs) at the EU level presented by *Laurie Boussaquet* and *Renaud Dehousse* (Science-Po, Paris). Due to the controversy surrounding scientific evidence and the overall 'democratic deficit', the contact with laypersons is designed to overcome the lack of participatory democracy. The debates between lay people usually result in formulation of public opinions and recommendations. They concluded that the absence of 'European people', the issue of languages and the representation of different Member States turned out to be problematic in relation to the CCs whilst the actual impact of such conferences on decision-making remained uncertain. Discussant *Ruud Hendriks* (Maastricht University) expressed his doubts as to the usefulness of resorting to CCs since many issues are already predestined, the citizens seldom can come up with their own agenda and the conferences basically serve a larger agenda to create European citizenry.

Finally, the focus of the workshop shifted towards the *effectiveness* aspect of European risk governance. Compliance and enforcement of European risk regulation was elaborated by *Rob Widdershoven* (Utrecht University). Starting from the general 'enforcement deficit' of the EU and decentralisation of enforcement, he suggested that, generally, enforcement of European risk regulation should remain the responsibility of the Member States while Europe should provide for regulatory guidance in order to ensure effective enforcement in the Member States. Further, in the area of food safety, he suggested establishing a European investigation office, which should have the power to conduct inspections in the Member States. Sanctions with punitive nature should be prescribed by the EU, to guarantee effective and dissuasive sanctioning in the Member States. Discussant *Tetty Havinga* (Radboud University Nijmegen) questioned such 'top-down' approach and pointed to other possible mechanisms to ensure compliance. For example, this could be the sensitivity of some actors to the loss of reputation, self-regulation or other market forces. Further discussion pointed out that there should perhaps be a rethinking of the concept of the sole responsibility of the Member States for

enforcement and put forward the idea that the Commission should possibly have a stronger role in enforcement. In addition, issues such as self-regulation, naming and shaming, certification and verification mechanisms were mentioned.

Adriaan Schout (EIPA, Maastricht) discussed the inspection powers of EASA, the European Aviation Safety Agency. He stressed the ambiguities relating to assessing the success of EASA, generally due to the huge relevance and the high political profile of the sector covered. In spite of that, he described EASA as a major 'institutional surprise'. He pointed out that the final outcome of negotiations concerning EASA was different as initially intended. Namely, EASA did not get the necessary funds, inspection tasks returned to the national aviation authorities (NAAs) and EASA's inspections were limited to inspections of the NAAs. Discussant *Frans Leeuw* (Ministry of Justice/University of Maastricht) criticised the 'inspection/audit pyramid' and pointed to the law of diminishing returns and to the danger of regulatory capture of inspection agencies.

Planned outcome

It is still to be discussed in what form papers presented at this workshop will be published (Connex Reports series, book or international journal).