Standards of Scientific Advice. Risk Analysis and the Formation of the European Food Safety Authority

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A common depiction of the process of scientific advice, at least as concerns the regulation of health risks, is that it should be contained to risk assessment. And that risk assessment should be separated from risk management and risk communication. This depiction of the process of scientific advice was very common during the creation of the European Food Safety Authority (EFSA). It informed the decision to define and delimit its powers in terms of risk assessment. This approach was inspired by the risk analysis framework of the US National Research Council (NRC 1983). According to this framework, the scientific and political dimensions of decisions about risks are impossible to separate. So these decisions should rather be understood as the outcome of a succession of sequences, starting with risk assessment, followed by risk management and concluded by risk communication. Each of these sequences, so the report argued, contains scientific and political aspects at different doses.

The framework quickly gained currency as the right approach for decision-making in federal agencies like the Food and Drug Administration and the Environment Protection Agency (Jasanoff 1987, 1992). It also gained currency, but much later, in Europe. The European Commission or the European Parliament proposed the creation of a food regulation body on several occasions in the 1980s and 1990s. Following the mad cow crisis of the mid-1990s, it became clear that such an independent body should be one of scientific advice. Risk analysis was taken up in that context. It even became law in the European Union: the General Food Law Regulation passed in 2002 turned risk analysis into a fundamental legal principle. It also became the backbone of the European Commission's version of the precautionary principle (Dratwa 2004). This happened as risk analysis was becoming an international standard. The Codex Alimentarius, the international body for food standards, adopted an international standard for risk analysis, to be applied by national governments that have signed the World Trade Organisation treaty. However, in deciding to circumscribe the powers of the EFSA to the scientific exercise of risk assessment and to retain its powers in the political management of risks, the European Commission departed from the original US approach (Millstone/van Zwanenberg 2005).

This chapter studies the politics of organising scientific advice. Its substantive aim is to try to understand how risk analysis was taken up in the creation of a European food agency, but also why a particular interpretation of it prevailed. In the literature, the restriction of EFSA's competence to risk assessment is commonly explained as being the result of power plays. And that the European Commission prevailed to impose a particular interpretation of risk analysis, thanks to which it could retain most of its regulatory powers. This account fails to explain why the negotiation on the EFSA, however controversial, was couched in this rather peculiar and standardized terminology of risk analysis.

This chapter argues that risk analysis is an institutional standard. A standard is a »set of agreed-upon rules« (Bowker/Star 1999) for making regulatory decisions. Standards are institutions in the sense in which new institutionalists in organisational sociology define them: they are typified and commonly accepted ways of doing things. They inform, but do not suppress, political interests. Institutional standards play a key role in the contentious political episode of the creation of a scientific agency. They provide a common framework and vision of how regulatory activities will be deployed in the new environment. They allow envisioning, and thus negotiating, the powers delegated to scientific experts and the body that harbours them.

The chapter first describes the episode of the creation of the EFSA. It then reconstructs the dominant academic account of this creation process in terms of politics of institutional design. Finally, it discusses the ways in which risk analysis as an institutional standard intervened in the formation of the EFSA. Risk analysis, on the one hand, was commonly accepted as the right depiction of the institutional relations between the future food agency and regulators. The assessment-management-communication triad played the role of an institutional template, a common knowledge thanks to which the designing of the scientific advice body could be discussed. On the other hand, the relation between the different elements of the triad has been the object of strategic interpretations. The risk analysis template was used to legitimise the physical separation between its assessment and management components, favourable to the Commission and those member-states that wanted to restrict the powers of the future EFSA.

1 The Formation of the EFSA

The decision to create the EFSA emerged in a context of political crisis (Clergeau 2005; Millstone/Van Zwanenberg 2005). Following the revelation that the Bovine Spongiform Encephalopathy (BSE) could be transmitted to humans and a thorough parliamentary inquiry into the functioning of the Di-

rectorate General for Agriculture and the Standing Veterinary Committee, the Commission came under very strong pressure from member-states and from the European Parliament. It was accused of being biased towards industrial interests and of giving priority to the objective of achieving the single market over public health. The creation of the agency was a crisis-ending strategy for the Commission, to state its willingness to put safety first and follow scientific advice of the highest possible quality and independence.

The separation of scientific advice from decision-making emerged as a necessity in the aftermath of the BSE crisis, an event that demonstrated the lack of transparency with which scientific advisers to the European Commission imposed policy options. The adoption of a risk analysis framework, by which risk assessment and risk management are separated, represents a clear departure from the previous institutional regime in which the relations between scientists and bureaucrats were too close and their actions intermeshed.

An Agency To Do What?

The proposal to establish a body with some form of separation from the Commission was not new. The first proposal to create an agency dates back to the mid-1980s. It was related to the problem of meat hygiene. Deficient controls in the meat sector were emphasized by a White Paper as well as a parliamentary report in 1985. An agency was seen as a way to strengthen the capacity of the Commission to control national inspectorates and to improve compliance with food standards. The idea of establishing a European agency resurfaced at the end of the 1980s in the context of needing to improve the scientific evaluation of novel foods. It was believed that an agency could moderate the detrimental effects of un-harmonised regulatory initiatives by member-states. However, the Commission showed sensitivity to the industry arguments that an agency would be too bureaucratic and slow down the marketing of novel foods. It proposed instead to step up scientific cooperation between member-states through informal scientific networks.

The creation of a European food agency was called for again in 1997, to demonstrate the Commission's willingness to solve the errors it made in the handling of the BSE issue. That year, Jacques Santer, then President of the Commission, proposed to turn the Commission food safety inspectorate into an independent agency, with support from members of the European Parliament (Valverde et al. 1997). Before getting to the proposed creation of an agency, the Commission sought other solutions, however, more along the lines of its committee-based food regulation. In February 1997, Santer proposed to implement a two-fold reform. It was decided to transform the inspectorate into a separate unit of the Directorate General (DG) for consumer protection (DG XXIV at that time). All food-related scientific committees were

transferred to the same DG. The assessment of risks and of consumer health by scientific experts became a key »instrument« (Commission 1997). This sudden change was linked to the result of an extensive evaluation of the organisation of food control across European countries,[1] as well as to the difficulty to concentrate regulatory functions into an agency and break the modus vivendi existing between the DGs involved in matters of food.[2]

However, these reforms proved unsatisfactory. The committee system was not sustainable. Experts were given too much work while the Commission had troubles coordinating the activity of overloaded committees. Scientific experts started to ask for a more permanent body with greater staff. The proposal of an agency thus resurfaced. The commissioners for consumer protection and for agriculture raised this idea once more in 1998, before the European Parliament.

The Policy Shift Towards Risks and the ›Scientific Instrument‹

It is a context of political crisis that eventually caused the definitive setting on the agenda of the creation of an independent food agency. In 1999, the Commission collectively resigned under the pressure of the European Parliament and accusations of corruption. The nomination of Romano Prodi as candidate for the Commission's presidency in the spring of 1999 was decisive in unlocking the process to create a food agency. He took the responsibility to initiate this process after observing the disastrous consequences of even minor food crises on the career of politicians like Jacques Santer. In June 1999, Romano Prodi announced his intention to create a ›food and drug authority.‹ Prodi put forward the fact that the Commission President should not be held accountable for contaminations in the food chain, like the one that was unfolding at the same time in Belgium (the so-called ›dioxin scandal,‹, in which dioxin-contaminated oil concentrate intended for poultry and cattle feed were distributed in Belgium, Netherlands, and some parts of France). Creating an agency for scientific advice was an ideal solution for shifting the blame. The

1 All then fifteen member-states and the USA, New-Zealand and Canada. The conclusion of this evaluation, made by the Commission Service of Administrative Inspection, was that food control formed part of the core regulatory authority of the European Commission and should not be delegated. In other words, the regime by which food matters were regulated, of which veterinary and sanitary inspections were as important a component as risk assessment is now, no form of delegation appeared appropriate. The Commissioner for Consumer Protection Emma Bonnino came along to visit the FDA in 1997, to come to the conclusion that this model could not be adapted to Europe given the regulatory powers granted to the FDA and its lack of independence.

2 Food hygiene and inspections were of the competence of DG VI (Agriculture). Regulation of novel foods was a competence of DG III. Consumer protection aspects grew in importance as the Service of Consumer Protection was transformed into DG XXIV in 1995.

Commission published a White Paper on Food Safety in 1999 in which this solution was established.

The proposal to create a *European Food Authority* (the name initially proposed by the Commission) came along with an important shift in the framing of the EU food policy. Whereas the creation of an agency had been envisaged for various functions – in the 1980s for veterinary controls, at the beginning of the 1990s to cope with the authorisation and assessment of novel foods, in 1996 for inspection purposes again – the shift towards a science-based concept of food safety resulted in a new understanding of the principles of food regulation: that of being science-based and aimed at consumer health (Demortain 2006). This policy shift can be traced to the BSE crisis that »highlighted the need for a more conceptual approach to food safety regulation; a concept which should define the nature and purpose of risk assessment and risk management« (Vos 2000). The EFA proposal was not an isolated measure. It was part and parcel of the redrafting of the whole EU food law. The ›farm to fork‹ principle and the ›comprehensive‹ approach to food safety oriented the re-engineering of this much fragmented set of regulations and laws. It included the setting-up of a specific food alert system, the reform of all hygiene-related and labelling legislations as well as the inclusion of the precautionary principle in EU food legislation (Beurdeley 2002). The setting up of an agency equates with a complete reorganisation of the regulatory structure and a solution to many of the »fundamental pathologies« of food policy in the EU (Caduff/Bernauer 2006).

This political context explains a change in the overall attitude of the Commission towards delegation. Whereas certain stakeholders had advocated the creation of a regulatory agency with decision-making powers ever since the 1980s, the Commission chose another option: a ›risk assessment‹ agency, more in line with its own interpretation of the European Community Treaty and overall negative stance towards the delegation of powers (Lafond 2001). In this, it opposed the recommendations of three scientific experts, from which the DG Sanco had requested a report on possible arrangements for scientific advice. The three experts and members of the Scientific Steering Committee of the European Commission, Philip James, Fritz Kemper and Gérard Pascal, handed in their report in December of 1999. They proposed a blue print for a truly independent, public health oriented regulatory agency with some regulatory powers (James et al. 1999). A lawyer by background, David Byrne stressed the importance of staying in line with the Treaty and the Méroni Doctrine which forbids the European Commission to delegate powers delegated to it by member-states (Majone 2001; Dehousse 2002). The Commission thus turned down their ambitious proposal in favour of a much more restrictive approach: an agency with competence for food safety rather than public health, and tasked with risk assessment only.

The report of the European Parliament BSE inquiry committee of the Parliament also seemed to open the way for a risk assessment agency. The Parliament positioned itself against the far-reaching authority that the three scientists argued for. In the aftermath of the crisis the main imperative was to separate science from politics or to draw a line between risk assessment and risk management. This imperative of the independence of the agency and the separation between scientific advice and regulatory decision-making guided the choice of possible models for the future EFSA away from existing integrative models, such as the US Food and Drug Administration (which detains regulatory power, see Alemanno 2006) or the European Medicines Evaluation Agency (EMEA).

The opposition between scientists and politicians on the agency's power derived from broader differences in their approach to regulation. Scientific and political actors were in conflict during the process of designing the EFSA, because they have different views concerning the interconnectedness of risk assessment, risk communication, and risk management (Buonanno 2003, 2006). Given the fact that the division of science and management is illusory and that risk assessment is not an objective technical task, this is a never-ending debate (Jasanoff 1987; Vos 2000; Buonanno 2003). The creation of the EFSA reveals the nature of science and the salience of risk issues in modern societies. The imperatives put forward by the Commission in this reform (democratic accountability and transparency; Commission control and management as the most effective protection for the consumer; and prohibition of the delegation of regulatory function under existing treaty provisions) were direct answers to the »principal controversies regarding risk tolerance in modern society« (Buonanno et al. 2001). Since the proposal for a European Food and Public Health Agency of James, Kemper and Pascal was rejected, it may be argued that scientists lost the battle.

2 The Politics of Agency Design

There is a predominant view of the formation of agencies, and of the EFSA in particular, that the actors involved in the designing of the organisation and the choice of its regulatory powers act strategically and instrumentally.

Power Plays

The designing of agencies is inherently political and contentious (Flinders 2004), particularly when it concerns a socially valued matter such as food safety (Hellebø 2004). It is the object of a full decision-making process dur-

ing which inter-institutional conflicts flourish between the Commission, the Members of the European Parliament and member-states. From one case to another, the same contentious issues arise. Vos summarised them: the appointment of the executive director; the composition of the management board; the allocation and control of agencies budgets (Vos 2003). The conflicts and negotiations between principals for the design of agencies could be described as ›constitutional politics‹: Legal doctrines and democratic principles form the basis of arguments which principals, and a number of academics or lawyers, exchange in order to defend their or other's institutional interests. According to that view, the decision to entrust agencies with a limited mandate and powers stem from the wish of the European Commission as well as of the member-states to protect their own power and authority in regulation (Dehousse 2002).

The case of the EFSA is particularly representative of the view of Kelemen, according to whom the design of agencies is the result of a confrontation of institutional interests and of political arguments on the possible organisation of the new body and its legal competence. Kelemen takes the view that the design of the EFSA is the result of inter-institutional negotiations, which are largely influenced by the defence, by each institution, of their power (Kelemen 2002).[3] Indeed, the creation of the EFSA has been a contentious process. The Commission has continuously tried to make it ›its‹ instrument. The member-states specifically tried to ensure they would be well represented on the board. The Parliament managed to make the agency more autonomous but also specified the definition of risk assessment and argued in favour of the topic of animal health to be included in its remit. With the EFSA, the Parliament was for the first time involved in the design of an agency as a ›legislator.‹ It resulted in heightened political challenges and a stress on openness and transparency. The Parliament's role made the formation of this agency a particularly politicised and public process (Kelemen 2002). Historically speaking, the food policy area is one on which MEPs have based themselves to raise the profile of their institution in EU policy-making. Food issues are the core speciality of a number of MEPs, which have been very active early on as the BSE crisis unfolded.

3 According to him, the hesitations of the Commission to create an environment agency are linked to its possessing wide powers in environmental protection. On the contrary, the Commission had little authority in the regulation of pharmaceutical products. Therefore it did not oppose the creation of the EMEA. As the second wave of agencies appeared, the Commission saw the advantage of delegating in order to avoid accusations of being an ever-increasing bureaucracy and to concentrate on long-term planning and strategic policy orientations as its core work. This explains why the Secretariat General of the Commission became much more active in the formation of agencies of the second wave, between 1990 and 1994.

Buonanno and Nugent also argue that the Parliament behaved as a »power maximiser« during this process (Buonanno/Nugent 2002).[4] Over the past, the Parliament used several strategies to raise its profile. Either a maximalist strategy: pressing for major and formal treaty amendments; or an incremental strategy: pushing for the development of informal institutions. The BSE temporary inquiry committee is an example of the first strategy. The Parliament put pressure on the Commission, capitalising on a de facto alliance with consumer representative bodies (Buonanno 2003; Clergeau 2005). With the European Parliament report on the wrongdoings of the Commission in the BSE crisis, the MEPs found a way to respond to the democratic deficit and a formula for reaching Europeans: attacking the Commission. That attack contributed to the resignation of the Santer Commission. The MEPs have been politically opportunistic: the Parliament's power on an independent agency has not been tested while the BSE crisis enabled the Parliament to wrest concessions hitherto unsuccessful with the Commission. The Parliament avoided the creation of a too powerful agency in order to preserve its own administrative powers (Kelemen 2002) and its chances to threaten the European Commission, the control of which is its ultimate institutional aim (Buonanno/Nugent 2002).

Power plays explain that existing institutional models and standards of regulatory agencies are distorted during the negotiations. Most authors agree on the fact that the EFSA is in no way modelled after another agency. Taylor and Millar (2002) are among the rare authors that defended a view more attentive to policy ideas and learning in the process of institutional formation. They argue that the EFSA is modelled after the Food Safety Authority of Ireland, which was put forward as a possible model by the Commissioner David Byrne. But they are the only ones to argue this way. For instance, Roederer-Rynning and Daugbjerg (Roederer-Rynning/Daugbjerg 2004) contradict this idea of cross-domain institutional learning. To them, the EFSA is an unidenti-

4 The paper by Valverde, Cabezes Lopes and Piqueras Garcia – MEPs themselves – shows how closely involved the European Parliament was in promoting food safety reforms since the mid-1990s. According to them, the series of reforms proposed by the Commission in 1997 were going in the right direction, but were to be provisional. They argued already then in favour of the creation of a fully-fledged regulatory agency with extended functions (veterinary controls, novel food evaluation, monitoring of member-states' decisions concerning the circulation of foodstuffs). Its mission would be to provide to member-states and community institutions the best possible scientific advice on any matter related to the evaluation of the quality or safety of foodstuffs. The agency would integrate the functions currently exerted by committees and the food and veterinary office (the Commission internal directorate for food and sanitary inspections). Much like the EMEA, it would be responsible for the opinions delivered while the Commission retains responsibility for actual decision-making. This agency could not be a transposition of the FDA, as Santer suggested in his speech (the FDA does not take care of all ›foodstuffs‹; secondly, the FDA rather resembles a directorate in a national ministry than a European independent agency; thirdly, the FDA has a bigger staff and makes direct interventions) (Valverde et al. 1997).

fied political object. The EFSA does not resemble its US counterpart: it does not have the strong centralisation of regulatory authority, the large resources, and the inspection competence. It does not look like the EMEA, to which it was compared (Demortain 2008), because it neither runs authorisation processes nor raises its own financial resources. The hypothesis that the Commission learned from national approaches is also undermined by factual evidence. Although the separation of risk assessment and risk management is a common denominator for most European countries, some merged these two strands of activities but some did not. Institutional responses to the BSE crisis varied.

The common thrust of most analyses is that rational power-seeking actors choose an institutional design – limited powers or scope and particular rules for control and monitoring – that is most likely to preserve or enhance their power in the future regulatory process. In this view, the procedure of risk analysis, by which decisions on food safety issues are the product of separated stages of risk assessment, risk management and risk communication was instrumental for the European Commission, and European Parliament in particular, to preserve their emerging powers in this policy area.

Institutions Inform Interests

The literature tends to use a ›negative‹ argument: it explains how actors are on a defensive and pro status-quo position and why they consistently refuse the creation of an agency. It does not provide any positive view of how proposed institutional designs emerge. The origin of the proposed design is hardly ever studied, which makes it hard to understand the starting point of the negotiations between principals. Why, for instance, have these distinctive terms of ›risk assessment‹ and ›risk management‹ started to be used after 1997 to formulate the institutional design of a food agency?

The assumption that actors rationally establish their preferences for an institutional design in order to protect or enhance their powers is beyond doubt. However, there is a need to highlight what the parameters are that allow these actors to realise whether an institutional design is favourable or not to their own power. What are the ideas and institutions that inform their interests?

The creation of an agency involves certain effects on regulatory and power relationships that are hard to predict. Creating an agency means creating new participants, new roles and relationships in the regulatory process. Political actors are not necessarily as instrumental and far-sighted as they are depicted in the literature (Pierson 2000). Norms and practices around risk assessment and risk management form a kind of cognitive template (Hall/Taylor 1996), on the basis of which actors interpret proposed designs in terms of the consequences on them and elaborate new ones. It complicates the regulatory

space and disperses resources among a greater number of participants that were not necessarily formally recognised until now. The extent to which these participants – most notably the agency – will be able to strategically gain from the role they are given, to expand and gain more power, is uncertain (Tallberg 2002). The capacity of existing political actors to gain from the new regulatory relationships that are established is also uncertain.

Arguably, this uncertainty is averted through experience of the regulatory process and visions of the future configuration. A knowledge of the behaviour of participants to the regulatory process can be derived from experience to anticipate on how, for instance, regulated businesses might behave towards a central agency or how national regulatory bodies, through their representatives in the newly created central agency, may try to influence the strategy of that agency. Experience and visions of the regulatory process are shaped over time and enable actors to predict and anticipate the effects of institutional creation.

Going even further, one can build here on the vision developed in science and technology studies, in which the identities and interests of actors are defined by a common knowledge – in this case an institutional knowledge of what procedure would be followed to make science-based policies. Institutional identities are fluid and contextual, particularly where they concern actors involved in the production of science and resolution of uncertainties.[5] An institutional set-up is the result of a negotiation of the identity of the future agency between actors with competing cultures, knowledge bodies and experiences which constitute a political order (Waterton/Wynne 2004).

Below, I propose to apply this vision of institutional interests as informed by knowledge and experience of institutional practice. I do this by conceptualising risk analysis – and the separation of risk assessment and risk management – as an institutional standard, or a body of knowledge about the way in which institutions function, expressed in rule-like forms.

3 Risk Analysis as Institutional Standard

In the literature summarised above, the case seems pretty straight-forward: the European Commission, with support from the European Parliament as well as

5 Buonnano opposes science and policy-making in very general and essentialist terms: »Policymakers ask, ›How much will it cost? What constituencies will be impacted? Will the regulation (or lack of) be harmful to producers?‹ Scientists ask, ›How can we prevent an undesirable outcome?‹ Scientists recognize the impossibility of zero risk; whereas policymakers face personal risks when they attempt to convey to consumers the scientific truth; i.e., even the best conceived and implemented regulatory policy cannot ensure zero risk.« (Buonanno et al. 2001: 2).

a few member-states, chose to restrict the powers of the future food agency to risk assessment, retaining risk management in its competences. The adoption of a risk-based framework was an institutional innovation and the advent of a new mode of relation between science and politics. It was imposed by the European Commission in its own interests and in opposition to scientists, confined to a role of risk assessors that should strictly be delimited and differentiated from risk management.

The politics of institutional design approach leaves aside many empirical elements concerning risk analysis and the way in which it mediated, rather than changed, institutional formation. It is better depicted as a commonly accepted standard, rather than as a new distribution of regulatory tasks designed by actors in relation to their political interests. The formation of the EFSA is an episode in a longer process of inducement of risk analysis in the food policy arena. It shows that there has been a continuous crafting of institutional practices by scientists and Commission officials, before and after the creation of the agency, institutionalising the standard from the bottom up. It was the template on the basis of which an institutional design could be negotiated.

Institutional Inducement

The principle of risk analysis was originally elaborated by the National Academy of Science of the United States in 1983. The Codex Alimentarius, the international food standard-setting body that is under the supervision of WHO and FAO, developed a guideline for risk analysis for regulating its own process of setting science-based food standards. The European Commission copied the wording of this guideline in its proposed General Food Law. This results from the fact that the WTO agreements had been signed and the Codex Alimentarius was recognised as the reference organisation in food-related trade conflicts in the meantime. This made risk analysis an international legal principle and increased the pressure on the European Commission to comply with it (Taylor/Millar 2002).

However, the advent of risk analysis in Europe was as much the result of an institutional inducement (Scott 1987) as it was forced compliance. In parallel with the signing of the WTO agreements and the subsequent obligation for the European Union to comply with risk analysis, another channel of inducement was active. Long before the final adoption of a Codex guideline, scientific experts of the WHO-FAO joint expert committee for food additives took up the risk analysis framework. The framework quickly became the standard for science-based regulatory decisions about risk within transnational networks of scientific experts. It is by convening those experts in the mid-1990s that the WHO managed to produce an authoritative version of risk analysis that prepared the ground for the adoption of the Codex guideline.

The European Commission hired some of these scientific experts in 1997, at a time when it sought to reinforce the use of the »scientific instrument« (Commission 1997). In a dedicated risk assessment unit inside the Health and Consumer Protection Directorate, scientists acquainted with the common wisdom of the evaluation of chemical risks in food took on the task to disseminate the risk analysis concept inside the European Commission. In parallel, other scientists sharing this vision socialised their national governments to the framework. There has been a form of political acculturation to the language of risk analysis, diffused by mobile and influential specialists of regulatory science.

The active role of scientific experts is also noticeable in the production of two reports that were important in framing the Commission's thinking. The first of those is the European Policy Centre report produced by a college of corporate scientists from major agri-food companies (EPC 1999). The EPC experts looked at the agencies that were in the course of being created in Ireland, the United Kingdom and France. They summarised the possible designs in the terms of risk analysis and proposed their own set-up to the European Commission through meetings with the cabinet of David Byrne in 2000. The other report is that of the three members of the Scientific Steering Committee of the European Commission. They failed to influence the Commission because they took a too radical institutional option, recommending giving powers to the agency. This proposal was not politically acceptable. However, their report – and the whole preparation of it, involving several civil servants from the European Commission – functioned as a form of institutional socialisation to the standard and a learning exercise on how to appropriately use these internationally received terms.

Institutional inducement is typically the sort of process that standards initiate: the creation of institutional forms by actors who have no formal authority to do so. Scientific experts played the role of carriers of a standard (Scott 2003).

Crafting Institutional Practices

That risk analysis is an institutional standard is also illustrated by the process of crafting institutional practices that continued throughout the episode of creation of the EFSA. In theory, a standard is not simply ›applied‹, but appropriated. It produces its effects through an encounter between an external generic reference for action and endogenous learning processes (Brunsson/Jacobsson 2000). Risk analysis, in its origin, is such a product of an abstract language that allowed producing a generic version of concrete practices. And the further spread of a standard-like risk analysis involves local

acts of organising and rationalising, spurred by the encounter with this generic institutional form.

This took place throughout the formation of the EFSA, from 1997 to 2007. In early 2000, the Scientific Steering Committee endeavoured to harmonise the process of scientific advice across the different domains in which the European Commission seeks advice from scientists – pesticides, novel foods, environmental health matters, emerging risks, etc. It led to an ample review of the experience of scientists and the writing of reports that tentatively established a standard terminology and set of practices concerning risk assessment and its relation to risk management (Scientific Steering Committee 2000, 2003). In the same way, a younger expert of one of these committees observed that the line between risk assessment and risk management was insufficiently clear and that scientists were too often asked to comment on risk management issues. This led to a workshop funded by the 6th European Framework Programme, by which scientific experts, most seniors in particular who were both active in EC scientific committees and went on to become members of EFSA panels, also put in their common experience. A report highlighting ›best practices‹ in matters of risk assessment and risk management was produced after the workshop (Hart 2003), adding to the multiple occurrences of the same thinking around risk analysis.

This process of endogenous crafting and rationalisation of practices was an essential infrastructure of the political debate on the EFSA. The shared imperative at the European Commission and elsewhere was indeed to restore the independence of science from politics and the transparency of scientific advice by instituting a physical separation between risk assessment and risk management. The difficult question of whether this separation should be functional (carried out by different people inside the same organisation) or physical – an issue that is as old as the risk analysis concept itself as the founding discussions of the US National Research Council show – never really surfaced. The second option was clearly preferred.

As said by one of the three senior scientists consulted by DG XXIV, »the main thing was to separate risk assessment and risk management, and there was a broad agreement on that. We thought it would always be time later to organise the interaction between the two.«[6] In essence, this means that the political decision to take the risk analysis principle in one particular sense (the physical separation of risk assessment and risk management, the latter embodying the political component of risk analysis) was dependent on the existence of an underlying set of practices and ways of doing things, crafted by the bureaucrats and scientists who practiced risk assessment and risk management – rather than by the stakeholders (government representatives, MEPs, Commissionners) who negotiated the institutional design of the EFSA.

6 Interview with the author, September 2003.

And indeed, a couple of years after the launch of the EFSA, the difficult relationship between its Director Geoffrey Podger and the European Commission did not prevent Commission and EFSA officials to create the conditions for a smooth day-to-day cooperation. They invented and applied their own routines and recipes for collaboration, emerging from practice and catalysed under the label of risk analysis.[7]

Negotiating the Template

Risk analysis has a history which shows that it has always functioned as a generic depiction of the relation between science and decision-making. It offered a language to describe the various ways in which this relation could be organised.

The concept permeated parliamentary and think-tank reports, interest group position papers and Commissioners' speeches. All institutions and stakeholders agreed on delegating risk assessment, even though some disagreed with the idea of leaving risk management to the European Commission – most notably multinational agrifood corporations, much concerned with the politicisation of novel food authorisation procedures. Comparisons with food agencies of other countries and ways of separating risk assessment from risk management were also extremely frequent. As noted above, the Commission administrative inspectorate evaluated all national models of organisation of food control as well as the food agencies of the USA, New Zealand and Australia. In the dedicated ›Friends of the Presidency‹[8] group of member-state representatives that digested the Commission's proposal before its negotiation in the Council, the risk analysis template helped to bridge the experience of national governments and the specific institutional forms and legal design of the administrations in charge of food safety in their country.

While the risk analysis talk was unused until the mid-1990s, it became central to the interpretation of the BSE crisis under the Prodi Commission. The concept supported the retrospective interpretation of the cause of the crisis. The accepted narrative expressed by the European Commission, scientific experts, interest groups, members of the European Parliament as well as consumer groups was that an insufficient separation of risk assessment and risk

7 For instance, allowing a Commission official to attend the relevant meetings of scientific panels with no right to intervene in scientific discussions of cooperation except for clarification of the legal dimensions of the topic; or requiring Commission officials who send a request for opinions to the EFSA to copy their colleagues of the ›interface with EFSA‹ unit in their emails, for the latter to verify if the request is couched in terms that can be processed by the EFSA to formulate precise scientific questions.

8 The member-state that holds the rotating Presidency of the Council of the European Union has the possibility to pause the decision-making process and to establish a special expert group to discuss a Commission proposal.

management (the capture of DG Agriculture by British veterinarians) led DG Agriculture to ignore the emerging mad cow problem. The blurring of responsibilities now causes consumers to lose confidence in institutions and policies. Hence, separating risk assessment from risk management would logically restore consumer confidence.

In other words, there were two separate aspects in the emergent design of the EFSA and of the relation between scientific expertise and regulatory decision-making. The concept of risk analysis was the commonly accepted depiction and the template through which the various options got articulated. And neither risk analysis, nor the ambiguous and interlinked terms of risk assessment and risk management, prescribed the adoption of any of these options by themselves. The choice to adopt one of these options was, on the contrary, a manifestation of strategic action.

This is where instrumental action resurfaces. Laying out its choice to not give regulatory powers to the EFSA in the colloquial language of risk assessment and risk management helped the Commission to justify its decision to retain powers. Risk analysis had the virtue of being principle-like: it could be promoted as a basic prescription of food law. As a horizontal principle, it cut across the domains of the different DGs involved in food regulation and pacified their relations. It was in line with the preservation of the Commission's authority. The Commission's *Inspection Générale des Services* recalled in 1996 (when Santer first envisaged the creation of a new agency) that there is no absolute best design for an independent regulatory agency. A good design is one that respects the architecture of regulatory powers and preserves the core authority of the European Commission. That prerogative that embodies the regulatory authority may not be delegated. The Commission has never stopped following this line. It has decided to consider that ›risk management‹ was the essential and core competence of a politically accountable public authority with regard to food.

This strategic use of risk analysis is noticeable in the transformation of a rather neutral and *procedural* concept of risk analysis that keeps various options open for the interaction of risk assessment and risk management, into a *substantive* definition of the respective authority of scientists and politicians.

4 Conclusion

In contrast with the idea that the separation of risk assessment and risk management has been adopted by certain actors against the will and interest of others, notably scientists, this paper emphasized the fact that such a separation was a way to implement a shared concept and institutional standard, that of risk analysis.

Analysing the institutional conditions in which scientific advice operates should not solely lead to emphasizing power plays. Politics do not only transpire from rational and instrumental action of stakeholders with distinct interests. They are also at play in the existence of shared ideas and institutions that frame political life. The emphasis on interests and power plays in the literature on delegation to independent agencies often seems to be a way to recall, above and in spite of what social actors actually say and do, that science is overridden by politics; that what scientists want – a right to manage risks – is impossible to obtain through institutional games in which they are powerless. This vision is underpinned by an essentialisation of what science and politics are, as if they had nothing to do with one another. There is a fair amount of common knowledge that unifies the two sides. What I have described as an institutional standard may as well be called a »civic epistemology« (Jasanoff 2004) or a political culture. It highlights the fact that the practices, protocols and knowledge which constitute regulatory science build bridges between both worlds and are the instruments through which a political order is produced.

There obviously were tense political conflicts involved in the creation of the EFSA and in the decision to restrict the powers of the agency to risk assessment, however ambiguous this delimitation is. These conflicts did not oppose scientists and politicians as much as they opposed two modes of organising the science-based regulatory process. One that is based on standards which incorporate a common knowledge of processes of scientific advice; and another mode, commanded by the political circumstances of the BSE crisis and of transnational food regulation, which works through law. In the latter, practices and procedural know-how get juridicised. They turn into a political ontology that prescribes identities to researchers and bureaucrats of being ›risk assessors‹ or ›risk managers.‹ This shift can be resisted and is a source of conflict. It is precisely what happened during the highly contentious and public episode of the creation of the EFSA.

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