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The Many Meanings of 'Standard': the Politics of the International Standard for Food Risk Analysis

David Demortain

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Abstract

This paper deals with the creation of international procedural standards. It studies the case of the international standard for risk analysis in food safety. The main argument of the paper is that the creation of one standard in one particular arena can reflect a diversity of relations to centrally composed rules and projects of harmonization, or regulatory languages. It is not sufficient to have a pre-established model of risk analysis, diffused by transnational experts, for a standard to be set. Creating a standard requires bridging the different regulatory languages that are expressed through the model. The emphasis on 'principles', or generic provisions, as a strategy to set standards - that is representative of the contemporary expansion of standards (Brunsson and Jacobsson 2000) - can be explained as such a strategy of reconciliation. The paper studies both the origin of the risk analysis model, the two distinct relations of transnational experts and of governments (that of Tunisia in particular) to the model, and the production of a standard in the Codex Alimentarius (with particular attention to the positions of the Tunisian delegate), to highlight this presence of politics in international standard setting.

Keywords

Risk analysis, standard, expertise, regulatory languages, Codex Alimentarius

Introduction

Standards have become key instruments of regulation, and of risk regulation in particular. Standards are abstract, principle-like rules presented as voluntary that leave a lot of decision making to the users of the rule. They are produced by organizations such as professional associations, inter-governmental and non-state international bodies, which have no power of enforcement but use expertise to develop and disseminate these rules (Brunsson & Jacobsson 2000). Many of these standards or 'rational designs' (Power 2007), which establish generic principles, are used in risk regulation.

Risk analysis is an example of such a rational design in environmental health and food safety. The existence of risk analysis as a decision-making framework in these domains dates back to the 1970s. A report of the National Research Council (NRC) published in 1983 (the so-called Red Book) argued that decisions in a context of uncertainty should be based on a dialogue between risk assessors and risk managers, because political and scientific arguments are hard, if not impossible, to disentangle. It also codified the procedure of risk assessment. The risk analysis framework later became a key principle of the international trade regime, embodied in the 1994 SPS Agreement (the sanitary annex of WTO agreements) and in a guideline of the Codex Alimentarius, the international body for food standards[1]. Although many governments had decided in the meantime to establish an institutional separation of risk assessment and risk management, against the recommendation of the original model, the Codex guideline simply reiterates the principle that risk assessment and risk management must be 'functionally separated, to the degree practicable', but without attempting to correct local misinterpretations. The Red Book thus remained 'mis-read' (Mirer 2003, North 2003).

This situation only confirms that, in standardization, a lot of the details are left for users to decide upon. Abstract rules are attractive for the very reason that they respect the autonomy of users. The resulting situation is that practices on the one hand, and ideas or 'accounts of practice' on the other, live independent or parallel lives (Brunsson et al. 2000, Brunsson 2002, Salhin-Andersson and Engwall 2002). In the words of Mike Power, 'the reality of local variety, of local scripts which translate generic models into operational practices, is not inconsistent with an observed isomorphism at the level of designs' (Power 2007). I will return to this topic and examine its puzzling nature. Quite simply, why is the choice made to craft general and abstract rules, which increase the probability that users of the rule may deviate from the intention of rule-makers? Why are non-prescriptive rules used as 'instruments of control' (Brunsson & Jacobsson 2000)? Although standard setters lack enforcement powers, they also often have the means to be prescriptive. The setting of standards is inseparable from legal regimes or the benefits of the action of third-party enforcement bodies. Standard setters have the legitimacy of

[1] The full title of the standard is 'Working Principles for Risk Analysis for Food Safety for Application by Governments'.

expertise and, more frequently, of representative institutions, since they give a central place to users. Lastly, given the potential misinterpretations of standards, standard setters have good reasons to try and be more precise in their prescriptions. For all of these reasons, it remains hard to understand why standard setters do not opt for rules that are more prescriptive. The choice between different sorts of rules or modes of prescribing practice remains to be examined. How are choices made for one particular type of rule and mode of prescription in international rule-making? Are 'standards' such a straightforward and evident solution?

In contrast to an approach in which standards and the expertise they are founded upon can be objectively defined, this papers highlights the fact that participants in projects of harmonization have different practical experience and references that relate to practices going on elsewhere. They also have different positions or interests concerning the level of harmonization to be achieved. In other words, in order to set their views on how and what to prescribe, actors mobilize different regulatory languages. And regulatory languages, although shared to some extent, are by no means unique. They coexist and compete, and need to be bridged for a standard to be set.

The case of risk analysis is precisely one in which two regulatory languages coexist and need to be bridged through the sharing of more references about practices of risk analysis, so that a common position concerning what and how to prescribe can be reached. Historically, the model of risk analysis has always contained two distinct positions about the virtue of rules. According to the first, local conventions are the best possible way to regulate the relation between science and politics, and standards should be limited to providing generic notions to help fabricate these local conventions. The other sees set procedures as the best way to produce objectivity, and advocates a much more prescriptive standard of risk analysis. These two languages were present in the arena that created an international standard for risk analysis, the Codex Alimentarius, a joint inter-governmental body of the World Health Organization and Food and Agriculture Organization (below, the Codex). During these negotiations, the focus on 'principles' is not so much the reflection of the dominance of one given expertise, but a strategy to demonstrate the acceptance of the variety of references and positions involved in the negotiation and the need to work to bridge them.

How are abstract rules selected as instruments of control?

I. The legitimacy of abstract rules

The SCORE approach to standards, based on neo-institutionalism, is the most insightful approach in understanding why maintaining the integrity of a principle-based framework seems more important than the attempt to correct through more precise rules. Standards are rules of a particular type: they spread because of the 'general, abstract and timeless ideas' they are based on (Brunsson et al. 2000). This is particularly the case in procedural standards: they provide plans and processes to achieve a generically defined goal and satisfactory result. Operations are concretely devised at the local level rather than inscribed in detail in the standard.

As they are not very prescriptive, those rules are highly legitimate, because they respect the autonomy of users and fully transcribe or store an expert and authoritative knowledge. Standards, in this regard, betray our belief in abstract, Cartesian or theoretical knowledge (Brunsson & Jacobsson 2000, Jacobsson 2000). This conceptual knowledge embodies a form of ideal rationality and the means to reach highly desirable goals (Meyer 1996, Meyer and Boli 2001). Standard setting is a natural consequence of the codification and abstraction of managerial knowledge (Strang and Meyer 1993, Suddaby and Greenwood 2001) as well as the action of institutional carriers that detach knowledge from sites of practice (Salhin and Engwall 2002, Scott 2003). Expertise not only detaches knowledge from the messiness and variability of practice, but also protects standards from it. Expertise is an excuse to refrain from organizing feedback from users (Jacobsson 2000). Standards thus benefit from a form of organized infalsifiability. Local deviations from the principles do not seem to interfere with the perceived value of these principles.

In a nutshell, standard setters opt for generic and abstract rules because these are the sorts of prescriptions that their resources – mainly expertise – allow them to impose. If they want to become more prescriptive and authoritative, they then need to gain legitimacy, for instance by becoming more open to users (Hulsse and Kerwer 2007).

This approach is founded on a particular premise, that of the objectivity and autonomy of expert knowledge. This assumption is problematic: it overlooks the construction of a particular relation between practice on the one hand, and knowledge of this practice on the other, within the course of standard setting. It should be considered that, for a standard to be set, there must be a certain degree of shared knowledge; knowledge about practice and about the effects of different types of prescription relating to this practice. In other words, any act of standard setting is determined by common representations of what the target of the rule is, and how users react to rules. Common cognitions and references, as well as practical examples and a whole history of standardization, guide the choice for particular formulations of ideal practices. This knowledge, however expert, is constituted by users or comes into contact with users. It is experience as much as abstract knowledge.

There is much more politics in the construction of an expert knowledge than has been assumed in this literature. In studies of standard setting, the claims to expertise made by standard setters are not considered worthy of investigation. The commodification of knowledge is presented as a 'linear and non-problematic' process (Heusinkveld and Bemders 2005), ignoring the insights gained by the sociology of science that any expertise or knowledge claim is contextual, and that what counts as context is contested (Nelkin 1984, Fritsch 1985, Wynne 1989, Edmond 2004). In other words, managerial knowledge – and the ensuing choice for abstract principles as a mode of prescription – does not seem to involve politics[2]. For all its recognition of the autonomy of users and

[2] Or politics only surface in the local use of standards (Mennicken 2008, Hodgson and Cicmil 2007). Of course, the literature has long recognized the ability of local actors to produce local arrangements on their basis (Thoenig 1991, Brunsson and Jacobsson 2000, MacKenzie 2006, Seidl 2007), but has seen this as

limited effectiveness of standards, this literature remains decidedly top-down. It continues to assume that some autonomous and set principled idea can command consensus and naturally install the appropriate distance with practice.

II. Accounting for the ambiguity of standards

In this paper, I try to account for the existence of common references and positions about prescriptions, which I name a regulatory language. A regulatory language is a set of references and positions that determine how actors behave and act with regard to the construction of a rule. Actors, when involved in the creation of a rule, use such languages. They defend a particular view of what should be explicitly included in the rule and the degree to which it should prescribe those practices.

Studying regulatory languages does not mean studying speech or discourse (Thoenig 2006, Lemieux 2009). It is up to the analyst to find proof of the existence of a language, which may or may not be observable as such. The fact that languages are shared does not mean they are unique. And as a matter of fact, the diversity of regulatory languages is more often the rule than the exception in standard setting. These different languages come into confrontation in standard setting. One genuine specificity of standardization is the fact that prescriptions and the nature of the rule that is being set are negotiated to get closer to what is received as law, or, on the contrary, as an internal professional or social custom.

The advantage of this theorization of standard setting expertise is that it leaves space to consider that there are various relations to rules and strategies of standardization that may be expressed within one common standard setting enterprise. Expertise is not an unequivocal knowledge that provides authority to particular descriptions of practice, but a language that is shared by a more or less large circle of participants, which contains references and positions about the practice to standardize and the necessary prescriptions to impose to achieve this. The case of risk analysis is a direct illustration of this fact.

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posterior to the adoption of standards. It was never considered to be the expression of an ability to take part in the setting of a standard. One reason for this lack of interest in the politics of standard setting is empirical: neo-institutionalist studies prefer to look at cases in which practitioners, standard setters and experts come from the same organizational field (Powell and Di Maggio 1991). Cases in which claims about the reality of practice in the field are multiple, such as in multi-professional (Ferlie and al 2005) or divided fields (Spee and Jarzabkowski 2009), but have been less frequently examined. Furthermore, research has focused on either the creation or use of standards, not on how this use is followed by participation in standard setting (Elligsen et al. 2007).

Rules against risk: the duality of risk analysis[3]

The risk analysis framework is not a model that stands apart, transported across time and space to be converted into a formal standard of the Codex Alimentarius. It only exists through two languages that give form to its prescriptions. In one version of risk analysis, it takes the form of a set procedure that lends itself to worldwide harmonization. In another version, risk analysis is approached as a set of generic notions that nominally influence local conventions. These two languages are present at the origin of the framework, in the National Research Council report. This section firstly examines the report and traces the presence of these two languages. It then shows how these materialize through two parallel streams of harmonization: the alignment of a professional risk assessment community on a four-step risk assessment code; and a nominal and local use of the risk analysis scheme by governments. Finally, this section details the discussion that took place in the Codex Alimentarius to show how these two languages were bridged through generic principles.

I. Two forms of 'Risk Analysis'

Set procedure and open framework

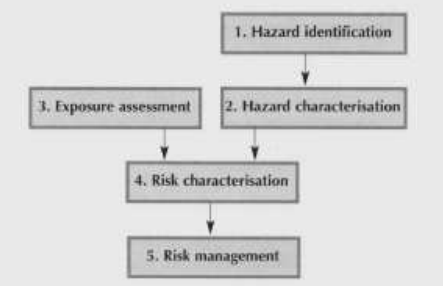
The risk analysis discourse, as expressed in the literature about food safety or in the words of scientists and officials, is dual. The duality of the discourse is evident in the following extract of a paper by a specialist of food safety assessment:

> Risk analysis is seen to consist in three interlocking components: risk assessment, risk management, risk communication. The identification and characterisation of possible hazards is the starting point for risk assessment, which, when coupled with the likelihood of occurrence or exposure, gives a measure of risk. […] Risk management then considers how any assessed risk could be reduced […]. Finally, in an ideal and wholly rational world, the process is completed by a cost-benefit analysis in which economic, social and ethical issues are considered and introductions weighed against the cost of inaction (Chesson 2001).

[3] Three sources are used here. To study the composition of the risk analysis framework in the NRC, I studied closely the Red Book itself and the recollections of members of the Red Book committee published in the journal *Human and Ecological Risk Assessment*. Some information was drawn from an exchange of email with the chair of the NRC committee. Secondly, I included data about the local use and effects of risk analysis in the reform of Tunisian food safety policy. The Tunisian reform was studied through documentation and a five-day field trip during which key administrative and technical actors involved in the reform were interviewed. Prior to this field trip, the opportunity to study the Tunisian reform locally *and* follow the Tunisian delegate during Codex negotiations is the most precious and original data that this paper uses, to understand how dominated users take part in a standard setting exercise. Finally, this paper looks at the elaboration of a risk analysis standard in the Codex Alimentarius, that both builds on the NRC report and accommodates local variations. To study this process, I attended the three-day Codex working group mandated to draft the risk analysis standard. I took precise notes of all the discussions and did interviews in the margins of this meeting. Reports of annual Codex CCGP sessions from 1991 to 2009 were used, as well as a background paper prepared by the chair of the Codex working group, which traced the whole history of the standard within Codex.

References to a risk assessment protocol ('starting point', 'risk management *then* considers', 'the process is completed') coexist with a less linear view of risk analysis and of its '*three interlocking components*'.

Risk analysis, when used to designate the more particular exercise of risk assessment, is a procedure: a succession of steps which, when followed and carried out in an orderly manner, leads to appropriate risk management decisions. Deploying these four sequences in their received order is the best way to formulate a risk in the most objective way, under the form of an exposure/damage curve and with explicit assumptions to compensate for the plausible lack of data on certain items. The execution of the procedure shapes a decision, which flows from the first four steps. Graphically, the discourse takes the form of a downward succession of steps that lead to and determine risk management (Benford 2000).



As a procedure, risk analysis creates a hierarchy between science (the four steps of risk assessment) and decision-making (risk management), and contains a theory of science as an objective aid in policy-making. Science comes first in the sequence of operations that lead to a decision.

This discourse reflects a particular vision of uncertainty and of the value of rules in managing it. In Theodore Porter's *Trust in Numbers* (Porter 1995), 'mechanical objectivity' refers to the application of replicable procedures as the best way to produce public trust in scientific evaluations and reduce scientific uncertainty. This instance of the risk analysis discourse is typically mechanistic. The deployment of a replicable procedure is taken to shape appropriate and legitimate political decisions about risks. The transparency, predictability and sequencing of various actions that comprise the procedures are key elements in that respect. In this light, and at least since Chauncey Starr's seminal paper (Starr 1969, Hacking 2003, Fabiani 1987, Burgess 2006), risk is defined as a combination of hazard and probability. In other words, the object of risk is defined by an act of calculation (the 'x probability'). It is this very act of analysis that defines risk. As an object, risk comes with analytical technologies attached to it, making it difficult, or impossible, not to follow up the qualification of a given issue of risk by a call for more analysis (or 'evaluation' or 'assessment').

Altogether different is the other facet of risk analysis as a set of 'three interlocking components' – risk assessment, risk management and risk communication – as in this picture (WHO 1995):

The use of a Venn diagram symbolises the fact that assessment, management and communication are three equal components of decision-making. The risk analysis discourse, in this instance, does not establish an operational order, much less a hierarchical one. It recognizes that the scientific process is imbued with policy and political assumptions – risk management. Science and politics cannot be disentangled (Jasanoff 1987). Risk assessment and risk management, therefore, are not the respective jurisdictions of scientists and bureaucrats. These are categories of understanding, by which regulatory actors can label an argument as 'mainly scientific' or as belonging to the realm of values and policy choice. Risk analysis is a classification that enhances the capacity to locally disentangle scientific from policy and moral arguments. It is a *code of conflict* rather than a *code of conduct*: one that explicates the conflict between science and politics (rather than prescribes what constitutes a scientific and a political argument) and provides a shared terminology to unravel it.

The epistemology that underpins this discourse is in strong contrast to the other epistemology presented above. Uncertainty cannot merely be reduced to a data gap, to be compensated for by default assumptions and probabilistic assessments. Uncertainty has an ontological dimension: it is linked to an irreducible variety of pre-existing world views and values, to the extent that any knowledge is contextual and can only convince those that are part of the same context. Risk is not an objective calculation based on a formula, but the outcome of a collective deliberation on what is known and what is not known – which is inseparable from what is morally and culturally accepted and not accepted. No set procedure imported from another context can resolve this uncertainty. Only local deliberation and the patient construction of shared conventions of truth and proof can do this.

A lasting duality

The framework and the procedure are not two applications of an overarching concept. They are two distinct statements about the relationship of science and politics and the management of uncertainty. They are both expressed in what is taken to be the origin of the risk analysis framework, the Red Book. The NRC report has indeed been praised for two very distinct outputs. Firstly, it is the first to have recognized that science and politics cannot be distinguished from one another, and that it is useless to state the predominance of one over the other. A 'science-based' decision-making process cannot mean 'science first'. Science and politics must be in constant dialogue throughout the process. Hence, the main recommendation of the NRC report: risk assessment and risk

management must be distinguished from one another, but not separated by organizational trenches. The other output is the risk assessment code, underlined by a different philosophy: science is distinct from politics, as it provides objective assessments. Guidelines can be a useful instrument to stabilize and standardize these assessments, and consistently arrive at accepted decisions.

In keeping with the first recommendation, the authors of the report showed reluctance to prescribe particular organizational set-ups, in the direction of either separating or merging RA and RM. The committee rejected the possibility of standardizing the decision-making process across the agencies it considered (the Environment Protection Agency, the Food and Drug Administration, the Occupational Safety and Health Administration). To that end, they emphasize the contextual dimension of these decisions or the fact that they are made 'case-by-case'. The Red Book did not create a hierarchy of operations, nor did it order them as the sequences of a linear protocol (North 2003). The report provided a generic terminology to codify the knowledge of how to run the process, a knowledge shared by actors on both sides of the boundary. According to the official from the NRC who chaired the committee:

> What the Red Book did, arguably, is help people see that risk assessments are inherently overlays of scientific and political factors; thus, neither scientists nor politicians can legitimately claim that they deserve the upper hand in performing them. In prior discussions, this was not clear to either group (Correspondence).

In this light, the contribution of the report does *not* lie in its effort to harmonize a procedure. And it cannot be reduced to being the point of origin of a scheme that was later diffused to the rest of the world. It was to have been a site in which the value of local conventions for the management of uncertainty was recognized. Reading the recollections of the members of the NRC committee, it appears that this rather extraordinary outcome is due to the diversity of profiles and epistemologies represented in the committee (Davies 2003). The committee managed to overcome this diversity by entering a process of systematic explication of what risk, risk assessment and risk management meant to all, trying to progress towards a common terminology. The framework articulated in the NRC report is the outcome of this internal clarification (Merrill 2003). Risk analysis here is an outcome, the product of an internal attempt to codify the knowledge that is common to the participants of a given local scene.

However, a more mechanical approach to risk analysis is *also* contained in the initial NRC report. One of the main outputs of the report, and a lasting one, has been its codification of risk assessment, defined as the analytical part of the regulatory process. The report defines risk assessment as a sequence of four neutral operations – hazard identification, dose-response assessment, and exposure assessment and risk characterisation (Krump 2003). Regulatory decision-making – hence politics – is not part of the protocol. The frontier between science and politics is dealt with separately in the report, under the first recommendation to distinguish, at least conceptually, RA from RM.

While the report emits a sort of negative recommendation concerning the organization of the RA-RM interface – to remain 'conceptual', as seen above – standardization is part and parcel of this enterprise of codification, which is seen by many members of the committees as its most important and successful contribution (Johnson & Reisa 2003, Krump 2003). The code has the virtue of simplicity and elegance. It has rapidly overtaken another code (comprised of three sequences of 'identification of hazard', 'characterization of risk' and 'reduction of risk'), which had failed to convince practitioners (Omenn 2003). In the NRC committee, the contribution of those with experience in assessing products and industrial dossiers was instrumental. The four-step code is the result of their attempt to review, synthesize and standardize their experience in the matter to produce a scheme. And while the report remains conceptual and defers to local actors on how to assemble and articulate RA and RM together, when it comes to RA alone, the recommendation is to establish uniform guidelines, on the basis of which the risk assessment activities of the various agencies could be monitored and approximated. The inference guidelines were the method chosen by the committee to enforce the RA-RM separation (Davies 2003).

II. Two relations to expert risk analysis

Risk analysis contains two distinct discourses, which value differently the creation of rules to manage the contentious science-policy interface. Risk analysis standardizes in two ways: through the diffusion of a set procedure of risk assessment, as well as through the generic use of its constitutive categories. The two epistemologies are used as references and positions towards the central composition of rules, as shown by the trajectory of risk analysis after the Red Book.

The diffusion of the risk assessment procedure

By the turn of the 1990s, the four-step code of risk assessment had become an internationally accepted principle, to the point of becoming a key instrument of the international trade regime (Horton 2001). The reform of the GATT Agreement inaugurated in the mid-1980s consecrated risk assessment as an instrument to regulate trade. National decisions to block the import of a product must be based on formal scientific methods, establishing the probability of the hazard to the population. This testifies to the success of the diffusion of NRC's code for risk assessment. Scientific advisory committees of the World Health Organization (WHO) and Food and Agriculture Organization (FAO) next took up the risk analysis framework. Some scientists who participated in the elaboration of the NRC report were also members of the Joint Expert Committee for Food Additives of the World Health Organization and the Food and Agriculture Organization. Risk assessment specialists took part in the working group convened in 1988 to draft the SPS Agreement, as well as in FAO and WHO 'expert consultations'. Several members of the 1983 NRC committee were among those experts (Debure 2008).

International agreements and standards prolong the codification of the expertise of the emergent risk assessment profession (Demortain 2006, 2009). Toxicologists are particularly prone to defending the orthodox application of the four steps of risk

assessment. The procedure pertains to this abstract knowledge that is so crucial for occupations to differentiate and insulate their expertise (Friedson 2001, Abbott 1988). The creation of the Society for Risk Analysis was contemporary to the meetings of the NRC committee. Several members of the NRC committee were closely involved in the series of meetings that eventually led to the foundation of the professional body. A prominent place was given to issues of chemical safety, and to the professional conception of risk assessment shared by toxicologists (12 out of the 34 founders of the Society are toxicologists or biochemists). The Society's official journal has been a key vector for the confirmation and diffusion of the orthodox view of risk assessment as a four-step process. The defence of the integrity of the code and its diffusion are also noticeable in the work of the International Life Science Institute (ILSI), an agro-food and industry-funded regulatory think tank. The successive publications of the ILSI both in the US and in Europe all build on the orthodox risk assessment code. The code is now used for the evaluation of the safety of genetically modified foods (Konig et al. 2004, Levidow et al 2007). The content of the code has not changed in 27 years.

The generic use of risk analysis

The development of an international legal trade regime meant that governments around the world had to acquire risk analysis and risk assessment as part of food safety regulatory practice. This did not equate with the imposition of an institutional architecture, much less a procedure. It provided a common discourse to explicate the existing situation and play political games around local institutional reforms.

Many Tunisian civil servants participated in FAO or Codex meetings, dedicated to diffusing the orthodoxy of risk analysis and food safety systems within developing countries. A more compelling development was the adoption in the European Union of the so-called 'General Food Law', a regulation that established risk analysis as a fundamental legal principle in 2002. Later on, Regulations 582, 583 and 854/2004 on food hygiene and controls required countries exporting foodstuffs towards Europe to comply with EU legislation. Since Europe receives 80% of Tunisian food exports, the President of Tunisia requested in 2004 that a general food law modelled on the European one be adopted.

The risk analysis principle encountered a conflictual local situation. In 1999, as the BSE crisis unfolded in Europe and led to administrative reforms, the Tunisian government created a specialized administrative agency for food safety to emulate European countries and demonstrate effective commitment to securing foodstuffs. This agency, a body of the health ministry, was tasked with missions related to food control (not risk assessment, as in European countries): to ensure compliance with national and international sanitary rules for control of food and other products, to arbitrate in case of conflicts relating to the procedures and results of tests and analyses made on those products. In other words, the agency is tasked with coordinating and improving the efficiency of the action of control bodies of the health, agriculture and economic affairs ministries. Quickly after the creation of the agencies, this legal design proved to be a source of conflict. Most bodies of control refused to recognize the authority of this agency. The people chosen to run the agency approached their tasks ambitiously and started head-on to establish projects for

the reform of sanitary controls. They undiplomatically displayed their willingness to appraise all control bodies and reallocate domains between the different ministries. They regarded part of their mission as being to collect laboratory data and make epidemiological analyses, to establish priorities in other ministries' control plans.

Far from a mere import of the concept of risk analysis, the process of drafting the Tunisian food law became a hostage of these political conflicts. The preparation of the law started under the aegis of a technical committee that availed itself of European funds to hire a French expert in food regulation. Several parallel meetings were held with the various ministries involved so that a division of labour could be agreed upon. Indeed, modern food law is a substitute for a horizontal functional approach – food safety is conceived of as the result of a 'food safety system' comprised of a series of inter-related functions: food control and analyses, risk assessment, self-control and hygiene at the industry level, risk management, etc. Typically, veterinary and consumer fraud inspectors, until then responsible for separate sectors of the food industry (primary production on the one hand, distribution on the other, although this distinction by no means avoids jurisdictional conflicts), are now supposed to redefine and explicate the division of labour between them, as they co-constitute the control function. The same thing is supposed to happen between bodies in charge of risk assessment and those in charge of risk management functions.

The RA-RM distinction rapidly proved useful to all actors of this policy sub-system. The ANCSEP picked up the terminology to defend its position. It argued that the European Commission expected to have a single risk management body, nominated in Tunisia, to be its correspondent. This was clearly an argument in support of the contentious 'coordination' task entrusted to the ANCSEP. Other ministries denied the existence of a coordination issue. In their view, the law allocated well-delineated domains to each service. Gaps and overlaps were not that abundant. The consumer affairs ministry boasted of its 'risk management strategy'. The health and veterinary ministries both argued that 'risk management' was what they had always done, and that it was merely a new label to put on their activities. Consistent with this, they mobilised the notion of risk assessment to corner the agency. They argued that they always thought the ANCSEP, since its inception, should be a risk assessment agency as in European countries. Risk assessment was its true role, not a coordinating mission chosen *a posteriori* to find a legitimate role for this newly created body. Another ministry emphatically explained that, even though food hygiene should first be tackled before highly unlikely risks of chemical contamination by exposure to, say, food additives, risk assessment is an imperative. According to the head of inspection in the health ministry, 'the answer to our problems lies in evaluation' (interview with the author). The consumer affairs ministry similarly accentuated the need for help from a body that is able to assess 'hidden' risks (idem). Continuing in that perspective, they try to implement a shift in the meaning of the 'coordination' imperative: official laboratories, not inspectorates, must be coordinated to produce comprehensive analyses.

Nowhere was the internationally received risk assessment code taken up. Quite the contrary even, the ANCSEP put forward the fact that Tunisia has neither any motive nor resource to undertake more risk assessment. The population of food scientists in Tunisia

is rather small. A lack of financial and material resources bounds the activities of official laboratories. Data needed to perform any local assessment about the prevalence of a given disease is missing. Scientific work is limited to evaluating the results of inspections, the prevalence of certain contaminations – i.e. basic epidemiological work rather than predictive and probabilistic risk assessments. In this context, the meaning of 'risk assessment' drifted towards the appraisal of inspectorates or the review of the data they gather.

In other words, the local situation commands a strategic use of risk assessment as a generic rubric of administrative activity to institutionalise the jurisdictions of different ministries and services. It is because of the RA-RM distinction it contains that the risk analysis is adhered to. It is mobilised to justify, ex-post, the structure of a polarised politico-administrative system and entrench the ANCSEP and other administrative bodies. Risk analysis is simply a set of categories through which local political conflicts and institutional architecture are made explicit.

III. Negotiating prescriptions

The above shows that behind a more or less coherent discourse of risk analysis are hidden two distinct sets of references about food safety regulatory practice and positions concerning the value of set decision-making procedures. In the first language, risk analysis matters because of the invariable code and procedure of risk assessment it contains. In the second language, risk analysis is seen rather as a framework made up of categories that have a generic sense. They can be used to re-label existing processes and the institutional architecture in which they normally take place. The decision to create a standard for risk analysis in food safety by the Codex Alimentarius emerged at the end of the 1990s, but materialised only in 2005. This outcome, which was a long time coming, is explained by the difficulty in reconciling the two languages, or in recognizing the variations in the local use of risk analysis, within a project aimed at setting an invariable procedure.

Experts and Codex's agenda: 'Consistent and orderly decision-making'

The SPS Agreement prescribed that, although sovereign, governments should base their decisions on science, and do this in a transparent way. Risk assessment processes came about as the criterion against which scientific assessments of health threats put forward by governments could be accepted or refuted. Risk assessment was a key instrument, not only in controlling the use of science, but also in ensuring compliance with other SPS principles: the non-discrimination of foreign products at the benefit of domestic ones; the proportionality and transparency of trade measures. The WTO, followed by the WHO and FAO, pushed for the formalization of risk assessment methodologies under the form of a guideline. Ever since the first references to risk assessment in the draft SPS Agreement, the trend has been to formalize risk assessment. According to a WTO official, risk assessment was very much a 'forward-looking thing' when the SPS Agreement was signed in 1994. It was included in the text because 'a lot of countries needed to make progress'. The creation of a Codex guideline is 'a way to push

governments to move in that direction' and go beyond 'what we call 'back of the envelope' risk assessments' (interview with the author).

It was by mandating a scientist (a food microbiologist and official of the New Zealand food authority) that the process was initiated. His paper favours a mechanistic discourse on risk analysis and demonstrates the original affinity between the concept of risk assessment and projects of procedural harmonization. The paper (Hathaway 1993) lays out the basics of risk analysis and 'encodes' typical Codex decision-making processes (from the production of scientific opinions by expert bodies and the subsequent adoption of technical food standards (e.g. intake levels) by specialised Codex committees) in the new risk analysis terminology. The paper makes use of a mechanical epistemology and favours a stricter standardization of risk analysis under the form of a risk assessment procedure.

In the paper, risk is defined, classically, as the likelihood of the occurrence of a hazard assessed in a context of 'missing or ambiguous information, and gaps in current scientific theory'. The necessity of regulation is emphasized: 'Regulating to control risk is of little value unless there is a framework for consistent and orderly decision-making'. The lack of rules is one of the seeds of controversies:

> It is apparent that risk analysts have relatively few rules governing their approach. This can result in decision-makers being faced with different assessments of risk from different groups of experts considering essentially the same data set.

Indeed, the paper's main recommendation is to concentrate on the standardization of risk assessment. In his oral presentation before the CAC, the author further argued that harmonization of risk assessment in Codex and in member states will reduce risk management problems (Codex 1993). Other recommendations, and the ensuing discussion of the paper in CAC, concern risk assessment rather than any other matter. This testifies that risk assessment was a more advanced area of risk analysis. At a time when risk analysis was still a '*relatively new applied science in the field of food safety*' (Codex 1993), risk assessment appeared as the most advanced area, thanks to the work accomplished by toxicologists and, more recently, by microbiologists. In contrast, decision-making was much less equipped with protocols and criteria. The other main input in Codex's work is the report of an expert consultation organized by the WHO and FAO in 1995. Much like the other paper, the consultation and the resulting report focused on risk assessment. Risk management is dealt with in so far as it poses problems inside Codex, but is not seen as an area where harmonization can be promoted.

Considering the various instruments of standardization[4]

The drafting of a guideline in Codex continues this dynamic of standardization initiated outside its walls, albeit with difficulty.

[4] In the next two sections, all quotes are based on personal notes made during the working group, unless noted otherwise.

In 1995, the Codex Alimentarius became the reference body for all conflicts relative to food safety within the WTO regime. It is used, therefore, as the standard setting arm by the WTO as well as the WHO and FAO. In 1995, its overarching body, the Codex Alimentarius Commission, endorsed the results of the expert consultation. In 1996, it asserted the need to avail itself of formal documents for risk analysis. In 1998, the CCGP started to elaborate the working principles for risk analysis inside Codex. Risk management issues – and an alternative strategy of more gradual standardization open to local understandings of risk analysis – came through the back door.

As the CCGP started drafting the standard in 1998, discussions arose concerning the precautionary principle (Dratwa 2004). Should a reference to this mode of managing risks, current in the European Union, be included in the risk analysis principles? The US government was opposed to the introduction of a reference to an essentially European approach in an international standard. To avoid this, it pushed for the creation of two guidelines instead of one: the text under discussion would become a guideline to be applied within Codex (Poli 2004). Another text, created later, would apply to governments. This would avoid the need to discuss the precautionary principle, an irrelevant construction for Codex.

This decision to postpone the work on a guideline for governments shows the weight of local arrangements – in this case the specific use of the notion of precaution in Europe. Indeed, every year between 2003 and 2006, the CCGP had to consider, in the first place, whether it was appropriate at all to create such a standard. One issue is that risk analysis is a standard for regulatory processes, not just a product specification. The elaboration of this standard was seen as an extension of Codex competence as a technical body (Halfon 2009, Veggeland and Borgen 2005). Two other issues were critical: what kind of instrument should be used in this attempt to standardize? What are the risk analysis principles that can be agreed upon and used as a working basis?

The strategy chosen in Codex was agreed to enunciate ‘principles’ rather than elaborate ‘procedures’, in line with the acknowledgment that science-based decision-making processes may be designed in different ways (Codex 1997). However, the identification of ‘principles’ is not straightforward. It is ridden with conflict and disagreements. Each participant necessarily speaks from his or her particular point of view and experience. No one can pretend to know the practices and institutional designs risk analysis inspired across the world, and differentiate the specific from the general – even the few recognized ‘experts’ present in the room. Furthermore, the distinction used in this assembly between ‘principles’ and ‘procedures’ is not a clear one: procedures may well be described in a ‘principle-like’ and abstract way. There is no such thing as an objective principle. Anything can become a principle, provided it is enunciated in such a way that everyone can recognize his or her own practice in it.

No working method had really worked to shape this common knowledge, until the decision to create a physical working group in April 2006. The inter-governmental working group was comprised of 69 people, representing 28 countries as well as a series of ‘observers’ (consumers and industry associations, NGOs, etc.). The countries most active in the discussions were developed countries such as the US, European countries

(United Kingdom, Germany, the Netherlands, France) and New Zealand. Developing and emergent countries have also been active, in particular Argentina and Tunisia. Some of these countries are advanced in risk assessment science, others not. Many have arranged for risk assessment and risk management to be separate institutional functions entrusted to distinct organizations, against the principles of the NRC report.

Sharing references, manufacturing principles

The working group took place in Brussels and started in a studious and positive atmosphere, participants committing to work towards the identification of shared principles. The first hour was spent discussing a draft prepared by the chair – a new version of the risk analysis principles. This rapidly proved useless: the group was 'repeating history'. Discussing this new version, the same issues dealt with by those authors of the Codex guideline re-emerged. Governments were re-articulating a consensus that had already been reached, but at a great cost. This clearly was not the right approach to turn something around within the three days allocated to the group. The Argentinean delegate stated 'we know what we agree or disagree on. We need to come up with what is missing. We need to go to the heart of the issue. No need to discuss principles we agree on.' Other delegations having agreed to this, the working group decided to work from the Codex guidance, paragraph by paragraph, erasing/amending the provisions that do not apply in national contexts[5] - in *all* national contexts. The working strategy was to go for generic elements of risk analysis, points that everybody could agree on, and eliminate references to more contentious or singular practices.

This commitment to set principles worked as a practical injunction to codify its own knowledge and practice of risk analysis, to present it under generic terms and facilitate the exchange of experience between countries. The interventions of the Tunisian delegate, who represented a country that adopted a singular institutional design for risk analysis, are illustrative of this.

Discussion arose over the topic of how to describe and prescribe a particular mode of relation between risk assessment and risk management, among other issues. The starting point of the discussion is the 'functional separation' concept, inherited from the NRC and incorporated into the Codex guideline. The Dutch delegate argued that the separation should have much more emphasis. To him, a paragraph should be dedicated to emphasizing the necessity of separating risk assessment and risk management, distinct from the other paragraph describing the importance of the dialogue between the two. An opposition to this proposal quickly mounted. The Finish and US delegates argued that the concept of 'functional separation' was striking the right balance between the two imperatives of distinction and dialogue. The Tunisian delegate then intervened, adding to this that:

> There is another issue for developing countries, and that is when concrete obligations are defined that we cannot comply with because we are limited in our

[5] A paradoxical move, given that the decision had been made a few years before to dissociate the two, for governments to have free reign in creating the standard they were to apply.

> capacity to undertake risk analysis. That risk analysis is comprised of three elements, that is fine. That they need to be separated, that is fine too. But we should not go beyond this. It would damage the consensus.

The chair accepted this intervention and further added that 'we need greater clarity and less prescriptiveness.' Consensus emerged on this proposition, which reflects a vision of risk analysis as a framework rather than a procedure, and a preference for understanding standards as providing generic categories rather than precise procedures. As a result, while the Codex guideline maintained that 'there should be a functional separation of risk assessment and risk management', the working group agreed to add that this applies 'to the degree practicable', building even more flexibility into risk analysis.

In this arena, sensitive to issues of developing food-exporting countries, the strategy of the Tunisian delegate was to emphasize the limitation of their resources and the implementation issue, to reduce the precision of principles laid down in the standard. Her knowledge of risk analysis, however, did transpire from her comments, making them even more legitimate. As the group examined paragraph 12 of the initial text (mentioning that the 'needs and situations of developing countries should be taken into account'), several delegates argued it was in matters of risk management that resource limitation was most critical. At this point, the Tunisian delegate used the comprehensiveness of risk analysis to include risk assessment in these considerations:

> The problem is not a problem of risk management! Developing countries have a problem at every single stage of risk analysis: they have no food consumption database, no risk communication in place, no infrastructure for risk assessment. So there are loads of problems in the implementation of risk analysis. Concepts and principles are ok. They cannot be rejected. But one single sentence to make clear that implementation is an issue for us is important.

These interventions towards more generic descriptions and principles all progress in the same direction: blocking the interpretation of risk analysis as a set protocol. Risk analysis got broken down into its component parts, doing away with the temptation to define a hierarchical order of operations. The 'risk assessment policy' is a key example (Millstone et al 2006). Participants discussed how to ensure that risk assessments are regarded as useful to risk managers in the first place. Although the definition of this so-called 'risk assessment policy' by risk managers comes first procedurally speaking, 'it was recognized by participants that establishing such policy in advance of the risk assessment may not always be feasible at a national level.' (Codex 2006b). Similarly, when the Canadian delegate proposed to add that 'the need and scope of RA should be determined by preliminary RM activities', the Tunisian delegate responded that 'we are shifting from principles to procedures here, the 'who does what' etc. We said flexibility is important...' At this point, the chair intervened: 'this is an important point. But I still think that we are on principles more than process', illustrating the ambiguous distinction between the two. Indeed, the Canadian delegate did not mention the attribution of these operations to a particular organization or actor. But he designed a sequence, which would have had a particular effect in Tunisia (i.e. providing legitimacy to those administrations that successfully claimed they were undertaking 'risk management' there). After a couple of

delegates supported the Tunisian intervention, consensus emerged in favour of a lapidary statement: 'Each risk assessment should be fit for its intended purpose'.

The interventions of the Tunisian delegate are illustrative of a more general stance of all participants, which consisted of sharing with others the ways of practising risk analysis of which they are aware, in their home countries and elsewhere, so that formulations not represented in practice could be established. All of this goes to show that prior principles do not exist. They do not follow from the recognition of a pre-existing expertise that participants convert into a rule-like form, save for a few trade-offs and negotiations. Principles are statements about practice that are manufactured within the course of setting standards, to accommodate various references and positions concerning the purpose of a rule for risk analysis. In this process, the generic use of risk analysis as a set of notions that simply re-label and re-legtimize local conventions gave weight to those who fought against restrictive processes of harmonization, giving them the means to express their preferences.

Conclusion

The case of risk analysis is one in which two regulatory languages, rather than one single body of expertise, exists. The two languages embodied respectively in the procedure and diagram of risk analysis, partly overlap through constitutive categories like risk assessment and risk management as well as through the ambiguous reference to the 'separation' of RA and RM. As just illustrated, this overlap meant that some references could be shared and a common ground between actors that spoke different languages could be found. As the last section shows, the reference by the Chair and commitment of all parties to be 'generic', and establish principles rather than procedures, is not to be understood as a preference for abstract knowledge. It is a collective commitment to be as general as possible so that the ultimate standard accommodates all possible references and understandings of the practice of decision-making in conditions of uncertainty. It is a political commitment to strategically establishing a common language. This, in essence, is the answer to the question posed in the introduction: abstract, principle-based designs are preferred to more prescriptive rules because they represent the best possible strategy for the collective creation of rules, in conditions of plural regulatory languages.

There are several implications to this paper. One is substantive, and concerns current debates about whether the original NRC model was misread? Whether separation is a bad thing or not, and was recommended by the original model or not, does not matter. Local decisions to separate RA and RM must not be understood as a local deviation from a global and unequivocal model. It is a preference for local conventions, against the import of more tightly codified and exogenous norms such as the risk assessment procedure. It expresses a particular relation to standardization, rather than a strict rejection of such processes. Another implication concerns the treatment of expertise in standard setting. This concept of language allows me to shed more light on the politics of standardization, or the existence of various relations to projects of global harmonization and modes of action towards them, in line with more recent political sociologies of globalization (e.g. Bartley 2007, Sassen 2007, Smith and Jullien 2008). Different conceptions of what it is to set and harmonize a rule may coexist within one apparently coherent model.

One false interpretation would be that one language is global, and the other local. Both are global, in the sense that both establish ways to insert locales into transnational chains. The concept of regulatory languages helps to take into account certain paradoxes of international standards: the fact that they can easily be appropriated locally as generic categories, but still appear to be owned by experts; that they allow local actors 'to achieve dreams of universality', but at the same time insert those very actors into 'hierarchies of credibility and expertise' (Mennicken 2008). Like institutions in general, the categories and concepts comprising the expertise used to set standards — in this case risk analysis — both enable and constrain agents (Powell 1991, Meyer 1994, Campbell 1998, Lawrence 1999).

This paper sought to approach expertise in a different way than as a specialised, authoritative and self-contained knowledge that assures '*output legitimacy*' to standard setters (Hulsse Krewer 2007, Hulsse 2008). Users are legitimate as standard setters because they carry experience with them and references about this experience. Experts are legitimate because they have experience of practice and relations to users. Expertise is much better analysed as a currency of standard setting politics.

One of the obvious questions is whether risk, as a motive of regulation, is specific in that respect. Its ambiguity could indeed explain the fact that different regulatory languages come into action when standards are considered. On the other hand, many other general rubrics of regulation have such ambiguity. Comparisons between different principle-based standards motivated by other types of rubrics (sustainability, reliability, quality, etc.) would bring added value to this research. Does the diversity of regulatory languages then illustrate national cultural differences? Or does it have to do with the specific conditions of rule-making within international organizations? This only shows that more analysis is needed to understand in what conditions regulatory languages are enabled, suppressed or bridged, and the politics of standardization more generally.

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