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Enabling global principle-based regulation: The case of risk analysis in the Codex Alimentarius

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Abstract
This paper deals with the creation of global principle-based standards. For such standards to be accepted and effective, particular conditions must be fulfilled. One such condition, little explored, is that standard-makers and -takers share knowledge about the meaning of the principles, as well as the practices through which they are likely to be applied. The paper shows that this condition is fulfilled when transnational cultural systems exist, by means of which both types of actors engage in the explication and representation of their practices so that a common, standard understanding emerges of how principles may be interpreted on the ground and informs the negotiations. A transnational cultural system is a crucial governance infrastructure to set global standards, as shown by the long history of creating a risk analysis guideline by the Codex Alimentarius, the inter-governmental body for food standards.

Keywords: Codex Alimentarius, food safety, global regulation, principle-based standards, risk analysis.

1. Introduction

As one among many forms of standards, principle-based standards flourish in global regulation (Braithwaite & Drahos 2000). These standards prescribe outcomes and the broad and flexible ways by which they can be reached. They contain idealized goals and the plans or processes by means of which organizations can attain them (Brunsson & Jacobsson 2000). A variety of local scripts are developed in their name and coexist with them (Power 2007), because of the flexibility with which they can be interpreted (Gilad 2012).

In spite of their proliferation, as shown for example by the International Organisation for Standardization's (ISO) highly abstract managerial standards for quality or social responsibility (Higgins & Tamm-Hallström 2007), they remain under studied. This paper asks how a standard-setting body or a group of standard-setters finds itself in the position of opting for such a strategy, which requires specific and demanding conditions of "responsibility, mutuality and trust" (Black 2008a, p. 430). How is it that principle-based strategies are chosen to regulate food safety globally, although these conditions may not easily be met? When and where is a principle-based strategy attainable in the arenas that produce global standards?

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These questions are addressed by investigating the creation of a guideline for risk analysis in the Codex Alimentarius (the Codex). Risk analysis is a framework used in environmental health and food safety that constructs decisionmaking as a complex of three processes: risk assessment, risk management and risk communication. The risk assessment process should be clearly distinguished, though not overtly separated, from risk management; and policy judgements that frame the risk assessment should be made explicit. The framework became a global standard in 2008, in the form of a principle-based guideline of the Codex Alimentarius,[1] the inter-governmental body for food standards.

The creation of this guideline was a difficult endeavour, as evidenced by the 17 years that elapsed between the mandate given to the Codex in 1991 to create it, and its formal adoption in 2007 (Codex 2007a). Member states of the Codex had immense difficulty agreeing on a legal and effective regulatory strategy to harmonize very diverse ways of practising science-based decisionmaking at the national level – a matter on which national governments retain sovereignty according to World Trade Organization (WTO) agreements. The guideline that was finally adopted in the Codex Alimentarius allows countries to adopt a wide set of possible practices in the matter, according to the principle that risk assessment and risk management must be "functionally separated, to the degree practicable (Codex 2007a, p. 1)." It also refrained from prescribing detailed risk assessment practices.

This paper shows that a key factor in the outcome of the Codex was the confidence of governments that they had understood the practical meaning of risk analysis (the continuous improvement of communications between those tasked with scientific advice and administrative bodies that set and enforce food standards), and that they would generally be interpreting the principle in a correct manner. In the years leading to the adoption of the guideline, governments increasingly thought of their own institutional practices for food safety decisionmaking in the formal and standard terms of the risk analysis model. Knowledge was thus accumulated and shared among governments with regard to practical and appropriate ways of managing science-based decisionmaking on the ground, building up confidence that countries had common practices that could be reflected in formal principles. This explanation can be theorized in terms of the cultural links and system through which governments have been put in a position to present their practices to each other, monitor them, and evolve towards the promotion of exemplary practices. The paper substantively contributes to research on the global regulation of food safety and the Codex by showing what unlocked the creation of a risk analysis guideline. It also aims to contribute to the field of transnational governance and regulation by showing that the possibility of setting global standards emerges from transnational systems. The paper first reviews the available literature on global principle-based regulation, and then exposes the halting history of the creation of the Codex guideline. Finally it proposes an interpretation of this outcome as a result of the existence of a transnational cultural system, of which Codex meetings were a part, which enabled and constrained governments to identify the principles that underpinned their varied practices of science-based decisionmaking.

2. Making sense of global principle-based standards

There are three types of argument about the prevalence of "principles" in global regulation. The first, deriving from a realist literature, is that principles are instrumental for

dominant players. In global regulation, standard-setting agendas and institutional arrangements tend to be controlled by strong players with regulatory capacity (Abbott & Snidal 2001; Mattli & Büthe 2003; Prakash & Potoski 2004; 2009; Bach & Newman 2010). The setting of principles is a strategy that they employ to shift forum and create a more favourable context for negotiating rules (Braithwaite & Drahos 2000).

The socio-legal literature on regulation offers another argument: that, principles are more effective, reliable and certain in a complex, changing and high-stakes environment (Braithwaite 2002). Detailed rules lead only to more detailed rules when gaps in their implementation are noticed, and this multiplication only provides more room for manoeuvre for those who are tasked with their interpretation on the ground, or more opportunities for creative compliance by regulatees (McBarnet & Whelan 1991). Both factors explain the empirically observed reduction in reliability that might be caused by detailed rules. Principles, on the contrary, induce a process of information gathering and deliberation by enforcers of the standard, and an active search for consistency (Braithwaite 2002).

A third type of answer emerges from the literature on transnational governance, and is based on the observation that global standard-setting as a new form of political authority primarily faces a legitimacy problem (Tamm-Hallström 2004; Botzem & Quack 2006; Djelic & Sahlin-Andersson 2006; Quack 2010). Global standard-setting organizations seldom fulfil the traditional normative requirements for input legitimacy, and are, for this very reason, limited in the obligations they can enforce on their members (Bostrom 2006; Hulsse & Kerwer 2007; Hulsse 2008, Black 2008b; Tamm-Hallström & Boström 2010). Principles are, on the contrary, highly legitimate, because they incorporate credible and authoritative expert knowledge and respect the autonomy of potential rule-takers, thus eliciting their consent (Brunsson & Jacobsson 2000, Jacobsson 2000).

Regulating via principles nevertheless requires a high level of mutual understanding and trust between rule-makers and rule-takers – a reason for Black to call it a utopia (Black 2008a). In global regulation, the heterogeneity of national interests and legal regimes makes reaching a common understanding of rules even more unlikely (Picciotto 2007), specifically in cases of "organizational" (Kerwer 2005) or inter-governmental standard-setting, where there are many standard-makers and many standard-takers. Besides the arguments of power, functionality and legitimacy, a theory of the emergence of principle-based strategies needs to explain how those practices, or knowledge about them, is generated, codified, shared, and eventually, stored as a principle.

To do so, inspiration can be found in the anthropology of global culture. This literature approaches globalization as the lengthening and thickening of cultural links between societies, by means of which they get represented to each other and mutually observe themselves (Levi-Strauss 1955; Appadurai 1990; Hannerz 1990). Globalization reorganizes rather than eliminates the diversity among these societies, because what societies come to share in this process are models, templates or theories that reframe their particularities in standard terms. What Wilk calls a "system of common difference" (Wilk 1995, p. 110) is a set of contents and formats through which local actors can express their differences in a standard fashion. It serves purposes of distinction and classification. It puts local actors into relationships with one another, and motivates them to express and dramatize their differences. Proponents of the world society/polity perspective have argued in similar ways about global "templates" (Boli & Thomas 1997; Meyer 2000). But they tend to present things as a top-down diffusion of global forms to strictly homogenize

people and organizations (Buhari-Gulmez 2010). Anthropology more subtly considers that these global forms help to make distinctions and reflect certain differences. They get structured and change as they are repeatedly enacted in myriad inter-connected places. Becoming formalized and standardized is a process that is emergent from this interaction between localities, prompted by local actors (Mennicken 2008), as much as by dominant cultural actors (Errington & Gewertz 2001).

This detour via the anthropology of global culture thus pushes us to consider the density of trans-governmental links through which particular formats get constructed and shared, and the emergence of global stages on which local practices are represented and evaluated via these formats. These two elements constitute a system of normalization of differences, which eventually permits the collective enunciation of common principles. Such transnational cultural systems appear as a key infrastructure of global regulation: a sort of transnational field of knowledge and practice (Djelic & Quack 2003; Djelic & Salhin-Anderson 2006; Quack 2007; Bartley & Smith 2010) that supports the forging of these very rules.

Various sources and methods were used to study risk analysis and the Codex Alimentarius from this perspective. Personal notes, taken while attending the three-day Codex working group mandated to draft the risk analysis standard, have been used. Interviews were also conducted at the margins of this meeting. All subsequent quotes in this paper are based on these personal notes, unless otherwise stated. Reports of the annual Codex Committee for General Principles (CCGP) sessions from 1991 to 2009, and a background paper prepared by the chair of the Codex working group that traced the whole history of the standard within the Codex, were also used (Codex 2006a). The study of the Tunisian case is based on a five-day field visit, during which key administrative and technical actors involved in the establishment of a legally-based risk analysis framework for food safety were interviewed. Particular attention was given to the positions expressed by the Tunisian delegate during the Codex workshop. Each session of the workshop was followed by individual conversations with the Tunisian delegate. The broader knowledge of risk analysis in the European Union results from conducting 15 interviews between 2003 and 2008 with officials of national agriculture or health ministries, food safety independent agencies, and the European Commission, as well as with scientific experts advising those bodies.

3. Moving towards the generic: the standardization of risk analysis in the Codex Alimentarius

3.1. What and how far to harmonize? The halting progress towards a Codex risk analysis standard

The creation of an international guidance for risk analysis is a long story that started in the second half of the 1980s. As the General Agreement on Tariff and Trade was being revised, consideration was given to the idea of including provisions about risk assessment in international trade treaties, in order to make sure national governments do not illegitimately use scientific and health arguments to block imports (Horton 2001). The Codex, which was to become the international reference body for food standards as part of the WTO agreement (Victor 1999; Huller & Maier 2006), was mandated in 1991 to develop guidance based on the emergent concept of risk analysis that could apply across all sectors of Codex regulation (Jukes 2000; Winickoff & Bushey 2010). Anticipating the

guidance, the Sanitary and Phytosanitary (SPS) Agreement was adopted in 1994, establishing that sanitary or phytosanitary measures must be based on an assessment of risk and that governments must make use of the risk assessment techniques developed by the relevant international organizations (Article 5.1) (WTO 1994). In 1995, the Codex Alimentarius Commission (CAC; the overarching assembly of the Codex comprising 185 national delegations, which reviews the standards developed in separate committees for adoption) officially opened the work to elaborate formal documents for risk analysis. In 1998, the relevant committee, the Codex Committee for General Principles (CCGP), then started to draft a guideline. But it was not until 2006 that a breakout group of the CCGP effectively succeeded in agreeing on a common text.

This text contains four main parts. The first concerns the "general aspects" of risk analysis; that is, principles that apply to its three components (risk assessment, risk management and risk communication) and their interrelations. This part establishes the notion of the "functional separation" of risk assessment and risk management (a "distinguish-but-don't-overtly-separate" principle). It prescribes that these processes should be conducted in a transparent, documented, consistent manner. It sets public health protection as the overall objective of risk analysis. The three other parts of the guideline respectively cover risk assessment, risk management, and risk communication. They stipulate objectives and values, much as in the "general aspects" section. They also contain procedural rules (e.g. Article 23, risk assessment comprises four steps of hazard identification, hazard characterization, exposure assessment, and risk characterization), and substantive rules (e.g. types of data to consider in a risk assessment). The text, overall, relies on value- and goal-based prescriptions, and a great variety of practices by governments, which are likely to fit the guideline.

The guideline replicates the conceptual structure of risk analysis as shaped in the US in the 1970s and presented in the 1983 report of the National Research Council called the "Red Book" (National Research Council 1983). This report deals with decisionmaking in risk-related regulatory agencies, such as the Environmental Protection Agency or the Food and Drug Administration. The report is consistently referred to as the origin of present-day risk analysis standards (Jardine *et al.* 2003; Omen 2003; Jasanoff 2005). The Codex built on three key elements of the report. The first and principal element is the definition of risk assessment as an analysis of scientific facts and as a process comprising four operations: hazard identification, dose–response assessment, exposure assessment, and risk characterization. The second element, much more principle-like, is the recommendation to distinguish – but not separate – risk assessment from risk management or regulatory/policy action. The report admits that in a context of uncertainty, scientific assessments are influenced by particular policy assumptions and values. The best way to manage this unavoidable politicization of science is to place scientists and regulators in a constant dialogue – hence the main and often misread recommendation of the NRC report to distinguish risk assessment and risk management but not to approach them as separate organizational functions (Mirer 2003; North 2003). The third major output for which the report is recognized and that the Codex built on is the notion of "risk assessment policy:" a policy that comprises all of the non-scientific judgements that are made during a risk assessment process and that should be made explicit and transparent.

The creation of a Codex guideline built on the more scientific and prescriptive part of the NRC report: the four-step code for risk assessment. Emphasis was placed from the

start on the definition of a guideline on risk assessment specifically, rather than on aspects of risk management that were thought to be more difficult to harmonize. According to the WTO official who negotiated the SPS agreement and participated in the Codex developments, risk assessment was very much a "forward-looking thing"[2] when the SPS Agreement was signed in 1994, and "a lot of countries needed to make progress" in this practice (see also Büthe 2008). The creation of a Codex guideline, therefore, was seen as "a way to push governments to move in that direction" and go beyond " 'back of the envelope' risk assessments."

This stress on risk assessment shows the mutual reinforcement of the experts' technocratic approach and the WTO's search for an effective and legally authoritative regime of food standard-setting (Livermore 2006; Peel 2010; Winickoff & Bushey 2010). It results from the major input that early risk assessment specialists had in the Codex. Back in the mid-1980s, the ideas and formulations of the NRC became attractive to a number of experts, in particular toxicologists. They appeared especially motivated to advance a global standard methodology for risk assessment based on the four steps of the NRC, an ambition that crystallized in the Joint Expert Committee on Food Additives (JECFA) of the World Health Organization and the Food and Agriculture Organization (FAO). Toxicologists who participated in the elaboration of the NRC report were also members of this committee, and later took part in the working group convened in 1988 to draft the SPS Agreement (Debure 2008).

This expert input continued throughout the Codex process, which was initiated by commissioning a scientist (a food microbiologist and official of the New Zealand food authority) to write a discussion paper (Hathaway 1993). The paper emphasizes the need to set standards for making decisions to improve food safety, and recommends concentrating on the standardization of risk assessment. The lack of rules in the matter is the seed of controversy, "decision-makers being faced with different assessments of risk from different groups of experts considering essentially the same data set" (Hathaway 1993, p. 193). In his oral presentation before the Codex, the author further argued that harmonization of risk assessment in the Codex and in member states will reduce risk management problems (Codex 1993). At a time when knowledge about risk analysis was sparse in the Codex (Codex 1993), such early specialists and publications proved very influential. Hathaway's paper was officially endorsed by the CAC in 1996. It was used as a starting point for the discussions, along with a report by a group of experts organized by the WHO and the FAO in 1995 that similarly focused on risk assessment (Codex 1995).

Risk management overall was dealt with in so far as it posed problems inside the Codex (in terms of the use of scientific opinions by Codex committees to make regulatory standards), but was not seen as an area where harmonization could be promoted. The conflict arising between the USA and Europe on the precautionary principle made this clearer (Poli 2004). European countries were in favour of allowing decisions that go against or beyond science, specifically in cases of lack of evidence. This European inclination was rejected by the US as mistrustful of science. The issue of "other legitimate factors" and precautions effectively blocked the creation of a risk analysis guideline. It helped to show that the topic stretched the competence delegated to Codex. As a technical body, it was not entirely legitimate for it to harmonize the very diverse and incommensurable ways in which sovereign governments handle science-policy relations (Halffman 2005; Veggeland & Borgen 2005; Post 2006; Gruszczynski 2010; Halfon 2010), especially

as it officially admitted the diversity early on in the process (Codex 1997). To escape the deadlock, the US government pushed in 2000 for the removal of any reference to the language of precaution and to the use of factors other than science in the setting of food safety standards (Poli 2004). This effectively called off discussions on the legitimacy of European approaches and the appropriateness of reflecting precautionary approaches in an international standard of legal force, and helped achieve progress: the construction of a risk analysis guideline for use within the Codex followed in 2003. The CCGP, however, kept debating, meeting after meeting, how and whether it should set an international standard on risk analysis for application by governments.

3.2. The transnational acculturation to risk analysis

In the meantime, national governments increasingly accepted the concept of risk analysis as a format for the relation between scientific advice organizations on the one hand and other administrations competent for food standards and their enforcement on the other. In response to the adoption of the WTO treaty (before the Codex produced any risk analysis guideline) many countries adopted laws that incorporated risk analysis. The European Commission started to consider integrating risk analysis in its legal regimes about 1995 in a particular conjuncture involving the implementation of the SPS agreement, the beef hormones dispute with the US, and the new imperatives of clarifying the boundary between scientific expert committees and policymaking following the BSE affair. The European Union General Food Law adopted in 2002 established a frank separation of risk assessment and risk management functions by entrusting the former to a newly created European Food Safety Authority and the latter to the European Commission. The Agence Française de Sécurité Sanitaire des Aliments in France, the German Federal Institute for Risk Assessment, and the Austrian Agency for Health and Food Safety, were all based on the interpretation that a separation between risk assessment and risk management was politically and legally inevitable – an interpretation that results from the reluctance of powerful agriculture and consumer affairs ministries to delegate some of their decisionmaking and enforcement functions, as well as the perceived public imperative of ensuring the independence and transparency of scientific experts. The European reforms influenced countries exporting to the EU. The Tunisian government, for instance, created an administrative agency for food safety in 1999, the Agence Nationale de Controle Sanitaire et Environnemental des Produits (ANCSEP), to emulate European countries and demonstrate internationally its commitment to food safety. The agency was also given a risk assessment mission and an advisory role to agriculture, health, and economic affairs ministries competent in risk management.

This appropriation of risk analysis was done in a context of constant transnational interaction between national officials. In the second half of the 2000s in Europe, risk analysis became the topic of myriad workshops, colloquia, and reports. It was taught in numerous training sessions for food safety officials, such as those organized by the FAO (through which the Tunisian CCGP delegate learned about the details of risk analysis), but also by the European Institute for Public Administration (EIPA 2003). Much cited reports by prominent scientific experts (James *et al*. 1999; SSC 2000) or industry think tanks (EPC 1999) on how to improve scientific advice also spread the concept. Officials of the European Commission visited other countries to see how they organized risk analysis (such as the 1996 mission of the European Commission that toured 17 countries; see IGS

1997). Scientists with international experience in risk analysis and regulatory science (very often toxicologists), were sometimes recruited by administrations to help, as with the "risk assessment unit" created inside the Directorate General for Health of the European Commission in 1997, or were offered opportunities to explicate notions of risk analysis at major policy conferences (EC 2000). The European Commission and the French and the European food safety agencies each organized a colloquium and disseminated colloquium reports to share their experience in organizing risk assessment and managing the risk assessment–risk management boundary (AFSSA 2000), building on a widely circulating report on the practice of risk assessment in United Kingdom agencies (ILGRA 1996). During those years, EPA and FDA officials were frequently invited to Europe to speak to their counterparts, to explain the meaning and practice of risk analysis as carried out in the US. Consultants travelled widely to inform countries about risk analysis (e.g. a French food law expert was invited by the Tunisian government to explain the content of the European General Food Law).

A general acculturation to risk analysis thus took place to inform WTO obligations, along with intensive exchanges of views and comparisons between national officials to find out whether separating risk assessment from risk management was a better institutional option or not. This transnational acculturation meant that national officials, whether in risk assessment agencies or in ministries competent in risk management, realized the value of discussing institutional functions and relationships back home in the standard terms of risk analysis. This model of thinking produced local effects in the direction of a practical improvement of the risk assessment–risk management interactions. After instituting a radical legal separation of risk assessment and risk management, the European Commission moderated the organizational gap by creating an "interface with the EFSA" unit in 2004. All requests for scientific opinions from the European Commission are checked by this unit, to make sure they are understandable by the EFSA. Conversely, the EFSA decided to allow for one European Commission official to be present in meetings of its scientific panels. Soon afterwards scientific experts of the EFSA launched a workshop and published a report on ways to improve the risk assessment–risk management interaction, with funding from the European Commission (Hart 2003). In short, five to ten years after policymakers started to think in risk analysis terms in Europe, the actors involved in risk assessment and risk management in practice started to become literate in it too.

In Tunisia the unusual legal design, by means of which the ANCSEP was given a mission to coordinate food inspections as part of risk assessment responsibilities, was gradually dropped, because it was causing a tense political conflict between the ANCSEP and ministries in charge of these inspections, and because of the well-noted discrepancy between this design and the standard notion of risk assessment. Ministry and ANCSEP officials started to work towards a better interaction between their organizations. This happened in the context of intensive discussions with European scientists and civil servants: the ANCSEP directors sought clarification from European Commission officials. Consultants and academic specialists in risk analysis were invited to Tunisia to present the concept of risk analysis and the organization of the process in European countries and in the US. Tunisia, as a country considered peripheral in the Codex and that considered itself non-expert in risk analysis, thus gradually came to master the language of risk analysis and the practical meaning of distinguishing scientific advice from regulatory functions and the necessary interactions between the two.

3.3. Reaping the benefits of the acculturation to risk analysis: the final progress towards a common guideline

The CCGP working group convened in September 2006 in Brussels in this context of acculturation to risk analysis and of the dissemination of risk analysis practices. The gathering of 69 people (mostly civil servants, but also scientists working for national food regulatory bodies, as well as a handful of "observers" from consumer and industry associations), representing 28 countries, greatly benefited from the context. To overcome previous failures, the delegates collectively agreed to focus on areas that continued to pose problems between governments, after taking stock of the many topics and principles on which they could agree. In the words of the Argentinian delegate, "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." The delegates had indeed realized that they largely agreed on a number of key aspects of risk analysis. This emerged during the first hours of the workshop, which was spent discussing a draft prepared by the chair – a *new* version of the risk analysis principles. This rapidly proved useless: governments were re-articulating with great difficulty a consensus that had already been reached in setting the internal Codex guideline. It clearly was not the right approach to turn something around within the three days allocated to the group. Other delegations, having agreed to the proposition by Argentina, the working group set out to use internal Codex guidance as a common basis, erasing/amending the provisions that did not apply in all national contexts as they went through the text.

Another method on which they agreed at the outset was to formulate flexible principles in preference to procedures, and to be more generic than prescriptive. The methodology was to set principle-like obligations that could be implemented in different ways at the national level. Where more precise obligations had to be formulated, some provisions would be added to allow adaptations for those countries that were not in a position to comply. A third element of method, emerging in the course of the discussions, was to refrain from introducing new provisions or terms that would differ too greatly from the terms of the WTO and SPS agreements, to avoid confusion and misunderstandings that would work against the applicability of the new guideline.

Altogether, this methodology signals that there was in this group a common political will to explicate what governments had in common, over and above introducing new substantive obligations that only a few countries would be interested in and capable of enforcing. This move towards generic rules was consistently applied throughout the talks. Discussions arose, for instance, over the topic of whether to prescribe a particular mode of relation between risk assessment and risk management. The starting point was the "functional separation" concept, inherited from the NRC and incorporated into the internal Codex guideline. The Dutch delegate argued that 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, in keeping with the mainly European practice of separating risk assessment from risk management in two distinct organizations. Opposition to this proposal quickly mounted. The Finnish 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 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 capacity to do 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: "we need greater clarity and less prescriptiveness." Consensus emerged on this proposition. 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*;" de facto recognizing the organizational separation of the two that was chosen by many countries.

The search for flexibility in the rules was consistent throughout the discussions. The emphatic interventions by the Argentinian and Tunisian delegates strongly helped this outcome. In this arena, sensitive to issues of developing food-exporting countries (Boutrif 2003), the strategy of the Tunisian delegate was to emphasize the limitation of her country's resources and the implementation issue, to reduce the precision of the standard. As the group debated the formulation of a paragraph concerning the implementation of risk analysis, this delegate intervened with: "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." The position of the Tunisian delegate reflected the situation back home: at no moment during the creation of the ANCSEP was the internationally received risk assessment code discussed. Quite the contrary, the Tunisian delegate (who was also a director of the ANCSEP) put forward the fact that Tunisia has neither any motive nor the resources to undertake more risk assessment. The population of food scientists in Tunisia is rather small. A lack of financial and material resources constrains the activities of official laboratories. Data needed to perform any local assessment about the prevalence of a given disease are missing. Being incapable of carrying out risk assessment in the way developed countries do, and acutely aware of the danger of increasingly precise international requirements in risk assessment for a food-exporting country like its own, the Tunisian delegate made sure the prescriptions were cast in more generic terms.

Other delegates in the working group showed some sympathy with this local situation and approach that coincided with the agreed-upon strategy to avoid being too prescriptive. 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 along the same lines – that it is in all matters of risk analysis (from assessment to communication) that resource limitation can be felt. There was a general reluctance to include more precision in the rules for risk assessment, as shown by the failed attempts of the New Zealand delegate, Steve Hathaway (the very scientist who authored the 1993 paper to initiate the Codex work on risk analysis), to gain agreement about which data should be considered in a risk assessment or the different sorts of assumptions that are made in the course of an assessment. Nor did the Dutch delegate succeed in inserting a phrase reflecting the likely increase in the use of sophisticated methods of risk/benefit assessment in the future.

The issue of the risk assessment policy, another central element of the concept of risk analysis, offers a final example of a negotiated move towards genericness, building on the participants' common practice of risk analysis. Participants discussed how to ensure that risk assessments are regarded as useful to risk managers in the first place. Although the

definition of a "risk assessment policy" by risk managers comes first, procedurally speaking, "it was recognized by participants that establishing such a policy in advance of the risk assessment may not always be feasible at a national level" (Codex 2006b). Similarly, when the Canadian delegate proposed, "the need and scope of risk assessment should be determined by preliminary risk management 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." After several delegations supported the Tunisian intervention, consensus emerged in favour of a definitive statement saying: "*Each risk assessment should be fit for its intended purpose.*" With this formulation, the guideline was transmitted to the CCGP in 2007 by the chair of the working group (Codex 2007b). After minor amendments, it was adopted by this committee, and later by the Codex Alimentarius Commission, in 2008.

4. Risk analysis as a transnational system of common difference

As the above history shows, the decision to formulate prescriptions in very generic terms and to stick to the principled nature of the original risk analysis framework was a conscious choice made by the delegates in the course of their negotiations. The strategy identified what was already common to all national governments, as opposed to imposing new practices. The various delegates – in particular those, like food-exporting countries, with an interest in more flexible forms of risk assessment – pushed for articulating the principles that concern all segments of risk analysis. The focus on risk assessment only was rejected as an over-codification of governmental activities. When obligations were set, they were explicitly designed in a flexible way so that the various practices of governments could still be continued and be justified under the new regime. Rather than introducing new terms, the group edited principles in which almost all of them could recognize their own national institutional rules and ways of doing risk analysis. It strove to simplify the prescriptions and distill principles into their purest and clearest forms.

A realist perspective emphasizing power negotiations does not seem sufficient here, since the choice of a principle-based regulatory strategy by the CCGP was collective, and one that was very much suited to smaller and peripheral countries. A functionalist view stressing the advantages of principles for legal reliability and certainty also seems misplaced because all delegates did not recognize these advantages ex ante. The principle-based strategy, first, was the result of the pragmatic realization that the creation of this guideline would be difficult after many years of debating its very creation. It reflected, secondly, specific concern in the Codex about the applicability of standards in developing countries. But, more fundamentally, it resulted from the fact that most governments had already normalized the institutional schema for food safety regulation back home, designating certain institutions (ministries) as risk management bodies and creating risk assessment institutions de novo, assimilating the meaning of the notions on the way. Most, if not all countries had taken steps by 2006 to distinguish risk assessment and risk management functions in their national legal frameworks and sometimes in their institutional architecture. The necessity to keep the interaction between those two was also increasingly understood over the years, and demonstrations of this appeared during negotiations in the Codex. The working group thus collectively earned the opportunity to

work through principles, relying on the knowledge of the aims and philosophy of a risk analysis approach that gained ground among governments, including peripheral ones.

The explanation of why the Codex ultimately managed to articulate a common risk analysis standard is that most member countries progressively consented to think and represent national decisionmaking institutions and practices in terms of a common framework, converging towards the recognition of the importance of practices of intercommunication between scientific bodies and regulators at the national level. The transnational cultural system, by means of which these countries effectively learned to speak in risk analysis terms and mutually compare themselves in order to progress towards an understanding of what were the ideal practices in the matter, thus appears to be crucial to explaining the creation of formal principles. Based on the analyses of anthropologists of global culture, two main factors can be isolated that explain this outcome.

The first is the existence and growth of a system of cultural references that allows – and in a sense motivates – the expression of local forms in global and shared terms. In the NRC framework, risk assessment and risk management are categories of understanding by means of which local actors on each side of the science and policy boundary 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 disentangle scientific from policy and moral arguments locally. It is a code of conduct for playing out the science–policy conflict, or a language that is shared by both sides. Such a dichotomous concept (risk assessment/risk management) is very appealing to local actors because it allows representing particularities (notably in terms of how the relationship between the two elements of the concept is thought of and practiced locally), while remaining within a given frame (i.e. the very fact of speaking in terms of risk assessment and risk management).

Risk analysis has had an influence on local actors and is easily appropriated by them because it caters for their need to organize and institutionalize their own practice in a way that is intelligible by their counterparts in other countries, or by international organizations aiming to regulate the process. In Tunisia, for instance, the generic categories were used to re-label existing processes and the institutional architecture in which they normally take place. The particularities of the local institutional architecture and policy regime (heavy involvement of the health ministry in issues of food control) were expressed in a standardized way. Modelling of the local policy regime in the language of risk analysis was a precondition for the participation of the Tunisian delegate in the proceedings of the Codex and the consideration of her position by other members of the working group. It was required in order to persuade other countries they were accepting the overall effort to distinguish and separate (harmonize risk assessment–risk management relations), but also to demonstrate the disadvantage there would be in setting risk assessment rules that are too strict. Given that risk analysis recognizes local particularities and recasts them in normalized terms, it enables countries to engage with others.

There is no sense in speaking about a transnational system if one cannot document the existence of links among individuals and organizations of different countries, through which they develop a sense of interdependence, if not solidarity, and become willing to present themselves and defend their identity in this field. The progressive acculturation to risk analysis documented above is linked to the emergence of relationships between all governments, as well as among governments and the various carriers of the concept of risk analysis – national officials from agencies or countries with greater

experience in risk analysis; food safety scientists who have published on this issue; and consultants. These relationships formed a transnational web through which practices were continuously represented, compared, and monitored. This took place before, during, and after the Codex meetings. These transnational links extended and widened from the second half of the 1990s, as discussions on risk analysis in the Codex intensified. The Codex worked as a central stage on which the contest for power to nominate the appropriate model for risk analysis and to select exemplary practices took place. In this case, the Codex meetings were the central stage in a set of interconnected sites in which matters of risk analysis were repeatedly discussed: international scientific committees such as the JECFA, international bodies such as the WHO, the FAO, and the WTO, but also the European Commission. Discussions in these sites were held in the shadow of a project of harmonization driven by the WTO and under the supervision of experts, which concurred in organizing a selection of good practices of risk analysis. It explains the motivation of local actors to share their experience in standard terms, but also the fact that they were constrained to do so to defend their practices in a context in which they were meant to be regulated.

5. Conclusion

The creation of a risk analysis guideline in the Codex Alimentarius offers an apt case to study principle-based strategies at the global level, specifically their use in intergovernmental arenas. It offers an answer to the questions of when and where the particular conditions of principle-based strategies are fulfilled, specifically the presence of a common practical understanding and knowledge of the standard among makers and adopters – these being the same people in this case. Governments in the Codex finally succeeded in turning out a guideline, after many years of intense fighting about the necessity of having one and on its content, because Codex meetings were embedded in a transnational cultural system by means of which local particularities were gradually standardized, represented, and selected. They came to constitute a set of references that most countries shared. This enabled governments to set principles in the verifiable trust that most countries would understand the principles and the exemplary practices to which they implicitly referred. The expansion of the cultural web and deeper acculturation of more countries to risk analysis was one key factor in the transition in the Codex, from the tense negotiations of the years up to 2003 (the creation of a guideline for risk analysis for use within Codex processes), to the setting up of the 2006 working group, that succeeded in drafting agreed-upon principles for application by national governments.

Much of the research on the Codex has focussed on the particular (top-down) effects of the institution of WTO rules, on the delegation of authority to the Codex, and on the negotiations as they happened within this arena. Not enough attention seems to have been given to the transnational connections between locales, and the gradual emergence and sharing of knowledge about the object that is being standardized, as this paper demonstrates. Importantly, the existence of a transnational system of translation of differences into common formats, and the ensuing representation of particular practices in standard terms in the Codex, does not eliminate power and hierarchies from the picture. Hierarchies remain, especially in terms of knowledge and expertise about what risk analysis is, as well as in terms of capacity to perform risk analysis and set rules for it. The WTO treaty gave the creation of this guide an imperative character, so that legal authority cannot be

removed from the analysis either. But the transnational cultural system described above mediates the expression of power and legal authority, and in a sense allows for its full expression. In passing, the paper shows that participation in the Codex is a mixed blessing for developing countries. While it allows them to defend their uniqueness and particularities in such a way that they can slow down the process of homogenization, participation is also synonymous with an ever-increasing acculturation to the frameworks within which standardization is discussed, and thus denotes their implicit acceptance of it. In many ways they are cognitively captured within these processes.

The above case has its particularities, including the rapid and widespread diffusion of a set of formats and categories of risk analysis benefiting from great cultural authority, and the action of scientific experts as carriers and prescribers of the model. Both factors suggest that the transnational acculturation and normalization of differences observed would have happened irrespective of the WTO and Codex projects for setting global standards. But the fact that a transnational system was a condition for the success of such projects is an indication that the case has broader value. This paper shows that transnational cultural systems are a key infrastructure in global regulation – one by means of which local places get connected to each other and to a global scene, and through which regulatory conversations may happen (Black 2002; Braithwaite 2002).

Overall, the paper concurs in showing that global standards emerge from transnational interactions between local sites, and between local sites and global scenes. Standard-setting cannot be reduced to a top-down process that bypasses national authorities and local actors. Projects of standard-setting build up through time and from the bottom up, by the accumulation of the effects of various standards and referenced practices in and across particular locales. The insights of this paper could be extended to cases of global standard-setting that involve a great deal of ambiguity, equivocation or open-endedness with respect to what is being standardized and the rules that are suggested, from ISO's creation of standards for the broad class of "nanotechnology," to those arenas that seek to define, e.g. what "sustainability" or "corporate social responsibility" is. In each of these cases progress in agreeing on a global standard is conditioned by the availability of experience and the knowledge of what is being and what should be standardized (Quack 2007; Sabel & Zeitlin 2010). This process has its own politics, as documented here, and is deserving of further examination since it undercuts many of the hopes of setting global regulatory regimes.

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Notes

1 The full title of the standard is "Working Principles for Risk Analysis for Food Safety for Application by Governments" (Codex 2007a).

2 All quotes in this paragraph are from a personal interview with the author, conducted on 12 April 2006 in Paris.

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