When experimentalist governance meets science-based regulations; the case of food safety regulations

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Abstract
This paper examines a central regulatory mechanism that shapes food economies. Food safety regulations in the United States rely on a science-based transnational regulatory system known as Hazard Analysis and Critical Control Point (HACCP), which bears central features of what Sabel and Zeitlin identified as experimentalist governance: a new form of regulation that is flexible, responsive, and involves stakeholders in iterative and direct democratic deliberation. The core theoretical question the paper examines is what the reliance on science means for the promise of an experimentalist policy regime to enable a new form of democratic politics. Based on a case study of the HACCP system implemented by the US Department of Agriculture’s Food Safety and Inspection Service since the late 1990s, HACCP’s reliance on food science has acted as an effective divider between producers who were able to take advantage of the system’s flexibility and others for whom this was challenging. There is clear evidence that HACCP posed a disproportionate burden on small processors and that some of them were unable to adapt to the requirements of the regulatory system. In so far as the HACCP-based food safety regulations delineated the kind of producer that thrived in the system and contributed to the demise of another set of producers, the regulatory system shaped market outcomes.

Keywords: experimentalist governance, food safety regulations, HACCP, science-based regulations.

1. Introduction: Experimental governance and food safety regulations

As markets become more global and complex, so does the economic practice and experience that governments need to regulate. Experimentalist governance is a way of regulating economic actors that departs from the notion of omniscient technocrats and instead relies on new forms of stakeholder involvement in rulemaking at the domestic and international level. Premised on provisional rules and iterative deliberation, it is, at its best, a flexible regulatory framework in which regulators learn and rules follow diverse practice. Experimentalist governance is also a form of regulation that explicitly acknowledges that regulation is intrinsically political. For Charles Sable and Jonathan Zeitlin (2010), the open-ended and potentially transformative deliberation at the heart of experimental arrangements hold the promise of a new form of politics, a type of direct democracy that involves stakeholders in public peer-reviews. This paper examines whether and to what extent this promise is realized in an existing experimentalist
policy arrangement – the food safety regulations by the United States Department of Agriculture’s Food Safety Inspection Service (USDA/FSIS).

The food-processing sector is a regulatory sphere in which economic practice is extremely diverse and dynamic, while also historically subject to public sector regulation. Food safety regulations in the US and elsewhere have been increasingly based on what is known as the Hazard Analysis and Critical Control Points (HACCP) system, which relies on a number of experimentalist principles (De Búrca & Scott 2006; Vos 2010; Sabel & Zeitlin 2010; Zeitlin 2010). The HACCP system refers to a transnational governance regime that promotes a preventative approach to food safety regulations. HACCP-based food safety regulations have been widely adopted in Europe and North America and in many other economies selling into these markets since the 1990s (Feltault 2009; Humphrey 2012). Coinciding with this shift in regulation, the politics of food sector regulations have also evolved. Reflecting consumers’ and producers’ concerns about the impact of industrialized forms of food production on the environment and public health, small-scale alternative and niche producers are among the fastest growing components of US food production. These producers exist and compete in a sector dominated by hyper-efficient industrial agribusinesses and niche producers must differentiate their products from food that originates from large vertically integrated industrial food systems. As public focus shifted to alternative niche producers, the effects of food safety regulations on these producers and products became increasingly political.

Food safety regulations are a central regulatory mechanism in the food system; the process, effects and politics of HACCP-style food safety regulations are, thus, an interesting medium to study how regulations construct markets. As inclusion and responsiveness are hallmarks of experimentalist governance, this paper asks specifically whether the USDA’s food safety regime provided channels for inclusive, iterative, and direct deliberative rulemaking and whether regulations were adaptive and flexible. To find an answer, the paper demonstrates: (i) how the USDA’s HACCP-based regulations function; then examines (ii) the political concerns generated by this regulatory system; and finally (iii) the flexibility of the regulatory system and the responsiveness of regulatory authorities to these concerns. In addition to debates on experimentalist governance, this study investigates how regulatory regimes produce economies (actors, organizations, products, and categories); in particular, it investigates how reliance upon science functions to exclude particular actors.

Two aspects of HACCP systems are key to understanding the functioning of this kind of food safety regulation. A first central characteristic of HACCP is that it is based upon self-regulation: responsibility for guaranteeing food safety lies wholly with producers. Producers design, implement, and constantly verify plant-specific plans – HACCP analyses – that attest how various hazards are dealt with at each stage of production, for each product. This is a process-based approach to regulating food safety that replaced an older “command and control” style of regulation largely reliant on testing the integrity of random samples of finished products and regulating sanitary operating procedures. A second central feature of the HACCP system is its scientific approach to controlling food-born hazards. The “scientification” of food safety regulation means that every regulatory decision and every plant-level procedure has to be justified with scientifically valid studies. The intrinsic strength of such a system is that, in principal, old rules can be challenged with new studies, and that processing innovations, can be validated with new research. Producers can conduct their own scientific studies to justify a particular processing step, which can then serve as the basis for how this process is regulated.
Unlike a finite set of rules, HACCP plans are intrinsically flexible and can rely on an expanding library of studies to regulate food safety hazards. At best, HACCP plans and regulations are “living, breathing documents.” The HACCP system then bears central features of an experimentalist policy regime: it enables actors to build their own rules and it provides a platform for ongoing participation and revisions in rulemaking. By design, a science based regulatory system should be conducive to iterative rulemaking and learning that lies at the heart of experimental governance.

Critics of HACCP have noted, however, that the shift in responsibility to the producer and the scientification of regulations has been detrimental to small food processors (DeLind & Howard 2008; Taylor 2008). Because experimentalism is premised on a regulatory system’s ability to learn from a variety of stakeholders, I investigate this critique. My research suggests that HACCP reliance upon science has indeed limited the participation of a particular kind of small actor and precluded the possibility that the regulatory system might learn from their experience. Scientification of food safety regulations after the introduction of HACCP has had a very uneven effect on small meat producers. Many small producers lacked the expertise and resources to adapt to HACCP and could not invest to update plant equipment to facilitate compliance. For these establishments, HACCP regulations posed potentially insurmountable challenges, eliminating the viability of particular products and forcing some of them out of business. Other small producers more easily incorporated HACCP requirements into existing operations. HACCP was their regulatory reality: “HACCP is a quality system. We see ourselves as part of this system.”

These producers possessed human and material capital that allowed them to take advantage of the flexibility of HACCP. They could interpret scientific studies and engage in science-making, they had modern facilities, and absorbed the cost of continuous self-monitoring through higher margins. For these plants, the cost of compliance with HACCP regulations was less threatening and more manageable. HACCP-type food safety regulations then created an outcome: they produced a particular kind of stakeholder that can viably exist in the system while eliminating others.

The politics surrounding HACCP center on the demand for safe food. But they also stem from these effects of the regulatory regime. The paper documents the main political concerns and positions generated by HACCP in the US meat sector. One of these claims is that production in small meat processing establishments is inherently different, and possibly safer, than that of large-scale industrial facilities. This paper is not in a position to assess the validity of these claims, nor is such an assessment the purpose of this research; rather, I am interested in the responsiveness of the regulatory system. The USDA has recognized the need to support small producers and a host of public support networks have formed to assist them. At the same time, I find that the USDA/FSIS’s responsiveness to political concerns is also constrained by an overwhelming reliance on food science, the discipline that undergirds food safety regulations. Food science centers on the study of the chemical and physical properties of food and while it may excel in this field, it is (at least currently) not well equipped to assess the validity of political concerns that pose questions that have not been examined and arbitrated by food science. Hewing closely to food science then, the USDA/FSIS did not assess and evaluate political demands that were, hence, easily de-legitimized as “unscientific.”

Finally, to presage the implications of these observations for debates on experimentalist governance, the paper concludes with the argument that the experimentalist character of science-based regulatory systems can be undermined, if – and to the extent that – the science underlying it excludes a particular stakeholder, either by raising the burden of regulatory com-
pliance or by de-legitimizing their concerns in the politics surrounding regulations. Experimental arrangements, then, will need to pay particular attention to the ways in which a particular scientific discipline that undergirds regulations disadvantages particular stakeholders or excludes them from political deliberation.

Two types of evidence serve as the empirical basis for these arguments. To understand how HACCP functions and its effects on small producers, I rely on in-depth semi-structured interviews with small plant owners and with regulators of the USDA/FSIS in which I solicited information about their experience with the HACCP system.\textsuperscript{10} For a representation of the politics of HACCP, I analyze comments submitted in response to a draft ruling that clarifies a controversial aspect of plant-level HACCP protocols known as “validation,” and the USDA/FSIS response to these comments.\textsuperscript{11} Nearly two thousand comments were submitted by a variety of interested stakeholders, including consumers, producers, retailers, and non-profit organizations; this paper is based on the 348 comments that the USDA made publicly available. Both sets of sources – the interviews and the comments – mainly reflect the experience of meat processors and consumers. Meat, poultry, seafood, and juice producers have been legally required to implement HACCP analysis since January 1998, after the enactment of the 1996 “Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems Final Rule.”\textsuperscript{12}

I should note that the implementation of food safety regulations at the plant level is a sensitive research area – processors are very reluctant to discuss any challenges related to the implementation of food safety rules.\textsuperscript{13} Existing studies on HACCP in developed countries either focus on the institutional architecture of governance and do not include evidence of how it functions in practice, or they rely on a smaller number of detailed case studies (Feltault 2009; Vos 2010; Tai 2010; Henson \textit{et al}. 2011; Demortain 2012; Humphrey 2012; Pachirat 2013).\textsuperscript{14} Triangulating accounts of producers, regulators, and the broader public, this paper provides a new angle on how the regulatory system functions. From here the discussion proceeds as follows: the next section introduces experimentalist governance and basic aspects of the HACCP system. Sections 3 and 4 outline how the HACCP system functions, parsing the costs that HACCP entails for small producers and the outcomes it produces. Section 5 and 6 address the political concerns that stem from the way HACCP functions and the USDA/FSIS’s responsiveness to these concerns. The conclusion discusses the implication of these findings for debates on experimental governance.

2. Experimentalist governance and the Hazard Analysis and Critical Control Point (HACCP) system

Most generally, experimentalist governance is an approach to regulating markets under the conditions of uncertainty. More precisely, it is a mode of governance that relies on “a recursive process of provisional goal-setting and revision based on learning from the comparison of alternative approaches to advancing them in different contexts” (Sabel and Zeitlin 2012, p. 169). Learning, and learning from difference, in particular, is a central component of experimental governance. Only if stakeholders share their experience, revise their practices and, potentially, their goals, can experimentalist policy regimes succeed. In Sable and Zeitlin’s formulation, goal-setting, rulemaking, and deliberation are exceptionally open and democratic processes; rules and goals are based on the “concrete experience of actors’ different reactions to current problems to generate novel possibilities,” with “methods, tools, metrics, and values for [a rule’s] assessment to be developed through the implementation process,” rather than being set ex ante
by the regulator (Sabel and Zeitlin 2012, pp. 170–171). The open-ended and potentially trans-
formative deliberation at the core of experimentalism offers new ways of governing democrati-
cally (Sabel & Zeitlin 2010). This claim has been criticized on the grounds that experimental
governance ends up being technocratic and elitist. Both the initial claim about experimental
governance’s potential and the subsequent critiques are a priori valid. The question whether
experimental governance can be legitimate, democratic, and, ultimately, successful in reaching
the framework goals it sets out is, at this point, an empirical question that can only be addressed
with a detailed analysis of how regulatory systems functions in practice. Who are the stakehold-
ers involved in deliberation? Are different types of stakeholders able to participate equally? Is
deliberation transformative – in the sense that regulatory arrangements change in response to
stakeholders’ concerns?

I address these questions through the lens of the HACCP system implemented by the
USDA’s FSIS. In the US, both the USDA and the Food and Drug Administration (FDA) regu-
late aspects of food safety, although so far the HACCP system has been most widely employed
by the USDA, the main regulatory authority for meat, poultry, and fish processing facilities. HACCP systems are often cited as prominent examples of experimentalist governance regimes,
because national and international features of the HACCP system incorporate elements of
flexible, ongoing, participatory rulemaking. First versions of the HACCP analyses were devel-
oped by the Pillsbury Company in the 1960s, on a commission by NASA to design a system
to assure quality standards of food supplied to space missions. The principles of HACCP and
the science that underlies the hazard analysis are the basis for contemporary food safety regu-
lations in the US and Europe, although notably in other advanced industrialized countries,
HACCP is voluntary. HACCP replaced a regulatory system based on a set of good hygiene
practices (GHPs, including the Sanitation Standard Operating Procedures [SSOP]), good 
manufacturing practices (GMP), facility level inspections, and end-product testing. The tran-
sition to HACCP was the result of a growing consensus among food scientists and regulators
that the random sampling of end products was too unreliable and that the system left too
much up to plant-level inspectors’ interpretation. Proponents also pointed out that HACCP
would further cross-border trade and save public resources, by shifting inspection and its cost
to producers. A number of influential promoters of HACCP then argued that it offered a far
better way to both prevent and detect hazards; in the US, the National Academy of Sciences
(NAS), for example, was an early promoter of HACCP principles. This scientific consensus
was buoyed in the wake of a series of outbreaks and the specter of the European bovine
spongiform encephalopathy (BSE) epidemic, which fuelled demands for political action to
guarantee safe food (Ansell & Vogel 2006). The transition to HACCP has been steady but
gradual. The USDA’s FSIS, which regulates meat and seafood, has most fully embraced and
implemented HACCP. The FDA, in charge of regulating other products and processes, has so
far not made HACCP protocols mandatory, and regulation based on SSOP and product
inspections remain an alternative to HACCP. At the same time, even these alternatives tend to
be heavily influenced by HACCP, and, as one observer noted, they “can only be called HACCP-
like approaches” (Demortain 2011). Since 2011, the FDA has also moved further in the direc-
tion of a full-fledged HACCP approach: after outbreaks triggered by tainted spinach, lettuce,
and peanut butter, the FDA Food Safety Modernization Act (known as FSMA, passed in 2011)
requires the FDA to introduce HACCP-based systems in more areas of food production and
processing. In which areas of food processing full-fledged HACCP-based protocols will
become mandatory and what kinds of exclusions apply is currently still under discussion.

I focus on the USDA’s HACCP system for the purpose of this paper because – having been
mandatory for a large number of producers and fully implemented for over a decade – it is both ambitious in scope and relatively mature.

HACCP-style regulations have been called management-based and process-based (Coglianese & Lazer 2003; Zeitlin 2010). Either label describes a style of regulations that prescribe a method, rather than a set of defined rules of behavior. Producers are required to design and implement HACCP plans according to a particular, prescribed methodology, but they are free to decide the particular steps and processes to control food born pathogens and hazards. The criteria that are used to justify a HACCP plan are based on an evolving but very particular body of knowledge – food science. Food science includes studies on the chemical composition of food, food engineering, and food microbiology. Core concerns of food science include the study of edibles’ deterioration and the study of principles underlying food processing. The Codex Alimentarius Austriacus, a collection of standards meant to ensure food safety and further trade established with support of the Austro-Hungarian Empire in 1891, was an early codification of this knowledge. Since then, food science has been a vibrant academic discipline that evolved in tandem with national and international institutions that endorsed its research and findings and issued standards and recommendations. Multiple international and national regulatory and advisory bodies are part of the HACCP network. At the national level in the US, a number of scientific advisory bodies under the auspices of the USDA/FSIS and the FDA advise policymaking bodies and the executive branch on regulatory issues, for example, on the microbiological criteria that underlie HACCP. The US is also a member of the Codex Alimentarius Commission, an international organization co-sponsored by the World Health Organization (WHO) and the Food and Agriculture Organization (FAO). Multi-level governance and the interaction between national, international, and transnational actors are key questions addressed by the literature on the experimentalist features of HACCP (Wendler 2008; Vos 2010, 2008; Zeitlin 2010; Demortain 2012).

This paper examines one aspect of this transnational governance regime, but its focus is scaled down to the experience of producers implementing HACCP. As it is wholly the producer’s responsibility to design, implement, and document the steps that ensure safe food, producers are key stakeholders. In the words of one producer: “We have to assume that meat is dirty. We have to assume it is contaminated. Then our process has to make it ready to eat. We are responsible.” In fact, HACCP entails a series of very demanding prescriptions for producers (Demortain 2011, p.120). Through the process of designing and implementing HACCP plans (“the hazard analysis,” a cornerstone of HACCP regulations) producers systematically identify potential hazards. Hazards are any chemical, biological, or physical contamination that renders food unsafe. Typically, and most lethally, these are bacteria, such as E. coli and Salmonella. Plant-level HACCP plans specify how hazards are controlled, how so-called “critical limits” are monitored, verified and, where exceeded, corrected. Ways to control hazards include heating/cooking or freezing a product, or other treatments, such as irradiating, washing, or spraying it with acidic rinses. When processors design HACCP plans, they have to justify that each processing step is effective in eliminating a particular hazard with scientifically acceptable evidence. Once approved, HACCP protocols have to be verified, that is, processors have to continuously monitor and record what they do and prove that that the chosen strategy effectively controls a hazard. This process is called validation – its requirements are controversial with small processors, as will be discussed in more detail. Regulations do not specify an exhaustive list of documents that producers can use to justify an initial HACCP plan or to validate it, although the USDA/FSIS provides a list of documents that are
typically acceptable. The most common way to justify a control procedure, that is, to prove that a particular processing step is effective in controlling a hazard, is to cite authoritative food science studies that detail ways to control the most common pathogens. Most commonly, these are studies published in peer-reviewed food science journals.\textsuperscript{31}

What did the transition to HACCP-based food safety regulations mean for producers? The advantage of the scientification of HACCP-type regulation is that, by design, it is synced with new research on the microbial properties of pathogens and the epidemiology of food-borne illnesses. HACCP’s ability to regulate diverse and evolving practice with rules that can adapt to new evidence and new findings, rather than from an artificial vantage point of a presumed static body of knowledge, is among its most compelling feature. Moreover, in theory, every producer can be an active participant in the interpretation, adaptation, and even production, of scientific evidence pertaining to food safety. In-house data can be used to generate new studies to validate new processes. In reality, the adaptation of scientific studies and participation in science has been less smooth and more uneven. Interacting with the science of HACCP has been challenging for small producers and they end up being unequal participants in these processes. A major problem stems from the fact that scientific studies that can be used to justify particular processing steps are conducted in labs or large plant settings, while the equipment and processes used by small plants differ significantly. "Often scientific literature is not helpful to small plants. The literature deals with methods typically found in large processing plants, which are not applicable to the experience of small plants."\textsuperscript{32} As small processors cannot replicate lab or large-plant conditions, they have to adapt studies to their process, equipment, and facilities. For example, food science studies utilize pathogen modeling programs with parameter settings that are difficult, if not impossible, to replicate in a small-plant setting.\textsuperscript{33} The HACCP system also expects processors to be able to easily access and navigate the scientific literature, that is, to be “science-literate,” which, according to FSIS representatives, many of them are not: “They [small processors] often have little education, even less time, and are still (as we are) unsure what qualifies as sufficient and acceptable validation of processes in plants that may only produce certain products three or four times per year.”\textsuperscript{34}

Most small plants need to conduct in-house studies in order to adapt existing scientific studies to meet their circumstances. When they did not have enough of a background in food science to do this on their own,\textsuperscript{35} they relied on support – either from established advice networks or, more typically, from external consultants specializing in HACCP validation:

There is a lot of scientific and technical information available from the past 100 years of research. The challenge is deciding what is “appropriate.” Many of these studies were performed in laboratory setting, with a specific product, prepared in a specific way, tested for a variable of interest – say bacteria reduction (\ldots). It is almost always the case that these studies, while providing inference on potential process design controls or validation methods do not precisely prescribe to the activities in question. Thus, additional plant-product specific tests are generally recommended to provide validation. This can costs as little as a few hundred dollars (\ldots) or thousands of dollars [depending on the process that needs to be verified].\textsuperscript{36}

All of this was particularly problematic for a certain type of processor – the “mom & pop operations, with two or three employees,” in the words of one insider.\textsuperscript{37} Many of the plant owners I interviewed ran very small businesses of this type, with facilities that had been in the same family for generations. They almost uniformly noted that HACCP is onerous: “[It’s] a lot of paperwork. More paperwork than is warranted to guarantee food security.”\textsuperscript{38} So, in sum, while
the scientification of food safety regulation is potentially among the most compelling aspect of the HACCP system, it also made the system difficult to navigate and entailed significant costs for small producers. The next sections disaggregate these costs and spell out their effects on producers.

3. The cost of HACCP

The costs that the HACCP system entails for small producers are \textit{a priori} significant. Unlike large establishments, plants with smaller output volumes are far less able to absorb the upfront and ongoing per-unit costs that the introduction and continuous validation of the HACCP system requires. Large processors with multiple facilities can spread costs across far larger production runs. They often have in-house labs and they can, for example, conduct in-house studies in one processing location to use the data to validate production in other facilities.\textsuperscript{39} According to a meat sector consultant:

\begin{quote}
The development, maintenance, and recordkeeping of HACCP plans is much more of a resource burden on small operators because of the economies of scale. […] There is not much difference in the cost associated with a HACCP plan whether an operator makes one hundred or one hundred thousand pounds of product (Taylor 2008, p. 530).\textsuperscript{40}
\end{quote}

Typically, the HACCP system results in three types of costs for processors: (i) the cost of designing a HACCP plan for each product line; (ii) the lump-sum expenses that the plant may need to make to update existing equipment and methods of record keeping; and (iii) the ongoing cost of validating product specific HACCP plans. The initial cost of adapting existing scientific studies to a specific plant-level context can be significant, as introduced above. One observer concluded: “The system does offer flexibility, but it depends how much money you can and want to spend. Each validation study costs $15,000–20,000.”\textsuperscript{41} But the cost of complying with HACCP went beyond the design of the initial hazard analysis. The HACCP system required that plants continuously monitor, document, and report data. A plant’s ability to comply depended in large part on the type of equipment it owned. The introduction of HACCP typically required that small plants update their equipment: “Many small plants are old-fashioned plants, with wood floors, for example. Inspectors don’t like that. Compliance can be expensive.”\textsuperscript{42} If the plant was not able to make capital upgrades and acquire new equipment, workers had to invest labor time to comply – manually measuring and recording temperatures, for example. Such cumbersome “work-arounds” made the endless paper-trails that processors mention particularly onerous: “Most very small plants do not have a pH meter, Aw meter [measures water activity], or data logger [device that automatically records a number of critical measurements] … no very small plants have the use of data loggers, thus [are] continually opening and closing the cooler doors in order to verify the cooling temps.”\textsuperscript{43}

A second class of costs was associated with ongoing measurements and reporting, what the FSIS calls “validation.” Validation means that plants have to prove that the processes they employ are actually controlling pathogens – in the language of the FSIS: “establishments have to validate the effectiveness of its HACCP plans in controlling those food safety hazards identified during the hazard analysis.”\textsuperscript{44} Validation addresses the concern that HACCP plans fail to function in practice. Since the implementation of the HACCP-system in 1998–2000, rules pertaining to validation have been among its most controversial elements. Validation requirements were initially vague, and the FSIS inspectors in charge of assessing plant-level HACCP plans were left with a lot of discretion as to how much validation to require and, therefore, validation was
unevenly enforced. The FSIS tried to clarify this aspect of HACCP by publishing draft legislation on validation in 2010, inviting processors to comment on the proposed ruling. The new rules (not yet in effect as of July 2014) will likely increase validation costs for small businesses that, unlike large plants with in-house validation programs, typically need to send probes and samples to external labs. The American Association of Meat Processors (AAMP) estimated that the cost of initial compliance with the new validation procedures could be as much as $12,000 per product, and several thousand dollars per year/per product in ongoing costs. The 2010 draft legislation resulted in an outpouring of dissent (discussed further in the section on the politics of HACCP).

Per-unit costs matter to small processors, but some small processors can benefit from higher per-unit margins than large producers. Small processors compete in an environment dominated by hyper-efficient, vertically integrated food giants who produce food at very low cost. At the same time, food processing giants tend to produce highly processed foods. Artisanal and traditional products allow small processors to differentiate themselves and they have been in increasingly high demand. Yet HACCP is particularly unfriendly to these to products. In the language of the FSIS, these are products that are “not subject to the common interventions,” relying on uncommon, “non-standard” processes to “control [microbial] lethality.” For less common products and processing steps and for artisanal and traditional processing methods, there are few, or likely no, existing scientific studies that a producer can rely on to justify the procedure. “In general, processes that are not common are more difficult to validate – anything non-typical. (. . .) Also, establishments trying to use older processes or more traditional processes provide challenges.”

In some cases, the adaptation of existing studies may be impossible or the producer needs to challenge existing studies to be able to produce a particular product. For both processes, plants can, in principle, conduct their own studies (these are called “challenge studies”) to justify a particular process. In reality, challenge studies are typically too costly for small producers: “Since a challenge study is very expensive, most very small guys are at a loss what to do.” There are no scientifically established studies for artisanal production and uncommon products. One commentator highlighted these concerns with regard to artisanal sausages: “[There is] not much information available for processes that are not common. (. . .) Often with specialty products, there is not a way the product can be made that can be validated.” The same is true for what regulators call “ethnic” recipes, for example, “Iraqi Kubba,” “Russian Pelmeni” and “German Metwurst.” What these products have in common is that they are meat products that are somewhere between the fully cooked “ready to eat” category, and uncooked/unprocessed meat, hence, particularly difficult, if not impossible, to justify in the HACCP system. Interestingly, these challenging, uncommon processes, include products that are less processed, that is, not processed with the standard heat, acid rinses, etc. Dry-aged meat, for example, does not undergo standard heat processing and several respondents mentioned it as a particularly challenging product. This is important, because it may be precisely these uncommon, non-standard, and less processed products that allow small producers to establish a niche in an otherwise highly competitive sector dominated by large, industrial processing facilities.

4. HACCP produces the producer

HACCP had very uneven effects on producers. The evidence outlined above suggests that the scientification of food safety regulations required plant owners and operators with a specific type of expertise (or access to networks with this expertise) and companies with the ability to absorb
a variety of up-front and ongoing costs. The world of small producers is diverse: some small producers do have these human and material resources and thrive in the current system. To make HACCP work, a small plant had to be able to utilize the system’s flexibility, to produce in-house studies, absorb the cost of new equipment, conduct ongoing validation, employ external consultants, and perhaps even needed to have a quality assurance specialist on staff. Likely this type of small producer succeeded and was able to benefit from the flexibility of HACCP because its products are sold at relatively high profit margins that make up for small batch production: the niche producer of prosciutto, for example, marketing it to high-end restaurants in metropolitan areas and to specialty retailers across the country. For these processors, and notably, for the consumers of their high-value niche products, the HACCP system worked as intended. According to one USDA/FSIS representative:

The beauty of HACCP is that the plant can produce their own scientific information about their practice (gained by doing their own in-plant study, and/or having the processing authority evaluate their process and give their scientific judgment), and if it is scientifically sound and defensible, then it can be used to support their decision in their hazard analysis.52

When the system works, stakeholders and regulators collaborate to determine which studies are relevant and how to adapt them to the processes at a particular plant.53 The cost of HACCP was simply “the cost of doing business.”54 Empirical research on other process-based regulatory systems suggests that participants who surmount the initial burden of participation derive significant material and operational benefits from the process (Espach 2009, Overdevest 2010).55 For other producers, however, the initial burdens were high and the flexibility that HACCP provides was inaccessible. For these producers, the HACCP system made a particular product line too costly to produce. Take, for example, a small slaughterhouse located outside of a major metropolitan area selling proprietary sausage or country ham to a local customer base. This plant could not charge much more than the local supermarket does for industrially produced sausage. Given the slim margins, the plant was not able to justify the cost of a challenge or validation study for this product. There is clear evidence that many small producers gave up particular products and processes, if there was no readily adaptable scientific study to justify it: “Sometimes [small] plant operators are driven to make tough business decisions resulting in eliminating a product because the cost of a HACCP plan cannot be financially justified” (Taylor 2008, p. 530, emphasis added).56

Note that to the extent that “firms change their processes,”57 rules did not follow practice, as HACCP and experimentalist governance envisaged. Instead, practices adapted to principles that are recognized by and easily justified in the current regulatory system. Altering or giving up a product is one point on the spectrum of the negative effects of HACCP on small producers. Effects range from being “overwhelmed” to going out of business. A producer is overwhelmed when a plant’s low-volume production is combined with the difficulty of navigating the science of HACCP and small profit margins. The various difficulties of adapting to the world of HACCP can easily compound: a processor who is unable to adapt existing studies to its proprietary product lines might have to drop products. Less able to differentiate its products from mainstream industrial processing, it loses sales.58 Finally, unable to invest in updated equipment, hence unable to comply with HACCP, it closed its doors: “The regulations put many small processors out of business.”59

This claim is supported by data on the decline in small meat processing establishments. The USDA reported on the number of small and very small meat processing establishments that
voluntarily withdrew from inspection when HACCP was first introduced between January 1998 and January 2000. Table 1 shows that between six and 10 percent of plants did not bother with HACCP; instead they withdrew from inspection, which means that the establishment either closed or converted to a retail-only operation.\(^6\) Note that the effect was larger for small plants that operated under a state inspection license, which are establishments that cannot sell across state boundaries. These tend to be the smallest processors with the most local relationships, both to farmers and customers.

The shrinking number of small meat processors, slaughterhouses in particular, exacerbates an already pronounced trend towards consolidation in the meat processing industry. A small and dwindling number of plants account for the majority of livestock slaughter across the US.\(^6\) In the nine years after the initial implementation of HACCP (2001–2010), the number of federally inspected small cattle slaughter establishments declined from 633 to 549, a 13 percent drop (Johnson et al. 2012).\(^6\) Although their decline started much earlier and HACCP was only one of many factors that put pressure on profit margins of small meat processing plants, the introduction of HACCP seems to have contributed to their decline. What this means is that the current food safety regulations molded the type of producer that can operate viably in the system and the kinds of products they can produce; that is, the regulatory system produced a particular producer and products. This outcome is clearly reflected in the politics of food safety regulations.

I want to point out here that these observations about the USDA/FSIS’s HACCP system add to debates on how process-based regulatory systems affect small producers. While such regulations are known to impose special challenges and burdens on small producers, a number of empirical studies have examined whether small producers can appropriate standards and regulations, and if so, if they derive benefits from doing so.\(^6\) Ongoing debates over the proliferation of Global Good Agricultural Practices (GAP) standards, a set of farm management standards that rest on HACCP guidelines, are particularly relevant for the current discussion of HACCP. GlobalGAP are a set of transnational private standards first developed by European food retailers in the late 1990s (initially known as EurepGAP). Researchers have investigated stakeholder involvement in the development of these standards and found that marginal stakeholders from developing countries typically found it extremely difficult to provide input in the policymaking process, even where inclusive participatory mechanisms formally existed (Henson & Humphrey 2009; Henson et al. 2011; Humphrey 2012). Other studies examine the impact of GlobalGAP on small farms in developing countries. They provide clear evidence that the cost of compliance for smallholder farms has been significant and that some farms are more likely to be able benefit from GAP certification (the established exporters and the recipients of technical and financial assistance, to be precise) (Henson et al. 2011). In terms of the effect of GAP regulations on producers, an interesting finding is also that the skills required for compliance tend to lead to the consolidation of the exporting firms (Henson & Humphrey 2009, p. 29). The experience of small

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Small meat processing establishments withdraw from inspection as HACCP is introduced (1998–2000)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total no. of small and very small plants</td>
</tr>
<tr>
<td>Federally inspected</td>
<td>3,162</td>
</tr>
<tr>
<td>State inspected</td>
<td>1,995</td>
</tr>
</tbody>
</table>

actors in a mandatory, national HACCP system that I document here, hence, mirrors the experience of small actors in exporting countries.

5. Politics of HACCP

Food safety regulations are a response to political demands for government oversight of the conditions under which food is produced (Vogel 2012). The risks of industrialized and internationalized food supply systems are almost completely hidden and inscrutable for consumers (Friedberg 2004). On the whole, consumers and citizens trust that this system delivers safe food. This trust is shaken when disease outbreaks seem to acutely threaten public health and even lives; political calls for more stringent food safety regulations are buoyed after such events. While we all want safe food, regulations also always operate in a social, political, and economic context, where the goal they promote invariably coexists and potentially competes with other political and social objectives. This means that in the political debates surrounding food safety regulations, demands for safe food are weighed against the complicated and uneven effects of HACCP described above. Experimentalist governance explicitly acknowledges that regulation is inherently political; indeed advocacy of a new kind of politics of regulation is among its most important contributions. Whether the experimentalist regime can recognize and respond to various, often competing, political demands is, thus, an important question. This paper set out to examine how experimentalism performs with regard to food safety regulations, and to make inferences about the prospects for democratic deliberation in science-based regulatory regimes more generally. What I will turn to next, then, is an analysis of political demands generated by HACCP and an assessment of the regulatory authorities’ responsiveness to these demands.

To grasp the politics of HACCP, I rely on comments submitted in response to a 2010 proposed ruling intended to clarify the validation requirements of HACCP. Validation refers to the “process of demonstrating that the HACCP system, as designed, can adequately control identified hazards to produce a safe, unadulterated product,” that is, that it works as intended. Validation was not included in the initial 1996 HACCP legislation, although over time the USDA/FSIS found that producers were not adequately validating their HACCP systems. Overall, comments conveyed strong support for small and local meat processors and a pervasive trust in their ability to uphold food safety standards. Table 2 summarizes these concerns.

The most common concern conveyed in these letters pertains to its expected effect on small and local producers. “I am very concerned about what these new regulations might do to my

Table 2  Summary of political concerns of the comments submitted to USDA’s draft legislation on HACCP validation (2010)

<table>
<thead>
<tr>
<th>Political argument 1: “Protect small producers”</th>
<th>Concern about cost for small producers</th>
<th>Concern about cost for local producers</th>
<th>Concern about cost/availability of products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total individual comments:</td>
<td>348</td>
<td>73%</td>
<td>20%</td>
</tr>
<tr>
<td>Political argument 2: “Meat from small plants is safer”</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Different pathogen loads at small plants</td>
<td>348</td>
<td>45%</td>
<td>54%</td>
</tr>
</tbody>
</table>

Source: Data compiled based on comments submitted to the United States Department of Agriculture (USDA). HACCP, Hazard Analysis and Critical Control Points.
ability to buy locally-raised, pasture-fed, and humanely-slaughtered meats,” is a representative example.68 Seventy-three percent of the 348 individual comments include the concern that the rising cost of validation will be detrimental to small processors; 20 percent mention that they are worried about the cost of validation for local processors and nine percent mention a concern about the cost and availability of products by small and local producers. The predominance of this concern is conspicuous because the proposed draft regulations apply to all processing plants, the majority of which are large-scale plants. While the commentators’ motivations vary widely and are variously spelled out,69 the comments clearly demonstrate a political demand to protect small producers.

A second political argument that features prominently in the comments is based on the claim that meat processed in small plants is inherently safer than that produced in large-scale, high-volume and technology-intensive processing facilities: “[S]mall local food businesses are completely different in their risks and challenges compared to large agribusiness, which is the source of most all the outbreaks that the HACCP system is proposed to respond to.”70 (Note again that this argument— that pathogen loads are more of a problem in large plants – and other political concerns discussed in this section are not arguments this paper puts forth nor seeks to assess, they are political concerns generated by the way the HACCP system functions. It is at this point unclear whether the record of small establishments is better or worse than that of their larger competitors.71) A number of commentators make a further claim that if something does go wrong, large plants produce problems that reverberate nationally, while the impact of a problem at a small plant can likely be controlled and contained far more easily:

Our little plant would need to produce tainted food every day – completely and continuously – for more than 20 years to generate the same amount of unsafe product as found within a the most recent significant single-processor recall in our field, which consisted of product that processor created in just a few weeks.72

Overall, 45 percent of the comments make the point that small plants are safer. The political demand that follows from these arguments is the call for a differentiated regulatory system, one that treats small and large producers differently, taking into account the kinds of risks that each is likely to encounter. “We need an inspection system that recognizes that the small plants do not put either the food economy or millions of people at risk.”73 Fifty-four percent of the letter writers call for a differentiated regulatory system (either because of different pathogen loads, different potential to cause damage, or because of the cost of HACCP).

All of the political claims discussed here are highly contested. These positions are opposed by arguments that seek to delegitimize them in a number of ways – either by cornering them as fringe concerns of “hobbyist and organic producers whose customers generally consist of affluent patrons at urban farmers markets,” or as unscientific.74 This latter claim, is an especially important rhetorical position and I will come back to its relevance for experimental and science-based regulatory systems.

6. HACCP’s flexibility and the United States Department of Agriculture’s (USDA) responsiveness

Because HACCP’s experimentalism requires flexibility and adaptability, it is critical to assess responses to the political demands concerning small/local producers. I will specifically examine the role of public and private support networks, of the peer-review system that support the regulatory system and of the USDA’s response to public comments on the draft legislation on
validation; a regulatory system’s flexibility and responsiveness can take on many other forms and
that this discussion is not meant to be exhaustive. Such responses are important to understand
the experimentalist character of food safety regulations in the US.

6.1. Public and private support networks
Whether or not a plant can adapt scientific studies to meet its own circumstances depends inter
alia on its ability to rely on public and private support networks. The advice and assistance
offered by these networks are relevant here, because they potentially foster the growth of
successful niche processors and forestall the trends towards further consolidation of the meat-
processing sector. A number of public and private initiatives offer useful advice to small estab-
lishments. The extension programs of land-grant universities play perhaps the most important
role in assisting small meat processors through a variety of programs, model HACCP plans, and
step-by-step guidelines that walk small establishment owners through the HACCP process. Regulatory authorities recognized the need for such advice and have offered training and help-lines for small processors since the inception of the regulation (Taylor 2008). The FSIS also developed two “standard” HACCP plans that are referred to as “safe harbors” – Appendix A and B of the Pathogen Reduction Act. These safe harbors are step-by-step processing guidelines that are backed by existing studies that processors can use. FSIS interviewees noted that these safe harbor guidelines were a lifeline for small plants and that there should be more of them. They also often added that they do “all they can” to reach out to small processors – “we do a lot a lot of hand-holding with small producers.”

There are also a number of private initiatives by industry associations and non-profit
organizations that assist small producers with advice and model plans. The AAMP and the Niche
Meat Processing Assistance Network (NMPAN) are two notable examples; although there are
also smaller, private initiatives that provide important resources. The availability of support
from networks seems to vary across states. One respondent noted that in states where there is a
strong tradition of small-scale artisanal processing in the meat and dairy sector (e.g. Wisconsin),
the networks that support small processors in navigating the HACCP process are strong, useful,
and reliable. This means that the experiences of small meat processors within the national
regulatory system can be quite different. In some states “they are on their own,” in other states,
there are various resources that help small processors. Further research is needed on how these
private and public support networks have evolved over the years and if they have managed to
help small producers transition towards the kind of small, successful niche processing company
that thrives in the world of HACCP.

While this kind of outreach is clearly important, HACCP protocols are, by definition, site and
product specific and producers must still adapt model plans provided by non-profit organiza-
tions. The support that the USDA can offer, as the regulatory authority, is also intentionally
limited: the same USDA contact that mentioned hand holding also said that “the USDA doesn’t
necessarily approve of that. Officially we can’t do it. It is not what HACCP is supposed to be all
about.” Moreover, standard HACCP plans (the “safe harbors”) provided by the USDA are less
than ideal on at least two counts: first, in the words of one regulator, they “undermine the spirit
of HACCP.” With these documents the FSIS lays down very specific processing steps that a plant
needs to follow, hence, reverting to old-style “command and control” regulation. Second, safe
harbor guidelines are very conservative in the control measures they prescribe, hence, they often
lead to the “over-processing” of food – something that is not desirable for a number of reasons. Following safe harbor protocols also precludes any type of unusual and artisanal processing that
potentially allow a small processor to differentiate their products.
6.2. Regulatory authorities’ responsiveness

How responsive has the USDA/FSIS been to political concerns generated by HACCP? One FSIS administrator upholds responsiveness as one of the system’s main assets: “one of the greatest strengths of the U.S. inspection system is that it is constantly being analyzed and critiqued by lawmakers, consumer groups, scientists, and industry, and we listen to these criticisms and respond in a positive manner” (Billy 1997). I found that while there are institutionalized processes to gather comments and take various stakeholders’ positions into account, the USDA has also been constrained in its ability to arbitrate political demands by its reliance on food science. This claim will need some explanation, which is developed in what follows. I am not making the point that HACCP is intrinsically exclusive; rather I will show that the USDA’s responsiveness was limited because the agency hewed closely to the scientific research generated by a particular scientific field (food science) that does not currently have the methodologies and metrics to evaluate the political claims generated by the way the regulatory regime functions.

A number of important channels for critique of the regulatory system and the way it functions do exist; they include peer-reviews of certain regulatory decisions and calls for comments on draft legislations. The literature on experimental governance relies heavily on the institution of public peer-reviews, “experts criticizing and responding to criticism in public,” as the forum for the new form of deliberative politics (Sabel & Zeitlin 2010, p. 6). The peer review system is, indeed, a central element of the HACCP system on two levels: peer-reviews are institutionalized in the academic discipline of food sciences, and, secondly, the standards, methods and models formulated by the USDA’s advisory committees are also subject to peer review at the level of the regulatory system. Peer reviews typically address issues such as the methodology of a pathogen-modeling program or the validity of risk-assessments developed by the FSIS. At the same time, the risks that USDA’s peer-reviews assess are strikingly different from the risks that the political demands address. There may be a number of explanations for this discrepancy. For one, peer-reviews are premised on a group of experts with a particular and similar background – “peers” after all – and the issues they were asked to assess fell well within the disciplinary boundaries of food science. If the political demands exceed the range of questions that are typically asked and arbitrated by food science, as I argue they do, food science and the institutionalized peer review system are not well equipped (at least currently) to assess the validity of political claims. As any scientific discipline, food science functions as a bounded and contextualized scientific system with particular metrics, methods, and technologies that can make a limited number of truth claims. Whether or not plant-size has an influence on the effectiveness of these interventions, or if plant-size matters in other ways to food safety, are issues that have not been studied by food science. This is perhaps not surprising; as introduced above, food science relies on lab or large plant settings, and the costs of such studies are considerable. What is more, as in many scientific disciplines, valid inferences in food science rely on a presumed “controlled environment;” hence much of the tangible and intangible context of food production is, by definition, held constant and not subject to analysis. An axiomatic assumption in food science is that safe food is guaranteed principally by interventions – the heating/freezing, acidic, or basic rinses – whose effectiveness is based on chemical properties of food, not by attributes, such as plant-size, or other aspects of what we could call the context of production, such as plant ownership, line speed, workers’ compensation, work hours, work conditions, small and infrequent production runs. This does not mean, however, that political claims concerning pathogen loads and the safety of processes cannot be assessed through scientific methods, rather that they have not typically been included in the range of issues and variables food science as a particular scientific discipline has examined.
In addition to peer-reviews, political discussion and deliberation in an experimentalist arrangement should happen in periodic reviews of framework goals and metrics (Sabel & Zeitlin 2012, pp. 169–170). Although such comprehensive periodic reviews of overarching goals, and how progress towards them is measured, are not an institutionalized part of the USDA’s HACCP system, such reviews have happened on a few occasions since its implementation. The deliberation preceding the legislation of validation requirements of HACCP was one such opportunity. The USDA/FSIS’s responses to the political concerns highlighted above are, thus, an interesting proxy for the regulatory authority’s ability and willingness to respond to political demands. One the one hand, the USDA/FSIS did solicit comments on several drafts of the legislation. In its response to these comments, the USDA did acknowledge the problems HACCP posed for small producers and made procedural adjustments to the ruling, for example, granting small plants more time to collect data if they produce a particular product only infrequently. At the same time, this response did not address the main concern regarding the cost of compliance. In fact, the agency stressed that it “has provided low cost ways in which establishments can validate their systems” and concluded, “[...] costs associated with meeting validation requirements will be minimal” (Federal Register 2013, emphasis added). This conclusion stands in marked contrast with the assessments of stakeholders detailed above. A second important disagreement between the agency and stakeholders concerns whether the regulation of validation was necessary for all establishments. The USDA/FSIS insisted on the need for universal validation, referring to investigations and data analyses following pathogen outbreaks, which indicate that improper validation was to blame. What I want to highlight here is that because analyses (based on the methods of food science) did not distinguish between small and large plants, the agency did not assess the argument that smaller plants are safer in its response to question whether universal validation is necessary, or whether two-tiered validation and small-scale exceptions are appropriate. The regulatory authority’s ability to respond to a salient political concerns was again hindered by this reliance on the findings of a scientific discipline that does not furnish evidence to evaluate them.

To sum up this discussion of the USDA’s responsiveness then, hewing closely to the scientific research generated by food science, the agency was limited in its responsiveness to political concerns produced by HACCP, even if it excelled in evaluating the issue it seeks to address. Food science has not adequately evaluated whether attributes of small plants render food production safer in small plants. As a result, these claims were vulnerable to appear “unscientific,” even if there was no intrinsic reason why they could not be evaluated with scientific methods and incorporated into the regulatory authorities’ decisionmaking. In the European Union (EU), political demands for a food safety regime that values artisanal processing methods have been stronger from the outset and they were not delegitimized in the same way. A large EU-funded targeted research project examined traditional sausage-making practices to evaluate methods to “improve the safety of traditional dry sausages from the producers to the consumers while preserving their typical quality.” Initiated in 2003, this project, in turn, gave rise to dozens of publications on various aspects of food safety, including “socio-economic” considerations, in traditional meat processing establishments over the last decade.

7. Conclusion – theoretical implications for experimentalist governance

At its best, the USDA’s HACCP-system was flexible and small producers that had the skills and capital to appropriate the science underlying it thrived. Not bound by specific regulations, they were able to adapt rules to plant-level processes and public and private support networks
supported them while also upholding the policy-regime’s framework goals. On the other hand, the evidence also suggests that the USDA’s HACCP-system excluded certain stakeholders and that its reliance on the mechanisms and institutions of a particular, bounded scientific system, with its methods, its data, its cadre of recognized experts was, in some instances, problematic. A number of the more traditional, older small plants were marginalized in two ways: first, unable to replicate the lab and large plant settings, their experience did not count as generalizable by the standards of institutionalized food science. Secondly, concerns about the effects of HACCP on precisely these small producers were easily deflected as “unscientific” and, thereby, de-legitimized. To the extent that the concrete experience of some actors (i.e. those who do not have the resources to conduct scientific studies) was excluded from regulatory decisionmaking and from influencing the policymaking process, the kind of learning from difference and the recursive deliberation that are the building blocks of experimental governance failed their democratic promise.

Political pressure has led to the adoption of a small-scale exemption in the FDA’s HACCP-based regulations that are mandated by the Food Safety Modernization Act, although the extent of this exception and its effects on small producers are not yet clear.97 The experience of the USDA’s HACCP-system should be considered an important precedent and learning opportunity for FDA regulations, although the two regulatory bodies deal with different sectors and products. Despite this caveat, one could imagine two potential “fixes” of the HACCP system as currently implemented by the USDA that would counteract its exclusionary tendencies: a first would provide small producers with more resources to participate in the production of scientific studies, and a second would encourage targeted research programs that specifically examine the experience and claims of alternative producers. The assistance networks and safe harbor protocols described above serve the former goal: they allow small producers to access scientific studies produced by large producers. They provide different kind of resources, although safe harbor protocols amount to something more akin to a loophole, as they prescribe particular processing steps. Given what I have attempted to demonstrate above, however, more diverse and interdisciplinary research on the processes and experience of small producers would enable the system to include these in the recursive learning process underlying experimentalist governance on their own terms. A re-examination of the standards of generalizability would enable small plants to count their in-house processes for the validation of HACCP plans. Aspects of the context of meat production that political claims assert are important can and should become part of studies about food safety, either by studies that push the disciplinary boundaries of food science in new directions or through inter-disciplinary research. Interdisciplinarity may be an important attribute of this research; precisely because regulations operate in a complex social and political context, political claims may need to be evaluated with the methods and data of multiple scientific disciplines. While in conversation with established debates in food science, such studies would assure that small processors’ experience fully registers in the iterative deliberation at the heart of experimental governance. Targeted research support for these kinds of studies should be conducive to the regulatory authorities’ responsiveness.98

The recognition that the cost, accessibility, and availability of scientific studies and the methods of the particular scientific discipline underlying a science-based regulatory regime may be limiting participation is a relevant finding beyond this study of HACCP-based food safety regimes. It has always been tempting for regulators, scientists, and particular interests groups to designate a particular domain as scientific, in order to control important parameters of regulation (such as criteria for assessing success and failure). This move de-legitimates particular political claims as “unscientific,” while de-politicizing issues within the “scientific” domain.99
Perhaps because scientists engage in elaborate “boundary work,” scientific disciplines tend to be constituted as separate realms, insulated and separate from other realms – from other disciplines, from the non-scientific, the irrational, and the political realms – where claims are not supported by similar standards, rules and methodologies (Jasanoff 1987, Fourcade 2009, p.294). Whether or not there is something inherently exclusionary about science-based regulation is not the question at stake here. Rather, what I am suggesting is that for HACCP-systems, and science-based regulatory systems more generally to work in an experimentalist fashion, science needs to live up to the ideal of producing knowledge in the kind of recursive, open-ended and democratic processes that lie at the heart of direct deliberative democracy. Only if various stakeholders can advance arguments and reasoning that reflects their experience and evaluates their concerns does the scientific basis of a regulatory system enable democratic deliberation.

By contrast, as long as regulatory authorities remain exclusively wedded to the metrics and methodologies of a particular discipline, their ability to learn and the experimentalist character of regulations will remain underdeveloped and skewed towards the experience of actors that can navigate this particular scientific discipline.

Without denying the validity of scientific evidence and science-backed claims per se, it is important for stakeholders in science-based regulatory regimes to recognize that the boundaries between what constitutes a political claim and a scientific claim are always artificial. Given the temptation for regulators and political interests to reify boundaries between political and scientific realms, what is ultimately at stake here is experimental governance’s ability to recognize the artifice of these boundaries and to keep them permeable. If an experimental governance arrangement can contribute to creating a processes of deliberation and learning that accepts rationales and proof backed by scientific reasoning that is multiple rather than unitary, it could make an important contribution to overcoming enduring dilemmas that arise at the nexus of science, regulation, and politics.

Acknowledgements

The author would like to thank Gary Herrigel, Jonathan Zeitlin, Chris Ansell, Jay Rehm and Tal Yifat as well as the four anonymous reviewers enlisted by Regulation & Governance for their thoughtful remarks and critical suggestions.

Notes

1 Federal level food safety regulations go back to the Pure Food and Drug Act of 1906, the US’ first national food safety law; see Law 2003.
2 A number of interesting studies address the effects of GlobalGAP standards on developing countries, see discussion in text below, at the end of section 4.
3 In economic sociology, this debate has taken place mainly as part of the debates on performativity based on Michel Callon’s work. In political economy, this research is emerging; see Carpenter (2010) for a compelling argument on how the FDA has shaped the type of pharmaceutical company that dominates this industry in the US.
5 For the prominence of science in the development of HACCP systems, see Demortain (2007). Science-based regulation is a broad concept for a variety of different scientific techniques commonly used in policymaking, for a discussion see Smith (1992). Cost-benefit analysis is one of the most widely used scientific methods; see Sunstein (2003 and 2012) for a staunch advocate of cost-benefit...
analysis. However, note that Sabel and Simon (2011) explicitly counterpose experimentalism to cost-benefit analysis.

6 The interviews with regulators are named after the state they are responsible for and the date of my conversation/correspondence. This is a comment by the FSIS contact person in Kentucky, which I will indicate in what follows as “Kentucky contact, interview 15 February 2013.”

7 A detailed examination of HACCP’s costs follows below.

8 Q. Meats, Iowa, interview 11 October 2012. Interviews with meat processors are also anonymized; see note 13.

9 The adoption of the HACCP system may have even offered a number of material and operational benefits. While my research design did not consider this possibility, I am grateful to one of the anonymous reviewers’ of *Regulation & Governance* for pointing it out. See also notes 52 and 61 below.

10 I conducted 36 interviews between 2011 and early 2013. The interviews with regulators were conducted in spring of 2013 with USDA/FSIS state-level coordinators; I obtained their contact information through the USDA. These are the FSIS’s point-persons for small plants in each state, who were far more open to discussing plant challenges based on their everyday experience working with small plants on their HACCP plans. I conducted phone interviews and/or received email replies to a set of questions with 22 regional contacts representing 20 states. The interviews with small plants were conducted primarily in Illinois in 2011 and 2012, based initially on USDA contact information of USDA certified slaughterhouses. I then continued utilizing the snowball methods – one producer suggested another that might be amendable to being interviewed. I conducted 16 in-depth interviews with small plant owners in the mid-West (Illinois, Wisconsin, Iowa).

11 Of the 1924 comments that were submitted, 526 were individual comments. The USDA made 384 of the 526 individual comments available online. The remainder of the submissions consists of 27 different form letters. Of the 27 form letters, the vast majority (1,039) was based on one form letter. As the USDA provides no information about who drafted and circulated the form letters, I did not include them in the analysis here. To assess USDA/FSIS responsiveness, I analyzed the agency’s official responses to “concerns about validation, its applicability and cost,” published 23 May 2013 in the *Federal Register*.

12 The Final Rule was published by the USDA/FSIS in July 1996. Small plants had until January 1999 and very small plants until January 1999 to implement HACCP. With the implementation of the Obama administration’s Food Safety Modernization Act (FSMA) more sectors will be required to follow HACCP style regulation in the future; more on FSMA follows below see also Humphrey (2012).

13 I found that owners of small plants were often reluctant to discuss specific plant-level issues and problems in detail. A company’s reputation relies on outstanding food safety records and unless a major food scandal or a product recall is necessary, HACCP protocols are confidential. “For a small plant, any issue, even a small one, that gets them into the headlines could be potentially very damaging to their reputation and to their business, because their customer base is so local and comparatively small,” W. Meats, Illinois, interview 28 June 2011.

14 Feltault’s (2009) study is based research with seafood exporters in Thailand. Henson et al. (2011) is an excellent ethnographic study of HACCP in action at an industrial slaughterhouse. Pachirat (2013) relies on under-cover research in one case.

15 Theorized as direct deliberative polyarchy (DDP). Debates on this aspect of EG discuss whether this could be a new way for European Union governance to overcome the EU legitimacy and democratic deficit.

16 Special issue of *Regulation & Governance*, Volume 6, September 2012. Several contributions to the special issue discuss this; see contributions by Verdun, Fossum and Börzel.

17 The division of responsibilities between the two agencies is arcane and its fragmentation has been subject to criticism for years, see GAO (2004). The USDA’s FSIS is in charge of meat and poultry inspections (though, notably not eggs) and it is the FSIS that has championed HACCP; hence my research focused on FSIS regulators.
18 At the same time, food safety’s reliance on scientific reasoning makes it a test case for experimentalism, because science and technocratic governance have been criticized for their exclusionary tendencies; for the case of food safety regulations, see Vos (2010). In more general terms, Beck’s work on the social construction of risk and his criticism of scientific expertise is interesting in this context. Beck argues that only some out of the many possible risks are quantified through scientific systems of risk calculation. He makes a further claim that each scientific system is “in a marriage” with particular political and economic interests, and that “the sciences are entirely incapable of reacting adequately to civilizational risks, since they are prominently involved in the origin and growth of these risks” (Beck 1992, p. 59). The relationship between science and technocratic and democratic governance is also discussed below.

19 In Japan, for example, the use of HACCP-based system is voluntary. In many countries food processors who export to the US and Europe rely on HACCP-systems (Japan, Turkey, Thailand, for example). For Russia’s experience with HACCP, see Berman (2009).

20 GHP, GMP and SSOP are today often called the prerequisites for HACCP. Several national and international regulators, including the EU for example, publish guidelines as to what these practices entail; unlike HACCP, they prescribe practices, rather than methods.

21 NAS recommended in an influential 1985 report that HACCP should form the basis of food safety regulations.

22 Demortain (2011) provides a comprehensive overview of how HACCP fundamentally reshaped food safety regulations in the EU.

23 The 2011 FSMA aims to extend the principles of HACCP, including its reliance on science, to new areas of food production, that is, beyond meat, poultry, and dairy. The details of the regulatory regime are currently debated; http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247546.htm. Last accessed October 17, 2014.

24 FDA invited comments on draft regulations in 2013; as of July 2014, no final rule has been announced: http://www.fda.gov/Food/guidanceregulation/FSMA/ucm334114.htm, last accessed October 17, 2014. Poultry plants rely on a combination of HACCP principles and line-inspections; a proposal to extend the reach of HAACP is being tested in what is called the HACCP-Based Inspection Models Project (HIMP). Many food safety insiders consider HIMP inadequate to guarantee food safety: http://www.nytimes.com/2012/04/05/us/usda-poultry-inspection-plan-sets-off-dispute.html?ref=us, last accessed October 17, 2014.

25 For an overview of what food science is, see for example, the Institute of Food Technologists, a professional organization for the advancement of food science and technology; http://www.ift.org/, last accessed October 17, 2014.

26 In the US many food studies institutes were established at large land-grant universities in the mid-50s.

27 These are the FDA’s Food Advisory Committee, the USDA/FSIS National Advisory Committee on Meat and Poultry Inspection (NACMPI), and the National Advisory Committee on Microbiological Criteria for Foods (NACMCF).

28 For the history of the Codex Alimentarius Commission, see Winickoff and Bushey (2010) and Demortain (2012).

29 The food safety regime of the EU also relies on HACCP. At the same time, as Zeitlin (2010) points out, “neither Codex nor EU regulations set out the specific features a HACCP system must have, but instead leave it to member states to define their own variants, with guidance from the Commission and a networked European Food Safety Authority (EFSA).” Similarly: “it’s not the USDA inspector’s job to design the HACCP plan or HACCP programs, [it’s] the responsibility of the establishment,” Ohio contact, interview 21 February 2013.

30 These include the Journal of Food Science and Technology, the Journal of Food Quality, Food Control, and Journal of the Science of Food and Agriculture.

31 Arkansas contact, interview 18 February 2013. Similarly: “[A] problem that small plants have is the lack of scientific and technical information that is similar enough to their processes to actually be able to use..."
those documents to support their processes,” West Virginia contact, interview 15 February 2013; and
“Small plants are struggling because scientific studies are not easily adapted to their processes,” Illinois
contact, interview 20 February 2013.
33 “If the process they [the small plants] want to use is significantly different from the scientific study they
choose to use, one of the biggest challenges is to meet all of the critical parameters of that study and
maintain the characteristics of their original product,” North Dakota contact, interview 13 February
2013.
34 West Virginia contact, interview 15 February 2013. Similarly: “One of the biggest challenges would be
in finding approved scientific supporting documentation, as small processors would not necessarily
know where to find this information without guidance from regulatory sources [. . .],” Alaska contact,
interview 14 February 2013. “The educational background of people running the plants is a factor. [It
is] sometimes difficult to understand the scientific studies or how to apply the studies to the case of the
firm;” and: “Knowing where to seek the information is difficult,” Minnesota contact, 19 February 2013.
35 “In some cases, they [small plant owners] may have the talent and resources to perform their own
validation work, but that is highly unlikely if a microbial hazard is involved,” Missouri contact, 12
February 2013.
36 Indiana contact, written response to interview question, 27 February 2013. Similarly: “if you want to
do something that does not have published research, you have to prove that what you want to do works.
You have to hire a lab that does a validation study of your process,” Q. Meats, Iowa, interview 11 October
2012.
37 Illinois contact, interview 20 February 2013.
It’s expensive,” C. Locker, IL, Interview 3 June 2011. “It is a very time consuming process, it needs to be
39 See a reference to this in the HACCP validation draft guidelines, p.10 http://www.fsis.usda.gov/PDF/
40 Similarly: “Costs are a big issue for small processors. These small processors operate under very slim
profit margins. And anything that puts additional pressure on them can be very threatening,” Illinois
contact, interview 20 February 2013: http://www.fsis.usda.gov/wps/wcm/connect/4fa81deb-7b7d
41 Q. Meats, Iowa, interview 11 October 2012. Similarly: “Generating new documents is often costly,”
Wisconsin contact 2, interview 20 February 2013.
43 Montana contact, written response to interviews, 22 February 2013.
44 See HACCP final rule, available on the FSIS website: http://www.fsis.usda.gov/oa/background/
finalrul.htm.
45 AAMP Perspective on Validation Guidance: http://www.aamp.com/documents/AAMPPerspectiveon
ValidationGuidance.pdf These estimates were reported widely, see for example, Boettemiller (2010b).
46 Arizona contact, interview 15 February 2013.
47 Wisconsin contact 2, interview 20 February 2013. Similarly: What types of processing are particu-
larly challenging? “Areas that do not utilize [the] recognized time and temperatures or the application
of [established] anti-microbial processes to control lethality,” Arizona contact, interview 15 February
2013; and “For niche products, there is not much research available,” Ohio contact, interview 21
February 2013.
48 Florida contact, interview 12 February 2013. Similarly: “The cost of a challenge study is prohibitive,”
Minnesota contact, 19 February 2013. “A challenge study is costly. Many small processors do not have
in-plant labs,” Wisconsin contact 1, interview 19 February 2013.
49 Wisconsin contact 1, interview 19 February 2013.
50 Illinois contact, interview 20 February 2013. Similarly: “The process categories we see the most lack of
scientific support for are products such as cold-smoked sausage . . .” North Dakota contact, 13
February 2013; and “In general, I would say that it is difficult for small plants to find scientific and
technical information for specialty products like country cured ham or dry cured bacon,” West Virginia
contact, interview 15 February 2013. This area of processing was mentioned by several FSIS contacts
and regulators: “The areas concerning production of dry cured and dry aged ready to eat products,”
Vermont contact, interview 14 February 2013; and “Often for dry cure or air aged meats there are no
validation studies,” Wisconsin contact 1, interview 19 February 2013. The full quote on ethnic products
is: “For some ethnic products there are no established HACCP rules,” Illinois contact, interview 20
February 2013.

51 See discussion below on the EU regulations of artisanal meat production.
52 Vermont contact, interview 14 February 2013. Similarly: “HACCP is a quality system. We see ourselves
as part of this system. (. . .) We don’t resent it, we are not angry about the tests that it requires. We are
interested in working within the system,” Q. Meats, Iowa, interview 11 October 2012.
53 This is also reflected in the following comments: “HACCP is actually a good thing. It has reduced the
room for interpretation of inspector. As long as we are doing what we said we are, we are fine. Before
HACCP, each inspector had his own ideas of what we should be doing. Now inspectors only monitor,”
54 Oklahoma contact, interview 17 March 2013.
55 See Espach (2009, p.88) While I do not have the appropriate data to assess this point for meat
processors, it is an interesting question that warrants further research.
56 Similarly: “If the current process cannot be supported with [existing] studies, then the process has to be
discontinued or the plant has to make a change;” and “The firms change their processes,” Minnesota
contact, 19 February 2013. In addition: “They alter their process to fit a supporting document,” North
Dakota contact, 13 February 2013; and “There is often quite a bit of back and forth . . . Sometimes there
isn’t a straightforward answer and producers and regulators find a solution to a problem. Sometimes
producers find another process that fits their need,” Illinois contact, interview 20 February 2013. While
I focus here on meat processing plants, media reports on the experience of restaurants that had to
discontinue the process of in-house dry-aging are interesting in this context; see http://
www.ediblebrooklyn.com/magazine/not-so-cut-and-dried/
57 Minnesota contact, interview 19 February 2013).
58 In interviews with small plants, they often noted that they can’t raise prices too high – even though their
product is different, they still compete with supermarkets.
59 Arkansas contact, interview 18 February 2013. Similarly: “some plants closed doors in response to the
new regulations in the first years,” Kentucky contact, interview 15 February 2013. Also interesting in
this context is a remark by a meat processor: “At the beginning [of the HACCP-system] some
processors went out of business. [Partly . . .] because of generational issues. Owners in the upper age
range were used to doing things their way. They were less willing to change the way they did things. [It
was] too big of a change for them,” W. Meats, IL, interview 28 June 2011). “[The process] can be
overwhelming for small processors,” Pennsylvania contact, interview 20 February 2013; and “A
common challenge we see is the processor is overwhelmed by the HACCP process,” Alaska contact,
interview 14 February 2013.
60 The source defines “very small” as “fewer than 10 employees and less than $2.5 million in annual sales.”
“Small” is not defined in this source, but in the USDA’s statistics, “small” refers to “10–500 employees,
and with annual sales of 250 million or less” (USDA 2000). The same source also gives information
about the number of enforcement actions relating to HACCP implementation undertaken during this
initial period: 48 (1.5%) federally inspected plants and 65 (3.3%) state inspected plants.
61 The exact numbers vary depending on the classification of establishment size: “For cattle, 14 plants
account for the majority (greater than 55 percent) of US slaughter,” (Johnson et al. 2012, p. 10).
62 In this study, “small” is defined as 1–9’999 heads/year.
63 For the adoption of private voluntary standards in the forest sector, see Espach (2009) and Overdevest
Friedberg makes the point that this trust persists, even though the risks are not well understood (2004, p. 6). See also DeLind and Howard (2008).

Nearly 2000 comments were submitted to the USDA’s proposed rule – mainly by consumers, though producers and farmers were also well represented, along with other interested commentators, such as specialty retailers, restaurant owners, non-profit organizations and academics. I focus on the 348 comments drafted and submitted by individuals and made publicly available by the USDA. While any individual could comment, I should note that there is a clear self-selection bias in these comments. They only represent the views of concerned citizens and stakeholders and should be seen as this, rather than being representative of an average consumer or producer’s views. This does not undermine their validity as a source to glean the political issue surrounding the HACCP-system. Comments are available on the USDA website: http://www.fsis.usda.gov/OPPDE/Comments/HACCP_Validation/comments_on_draft_haccp_validation.htm. The individual comments provide an interesting trove of information. Many of the individual comments are quite short, one or two paragraphs; others are longer statements detailing the commentators’ experience and concerns. Comments could be submitted in a variety of forms, including by email, regular mail, and via an online site. Another interesting set of debates preceded the passage of the 2011 Food Safety Modernization Act (FSMA).

This is FSIS’s definition of validation, see for example, FSIS, “HACCP Systems Validation, A Proposed Rule,” Federal Register, May 29, 2013; available online https://www.federalregister.gov/articles/2013/05/29/2013-12763/haccp-systems-validation (last accessed, Oct.17, 2014).

This is the assessment by the USDA/FSIS, see Federal Register (2013), response to comments, also discussed below.

Some calls to protect small producers resonate the demands of a social movement, which has drawn attention to the negative effects to welfare of a concentrated, vertically food integrated system on human health, the environment, and animals. Other comments defend small businesses against overbearing government regulations using tropes of an enduring anti-government theme in American political discourse.

The argument that there is no scientific data on differences in pathogen-loads has been made by commentators friendly to small processing, for example by Lauren Gwin, coordinator of the “Niche Meat Processing Assistance Network” and research associate at Oregon State University (interview with author). One of the comments submitted to the draft legislation from an FSIS employee also notes the importance of this issue, the absence of data on it, and that he would like data collected on this issue: “One of the issues we are continually faced with is the level of food safety risk the small and very small plants pose compared to the large volume producers. Please help us to support [our] effort by providing data regarding the number of positive test results, number of recalls, and especially food borne illness cases traced to small plants.” (Comment 5, batch 18)

DeLind and Howard make this point: “If scale – smaller production and marketing systems, in particular – does not eliminate problems, it does keep them manageable” (2008, p. 305).

This was the position of Senator John McCain and two other Republicans on the Senate agriculture committee in a letter sent to Tom Vilsack, (Boetemiller 2010a). The claim that opposition to HACCP validation is “unscientific” surfaced repeatedly, for example, in the discussion of the Tester Hagan Amendment, an amendment to the Food Safety Modernization Act (FSMA): “There’s no scientific basis for Tester . . . It’s an accommodation so that the bill would be able to make its way through the Senate and the Congress and get to the president’s desk.” Comment by David Plunkett, Center for Science in the Public Interest (Clark et al. 2011).

The future of food safety regulations under FSMA will be an important test case; for more on FSMA, see notes 23, 24 and 97.
This is also one of the findings of the literature on the GlobalGAP standards; see Henson et al. 2011.

The University of Wisconsin Madison’s Center for Meat Process Validation is among the most important such initiative; see http://www.meathaccp.wisc.edu/

This was mentioned in a number of interviews, including interview with Ohio contact, 21 February 2013. See also Taylor 2008.

“Plants were frustrated that many commonly used processes didn’t have documentation easily available like Appendix A & B – having more of those would really help,” Oregon contact, interview 16 March 2013. Similar point noted by Illinois contact, interview 20 February 2013.

Illinois contact, interview 22 February 2013. These conflicting imperatives for inspectors – to help and instruct the plant owner on what to do or, conversely, to document and report problems – are an interesting tension of the HACCP system. See the testimony by an inspector: http://www.pbs.org/wgbh/pages/frontline/shows/meat/interviews/mckee.html, last accessed October 17, 2014. See also Pachirat (2013).

AAMP can be found at: http://www.aamp.com/ and NMPAN at: http://www.nichemeatprocessing.org/ An interesting example of a local private initiative is a Kickstarter campaign to share HACCP: http://www.npr.org/blogs/thatsall/2013/10/02/228587024/how-s-the-sausage-made-hackers-want-to-open-source-it-to-find-out, last accessed October 17, 2014.

Missouri contact, interview 12 February 2013.

Kentucky contact, interview 15 February 2013. By contrast: “The University of Wisconsin Meat Lab is a great resource,” Wisconsin contact 1, interview 19 February 2013.

Some states have associations of meat processors and small plants can go the association for help. Kentucky does not have one. [Producers can turn] to the American Association of Meat Processors [AAMP] . . . [or to] the land grant universities that often have extension programs.

Illinois contact, interview 22 February 2013.

Illinois contact, interview 20 February 2013.

New Jersey contact, interview 27 February 2013.

For these protocols to be viable and promising for small processors seeking to produce niche products, they would need to move away from prescribing over-processing.


This should not be read as a disparagement of food science’s achievements, rather a clarification of what any one scientific system can and cannot arbitrate. Wagner, for example, has pointed out that science often does not have all the answers that regulators seek. Even if scientists have an interest in upholding the determinacy of their truth claims, as Jasanoj demonstrates, Wagner (2003) makes a convincing argument that every form of science provides evidence to regulators and policymakers that tends to be inconclusive, incomplete, and indeterminate. Wagner calls the reliance on agencies’ science to avoid public accountability the “science charade,” (1995, p. 1617). Jasanoj finds that policymakers tend to and have an interest in “emphasizing the indeterminacy in science,” contrasting this with scientists reluctant to have this indeterminacy exposed (1987, p. 198). In this context, I also found Fourcade’s (2009) work interesting. Wagner and Fourcade conclude somewhat differently from Jasanoj that policymakers also have an interest in upholding the determinacy of science, as this legitimizes agency independence (Wagner) and political positions (Fourcade). Where the fault lines of the “boundary disputes” between science and policy ultimately lie, perhaps depends on the political issue in question.

According to Gwin (interview with author) and FSIS representative; see note 69.

These are all elements of the political concerns that are evident in the comments analyzed in section 5. The underlying rationale of the small = safer argument is the following: Pathogen loads often result from improper handling (e.g. E.coli is omnipresent in fecal matter, but should not end up on carcasses
if handled carefully). Small plants, relying on manual and skilled labor, often with family ties to plant owners and better working conditions, can avoid these problems. Large plants handle thousands of carcasses; workers are under pressure to uphold line speed, which makes for conditions that are far more susceptible to pathogens.

92 Another interesting set of debates preceded the passage of the 2011 Food Safety Modernization Act; see notes 24 and 95.

93 The 23 May 2013 edition of the Federal Register details this process in the chapter on “Proposed Rule: HACCP Systems Validation.” One of the reviews of the draft legislation conducted by NACMPI (2011) explicitly pointed to the “unique needs of small and very small establishments, and recommend[ed] that additional resources be developed to assist them in meeting validation requirements.”

94 According to the ruling, an establishment needs at least 13 production days to establish validation. Many small plants infrequently produce certain products and have difficulties complying with this provision.

95 While political demands shaped the direction of scientific research in the case of the traditional and artisanal products, it has also been noted that European food safety regulators wanted to shield the scientific debates from politics as well. Vos has noted challenges for stakeholder involvement in science-making in the European Union’s Food Safety Authority (EFSA) that mirror the findings described above: “While opening up its opinions and other documents, EFSA has been reluctant to open up the debates leading to its scientific opinions. In fact, allowing access to meetings of scientific bodies is considered [by EFSA] to be particularly troublesome, as this could lead to external pressures on scientist and hence to a further politicization of their work.” Vos concludes cautiously that “leaving the construction of sound science only within a closed setting of certified experts may lead to a technocratic approach that one would wish to avoid” (2010, p. 158).

96 The research project was called “Tradisausage” and was based on surveys of producers and consumers. On the producer side, it drew data from 315 traditional processing units from six European countries (France, Italy, Portugal, Spain, Greece, and Slovakia); these producers “were surveyed for the socio economic aspects, the raw materials and the processes, the characteristics and the marketing of the sausages.” See summary of main results: http://www1.clermont.inra.fr/tradisausage/MainResults/Main%20results.pdf and articles published under the umbrella of this project: http://www1.clermont.inra.fr/tradisausage/Publi/articles.htm

97 The small-scale exception was added to FSMA through the Tester-Hagan Amendment, which excluded small-scale food processors that sell most food directly to consumers from having to comply with new regulations. The details of how the small-scale exception is regulated are still being discussed; see also note 24. The full text of the Tester-Hagan Amendment is available at http://www.worc.org/userfiles/file/Local%20Foods/QA_Tester_Amendment.pdf

98 Regulatory authorities should consider finding a way to validate and include the alternative experiences of small producers in the sector’s governance system on their own terms, for example, through something like an alternative scientific field of “small-plant studies.” This is only an example of the type of scientific reasoning that could become relevant to the regulation of food safety. Scientific research on the human microbiome has revolutionized how we think about many aspects of health and disease, and it is likely going to challenge established ways of thinking about food safety in the future. See: http://dnrc.nih.gov/docs/Human-Microbiome-Workshop-Summary.pdf

99 It is the temptation to create different realms – the political and the scientific – and draw boundaries between them that serve to delegitimize the claims of those without. Jasanoff (1987) published a landmark study in boundary work between policy and science. Fourcade (2009) notes experts and scientists attraction to this kind of boundary work. It also serves political aims. Genetically engineered crops have always been an area of regulation particularly susceptible to these kinds of arguments; see Miller (2007).

100 In Fourcade’s terms, this boundary work serves “to protect their professional autonomy, jurisdictional claims, and the ability to act” (2009, p. 293).
Fourcade, among others, has noted that scientific expertise is often celebrated as a way to “de-politicize issues” and to subject decisions to “unwavering standards of accountability,” but that this also ends up essentially excluding voices from political debates: “...if de-politicization means taking politics out, it also means taking out the basic democratic right to have a say, however “irrational” it may be” (2009, p. 294) Two examples from the food and agriculture sectors illustrate this problem vividly: Kinchy (2012) demonstrates that Mexican maize farmers were deprived of a voice in political debates about the detrimental effects of genetically modified corn on crop variety, because their position was deemed political, rather than scientific. Suryanarayanan and Kleinman (2013) show that beekeepers claims about the detrimental effects of insecticides on bee colonies were disregarded in the policymaking process, because there is no scientific evidence that proves the link between insecticides and mass extinction of bee colonies.

This conclusion — one the emphasizes the need to open up scientific debates to various disciplinary perspectives – echoes DeBurca’s (2010) and Vos’ (2010) response to critiques of elitism, namely that experimental governance arrangements should encourage the “broadest possible degree of stakeholder participation” to be successful.

References


GAO Federal Food Safety and Security System: Fundamental Restructuring is Needed to Address Fragmentation and Overlap, 30 March 2004. GAO-04-588T


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