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**One HACCP, Two Approaches:
Experiences with and Perceptions of the Hazard Analysis and Critical Control Points
(HACCP) Food Safety Management Systems in the US and the EU**

Richard Hyde, Ph.D.
Lecturer in Law
University of Nottingham
richard.hyde@nottingham.ac.uk

A. Bryce Hoflund, Ph.D.
Assistant Professor
School of Public Administration
University of Nebraska at Omaha
6001 Dodge Street, CPACS 113D
Omaha, NE 68182
Phone: 402-554-4042
Fax: 402-554-2682
ahoflund@unomaha.edu

Michelle Pautz, Ph.D.
Assistant Professor
Department of Political Science
University of Dayton
300 College Park
Dayton, OH 45469-1425
Phone: 937-229-3651
Fax: 937-229-1400
mpautz1@udayton.edu

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Abstract

This paper explores the differences in the use of the Hazard Analysis Critical Control Point (HACCP) system to manage food safety risks in the food chain from farm to fork in the EU and the US. In particular, this paper investigates the current uses and potential expansion of HACCP as a mechanism for the delivery of safe agricultural products, particularly safe produce. It considers not only whether HACCP systems are the best mode of governance for delivering safe food, and describes why HACCP has achieved an important role in the regulatory framework that governs food safety, but asks why this role is different in the EU and US. Within the EU, HACCP is compulsory at all stages of the food chain other than primary production, whereas the mandatory use of HACCP in the US is less widespread. However, the empirical work found that HACCP is being used by businesses in both the EU and US as a basis for organizing their business, even when not required by regulation. Using data derived from semi-structured interviews with regulatory actors in the EU and US, this paper argues that the different approach to HACCP is a result of differing ideas about the role that it plays in the governance of food safety, and the different concepts of the role of regulation in securing safe food. Finally, the paper explores the difficulties of utilizing HACCP to manage produce safety risks, and raises further challenges that must be met in order to ensure that HACCP can successfully fulfill its potential as a governance mechanism.

Keywords: Hazard Analysis and Critical Control Points System, food safety regulation, European Union, United States, democratic experimentalism, food safety management systems

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In recent years both the European Union and the United States have experienced a number of well-publicized food safety incidents that have called into question the capacity of the existing regulatory apparatus to ensure safe food for consumers. In the US, there have been recalls of spinach, peanuts (and peanut products), lettuce, ground beef, and other products. And in the last few years in the EU, Spanish eggs, Italian clams, French and Irish oysters, Polish sausages and minced beef from Sweden have all been recalled, along with other products. Over the last decade, in the aftermath of bovine spongiform encephalopathy (BSE) or “mad cow” disease, the EU has created a new integrated regime regulating food safety, but the US is still grappling with these incidents and debating which regulatory road to pursue (Haines 2009). Central to the EU regime is the requirement that a food safety management system based on Hazard Analysis and Critical Control Points (HACCP) be implemented at most stages of farm-to-fork food production, and it is strongly encouraged in all other areas, including primary production. To date, in the US there has not been a formal requirement to implement a food safety management system akin to the EU mandate, but such systems are encouraged, particularly by trade associations.

Here we are interested in the similarities and differences in the experiences of both the EU and the US in their approaches to food safety and, in particular, their journeys surrounding food management systems. Elite interviews with food safety professionals in government, industry, and interest groups in both the US and the EU demonstrate two current approaches towards increased food safety and use of HACCP. In the US, we have uncovered a growing interest and movement toward the adoption of flexible and customizable mechanisms, such as HACCP, to ensure food safety. Where these systems have been

implemented in the US, the drivers have generally been from industry itself. This business-driven use of HACCP contrasts with the current position in the EU, where a policy decision was made to create a centralized regulatory regime with HACCP as one of its centerpieces. Prior to the formal adoption of Regulation 178/2002, which requires HACCP within the EU, there was movement to adopt HACCP in the food-manufacturing sector, led by the supermarkets through supplier agreements (Havinga 2006). This may suggest that the US is following a similar evolutionary path to the EU, moving from business-driven to regulator-driven adoption of HACCP.

Accordingly, we are focused on attitudes toward HACCP in the US and the EU and we endeavor to address the following questions: What drives these different policy positions in the EU and US? Is the business-driven regime favored in the US deprecated in the EU? Why? Does ‘self-regulation’ mean different things in the US and EU, with the EU focusing on business choice of means of complying with externally imposed obligations and the US focusing on allowing businesses to set their own goals? What does this tell us about the different regulatory approaches of the EU and the US?

We argue that the different approaches to HACCP are a result of differing ideas about the role that HACCP plays in the governance of food safety and the different concepts of the role of business and of regulation in ensuring safe food. We illustrate the contrasting policy choices and attempt to illuminate the drivers behind the different policy decisions in the US and the EU. We consider how the two approaches create linkages between actors in the food production sphere, how the different approaches influence the actions of decision makers, and we illuminate the similarities and differences of approach. Finally, we explore the strengths and weaknesses of the contrasting approaches and consider how they may be applied to the primary production of produce in the US and the EU.

Part I examines HACCP and its use as a regulatory technology within the US and the EU, before considering how regulators are using HACCP, particularly in the produce safety context. It also places HACCP within the regulatory literature, and considers its role as a regulatory intervention. Part II provides a brief overview of the methodology. Part III examines data gathered from interviews with regulatory actors in the US and EU to consider, first, the role that HACCP can play in ensuring safe produce and, second, what is, and can be, the role played by HACCP within the EU and US. Part IV examines the two approaches, particularly in relation to primary production, and considers that the differences can be explained by differing pragmatic judgments on the part of policy-makers in the US and EU. It also argues that the approaches of the EU and US to HACCP can be viewed as an experiment on a transnational scale. However, the different contextual and cultural factors that can influence policy-makers judgment are drawn out. Finally, Part V asks why, if HACCP is an appropriate technology for governing food safety risks, is it not being used, either at all or in the same way between and across the US and EU, tentatively taking the first steps to analyze the data.

Part I – HACCP in the Context of Self-Regulatory Approaches

In this section, we focus on the regulatory alternatives that fall under the umbrella term of self-regulation (Ayers and Braithwaite 1992; Parker 2002). Sinclair (1997, p. 532) states “[s]elf-regulation, in particular, is a highly malleable term which may encompass a wide variety of instruments. These include voluntary and cooperative agreements, environmental covenants, co-regulation, enforced self-regulation, negotiated compliance, codes of practice...” Our focus is on self-regulatory tools because our interviewees in both the EU and the US felt that they are the most likely to address effectively the challenges in the existing regulatory structure. Indeed, both sets of interviewees present HACCP as a model of self-regulation.¹

Self-regulation requires the regulator and regulated community to collaborate to arrive at acceptable standards while shifting the direct monitoring role from government to firm. Instead of adversaries, regulators and the regulated community become partners. Numerous self-regulatory tools have been employed with the movement away from more traditional regulatory structures in a host of regulatory arenas;² for instance, management-based regulatory structures (Coglianese & Lazar 2003) such as systems based on the International Organization for Standardization (ISO) standards for quality management and environmental management. Process-oriented regulation, which governs the ways in which risk is managed, rather than the risk itself, is increasingly used to manage food safety risks (Fairman & Yapp 2005). As well as food safety risks, process-oriented regulation may be used to manage, *inter alia*, health and safety risks (Gunningham 2006) and environmental risks (Gunningham 2002).

Parker and Gilad (2011) identify a move in regulatory practice towards internal corporate compliance management systems. HACCP is one of a family of regulatory technologies that require businesses to engaging in “self-evaluation, design and management of their operations, governance and controls” (Parker & Gilad 2011, p. 170). HACCP exists as either true self-regulation, where businesses voluntarily create a policy to manage the risks in their business, or as “enforced self-regulation,” where businesses are required to assess, control and monitor the risks that they create. In general, the system in the US resembles the former, while the system in the EU resembles the latter. Despite its name, ‘self-regulation’ can be required either by the state or by other businesses (Havinga 2006).

In terms of food safety, a self-regulatory approach would require a peanut company, for example, to devise its own food safety standards and then monitor its operations to ensure that its stated standards are being met instead of relying on the infrequent visits of a US Department of Agriculture (USDA) or state agriculture inspector.

Undoubtedly, there is much debate about self-regulatory tools and their appropriateness (Baldwin 1997; Parker 2002). Interviewees in the US concluded changes are needed since the existing regulatory framework does not have the capacity to effectively monitor compliance with safety regulations and is unable to evolve as new food production innovations and safety challenges occur. In the EU, many maintain that the system that was in place before the introduction and mandatory use of HACCP, and which exists alongside the requirement to put in place HACCP plans, is very rigid and does not enable future-proofing for changes in biology and technology. The challenges of food safety and the desire for a different regulatory model, led our interviewees to focus on HACCP as a self-regulatory tool. This tool--which is already being implemented in addition to the current regulatory requirements--was routinely mentioned by a range of interviewees as the viable option (through implementation, or better implementation) for improving food safety regulation, particularly in sectors where it is not already in place.

Hazard Analysis and Critical Control Point Systems (HACCP)

HACCP requires food businesses to prepare and document a food safety management system to manage risks presented by the hazards that exist in the production, manufacturing, and preparation of food products. In the US, food safety assurance has been sought domestically since the early 1900's (Young 1985). In the EU, member states have grappled with the challenges of safe food for at least as long, initially concerned with problems of deliberate adulteration, but later with hygiene issues arising from the industrialization of food production (Paulus 1974). HACCP systems were initially developed in the US in the 1960's when the National Aeronautics and Space Administration asked Pillsbury to make food for its astronauts and ensure food safety. These systems approach food safety preventatively and emphasize food safety assurance throughout the process, as inspection of the end product is simply not enough to ensure safety (Varzakas & Arvanitoyannis 2008). Critical control points

are identified throughout the production process where risk to the finished product may be introduced; accordingly, once these points are identified, measures can be devised to reduce or eliminate the risk, and monitoring can take place to ensure measures are implemented. As such, in theory, the HACCP system can be employed during the entire food production and preparation process, including raw material production, through procurement, handling, manufacturing, and distribution of the final product, although practical difficulties may give rise to challenges at the level of primary production.

At the core of HACCP are seven principles: (1) conduct a hazard analysis, (2) identify critical control points, (3) establish critical limits for each critical control point, (4) establish critical control point monitoring requirements, (5) establish corrective actions, (6) establish verification procedures, and (7) establish recordkeeping and documentation procedures.

In the US the use of HACCP, though voluntary in most instances, is increasingly being incorporated into existing regulations. The USDA and the US Food and Drug Administration (FDA) mandate adoption of HACCP for the juice, meat, and seafood industries. In the EU incorporation of HACCP into food safety laws is even more comprehensive than in the US (Caduff & Bernauer 2006). All food businesses, except those involved in primary production,³ in the EU are required to put in place a system based on HACCP principles. The contents of the HACCP plan are the responsibility of the food business, or the business may comply with an approved good practice guide.⁴ The EU Commission has emphasized the flexibility of HACCP and makes clear that it means that food businesses do not have to “comply with rules or to implement procedures which are not relevant or adapted to the specific context for their activity” (Directorate-General for Health & Consumers 2009, p. 11). However, once a plan has been put in place, the business must follow the plan and amend the plan to take into account changes to operations. However,

there is variation in implementation across EU member nations, including lenient grace periods for compliance. Widespread data on implementation rates remains elusive to date.

Although government imposed adoption of HACCP systems is increasing, on a worldwide scale, firms that have embraced this approach are doing so largely voluntarily. The International Organization for Standardization (ISO) has developed a standard (ISO 22000) that incorporates the seven principles of HACCP into its broader food management system. Adoption of this standard, as with other ISO standards (e.g. the more well-known ISO 9000 series and ISO 14000 standards), can be independently verified and certifications obtained. In the US, Nestle (2010) notes that the American Cheese Society, the group representing artisanal cheese makers, recommends that its members use HACCP. HACCP is therefore an example of a transnational governance regime (Cashore, Auld, & Renckens 2011), extending beyond national boundaries to standardize the approach to risk management.

As with the broader push for self-regulatory policies in other areas, implementation of HACCP in the US has come largely from the food industry itself and there are many reasons firms embrace this approach voluntarily. Food businesses are able to design their own procedures, provided they conform to the HACCP principles, and to create food safety management plans that suit the practices and procedures that operate in their business. HACCP is not prescriptive and food businesses can implement innovative methods for ameliorating risks to food safety provided that they conform to the HACCP methodology. In the EU, businesses may choose to follow an approved template HACCP plan, rather than designing their own. The ability for businesses to build their own risk management structure is particularly important to businesses using innovative techniques in food production as they are not bound by command and control regulation that may prescribe unsuitable methods for

managing food hygiene risks, and can instead create policy and procedures tailored to their business practices.

Within the EU, HACCP has been legislatively mandated, but it has been supported by the food industry, particularly those large food manufacturers with systems and processes in place which are suited to a HACCP approach to safety. Among smaller firms, the implementation of HACCP has been less welcomed, with these businesses frustrated at the need to produce ‘paperwork’ for the relatively small volumes that they produce. In particular, our interviewees reported the catering sector has been unenthusiastic about the introduction of HACCP.

Varzakas and Arvanitoyannis (2008, p. 1730) state that, “HACCP is a proven, cost-effective method for maximizing food safety.” More specifically, there is some evidence that implementation costs are lower for larger firms (Unnevehr & Jensen 1999), which aligns with our interviewees comments. Caduff and Bernauer (2006) maintain that firms have adopted HACCP systems to address consumer concerns over the safety of their products, although few interviewees reported consumers’ examination of HACCP plans. Relatedly, many firms in the food industry have strong incentives to have universal food safety standards to ensure greater control over their finished product by stipulating standards for suppliers (Caduff & Bernauer 2006). But perhaps the most compelling motivation – and the motivation that transcends much of the push for more self-regulation – is increased autonomy.

These motivations fit well the rationale explaining the increase in self-regulatory strategies embraced by the regulated community. Management-based regulatory strategies are increasingly lauded as viable alternatives to the more traditional regulatory structures in achieving desired outcomes (Coglianese & Lazar 2003; Parker 2002). With this foundation of how HACCP fits within broader efforts at self-regulation, we turn our discussion to our elite

interviews for a better understanding of how these regulatory efforts are being seen and assessed.

Part II – Methodology

We used a qualitative research design for this exploratory study about the development and use of HACCP in the EU and the US. Such an approach allows one to describe the “naturally unfolding program processes and impacts” and allows for a certain richness in the research—the participants’ thoughts, opinions, and experiences are captured in their own words—that one may not be able to get through the use of another approach (Patton 1987, p. 14). That is, a qualitative approach allows one to “lift the veils” surrounding an area of study.

Although studies of HACCP could and have been conducted in other jurisdictions, and in both the US and EU (see e.g. Lowe and Taylor, 2013), we chose to examine and compare HACCP in the EU and US for a couple of reasons. First, the EU and US were selected because they are large markets for food (and particularly produce). In 2007, the EU market for food was worth approximately €875 billion (Eurostat 2009). Of this, produce accounted for approximately €18.2 billion or approximately 2 percent of the total market (Eurostat 2009). In 2009, the US market for food was worth approximately \$669 billion (Center for Economic Vitality 2010). Of this, produce accounted for approximately \$9.5 billion or approximately 1.5 percent of the total market (Center for Economic Vitality 2010).

Secondly, the EU and the US have *prima facie* contrasting attitudes to the use of HACCP. The EU is perhaps the world leader in mandating the use of HACCP. The EU requires all food businesses (apart from those involved in primary production) to adopt HACCP to manage food safety risks. This contrasts with the US approach, where HACCP is only mandated in limited industries, but it prevalent in many businesses. Comparing these

two systems may provide fruitful insights into the reasons for differences in the adoption of regulatory technologies.

Data Collection and Analysis

Thirty-two semi-structured interviews (18 in the US and 14 in the EU) were conducted in both the EU and US with a range of individuals intimately involved in food safety. Interviewees were selected from a base of professionals involved in food safety and food hygiene, such as academics, enforcement officers, consultants or employees of food business operators, and policymakers. The identities of the interviewees are strictly confidential.

Our interviews focused on attitudes towards HACCP, with questions asked regarding the current and potential uses of HACCP both generally and within agriculture, alternatives to HACCP, and whether professionals believe that HACCP is the optimal method for controlling food safety risks. We initially contacted potential interviewees by email or phone, briefly described the project, and asked each individual if s/he would be willing to participate as an interviewee. We used the “snowball” method to gather the names of additional potential interviewees, with interviewees asked to provide other names of individuals who knew about the issue. We conducted the interviews in person or over the phone from January 2010-March 2012.

Some interviews were recorded and some were not. Where interviews were not recorded we relied on our extensive handwritten notes. After each interview, the recording or handwritten notes were typed and compiled. We used NVivo8 to assist with content analysis to distill themes and other insights provided by the interviewees.

Part III – Findings

In this section, we discuss our interview findings and provide an overview of HACCP at work in the EU and US. We discuss and compare the implementation of HACCP in the EU

and US by five key themes drawn from our empirical work: business size, business type, routinization, enforcement perspectives, and perceptions of HACCP. In some cases similarities were discerned, whereas in others interview data identified differences.

Comparing HACCP Regulation in the EU and US: HACCP and Business Size

EU interviewees expressed the view that HACCP worked better for larger businesses because such businesses have greater resources and larger processes, both of which are conducive to the more efficient implementation of a documented food safety management system. US interviewees supported this conclusion. However, the more limited requirements to implement HACCP in the US meant that smaller food businesses could choose to produce documented procedures more tailored to their needs, whereas interviewees drawn from European businesses, that have no choice over adopting HACCP as a means of managing food safety risks, often felt that they are being asked to complete unnecessary paperwork. The suggestion of Gunningham (2002) that small and medium-sized enterprises respond differently to process-based regulation when compared to large enterprises is supported by this research. Interviewees highlight the more limited resources (of time, money, and personnel) and expertise of small food businesses as inhibiting the desire and ability of food businesses to implement HACCP.

Despite the tenor of comments, some enforcement officers have challenged the negative effect of HACCP on small businesses in Europe. One respondent to the UK government consultation on the rationalization of food regulation stated,

I would accept that the requirement to put in place, implement and maintain HACCP based procedures has the potential to be onerous for some (particularly smaller) businesses. However, Regulation (EC) 852/2004 which contains the HACCP requirement and which is implemented by the Food Hygiene (England) Regulations 2006 allows a great deal of flexibility. It does not in fact require a fully documented HACCP system but rather "...procedures based on the HACCP principles" and "...documents and records commensurate with the nature and size of the business". EU and national guidance on HACCP flexibility exists and the key objective is to ensure that all food safety hazards have been identified and are under control. As long

as businesses can demonstrate this to officials they should not have a problem, in theory.

However, this may ignore the importance of the business perception that there is a 'right' and a 'wrong' HACCP plan, and that achieving the 'right' HACCP plan requires extensive expertise and resource. Tailoring a HACCP plan may be stressful and resource intensive for a small business owner, leading to reluctance to spend the requisite time to achieve the benefits. Proportionately fewer resources will be necessary to achieve a tailored HACCP plan, which manages the risks of a larger business, making HACCP a more attractive response to food safety risks for these businesses.

It seems clear that our interviewees perceive large businesses as benefiting from HACCP more than small businesses. This is borne out by the US experience where large businesses have chosen to use HACCP, and small businesses have, by and large, chosen not to. The business benefits of HACCP, such as greater businesses efficiency, are more important to large business, that have more diverse operations, than to small businesses, where personal, rather than process driven, oversight is more likely to be adopted.

Comparing HACCP Regulation in the EU and US: HACCP and Business Type

As well as a divide between large and small business, in the EU, HACCP is perceived differently by food processors and manufacturers and by retailers who supply the food to the final consumer. While this may be partially an artifact of size, it also reflects the perceived usefulness of HACCP to these different situations. HACCP, initially created for large scale food processing where the monitoring of critical control points can be integrated into the work flows within the business, is seen as better suited to large-scale processing. With small-scale catering, where large numbers of different dishes may be created a small number of times each day, integrating HACCP into the businesses is seen as more difficult. One EU interviewee, a consultant food hygienist, went so far as to say that it was impossible to implement HACCP properly in a catering business. Although some general control points can

be implemented and monitored (e.g. temperature following cooking), businesses felt that they are being asked to tailor plans to each product, which is not necessarily feasible in a catering environment.

One EU chef in a small business found HACCP particularly difficult to implement because he changes his menu each day, depending on the available fresh produce. The advice he received from the local authority officers who helped him prepare his HACCP plan prior to opening was that he should devise a specific plan for each meal he prepared, taking into account the hazard that it presented. Changing the menu, therefore, means that the HACCP plan has to be modified along with it. Where products are being produced consistently on a large scale, a HACCP plan can remain consistently in place. However, where HACCP is required in catering, the plan may have to change with the menu. If the plan is not changed, and the specific hazards of a particular dish are not considered, then there is a potential that the risks to consumers are not managed, exposing consumers to greater risk.

Similar concerns were expressed in the US, with one interviewee expressing the view that HACCP should not be implemented in businesses that do not have fixed (or at least semi-permanent) critical control points. In the EU such businesses have to implement HACCP, but find it challenging given the shifting control points, and the difficulty with consistently implement monitoring into the production process.

In both the EU and US some skepticism was expressed about the possibility of implementing HACCP in primary production. Exposure to the elements means that it is difficult to control the process and to implement critical control points and associated monitoring. Risks, such as chemical contamination or animal fecal matter, could be introduced into the production process by external factors not easily anticipated in the design of a food safety management system. However, the EU is moving towards the implementation of HACCP in the primary production sector, once the science of risk

assessment has developed to enable the implementation of HACCP to take into account the vagaries of the elements. Some interviewees expressed concern that if and when HACCP is implemented during primary production, the identification of critical control points may prove difficult for some farm businesses and there may be a tendency to “over-monitor,” leading to increased cost.

Businesses that operate through an oft-repeated process are in the best position to implement HACCP effectively. These businesses tend to be large and involved in manufacturing food products. HACCP can be integrated into the process, which may already have an element of process driven quality control built into the steps necessary to manufacture their products. Monitoring at critical control points is simply another step in the process. The repeated nature of the manufacturing process means that the cost per product of creating and implementing a HACCP plan is tiny. In a small catering business, which has to think about the risks of each product and tailor their management steps to these, the cost per product is higher, as these products will not be produced on such a large scale. A catering business will produce many different products in lower numbers, meaning that the marginal cost in time and resource of assembling the HACCP plan is greater for those businesses. This is an incentive not to engage in the necessary reflection and consideration required to create a HACCP plan which manages the risks of the business, leading small-scale US caterers not to engage with HACCP and EU caterers to engage in a superficial and mechanical way, or to use precedent HACCP plans prepared for sector (or business type) specific use and approved by regulators. It is to such plans we now turn.

Comparing HACCP Regulation in the EU and US: Routinization

The European experience with an enforceable requirement to operate in accordance with a HACCP plan suggests that food businesses want guidance about the plan that they should put in place. In Europe, some food businesses, particularly small businesses, think

they lack the resources and expertise to create a bespoke HACCP plan (or employ a consultant to do so). European small businesses interviewed perceived the requirement to put in place a HACCP plan as quite burdensome (see also Lowe & Taylor, 2013 p. 270). They perceive that they need to either ensure that an employee of the business has the training and expertise to create a plan, or employ an external consultant to create such a plan. Interviewees in the US indicated the same hesitancy to implement a HACCP plan. Further, interviewees indicated that there is no incentive to create and implement a HACCP plan because the regulatory agencies charged with food safety in the US (primarily the FDA and the USDA) do not have the regulatory teeth to enforce it since it is voluntary.

EU interviewees said that such small businesses expressed a desire to routinize and universalize HACCP. This is appreciated by the EU, who allows businesses to comply by following approved plans. However, even in this case, some businesses argued for a move from the flexible standards set out in Regulation 852/2004 to a more definite set of procedures that businesses can be told, according to one interviewee, “if you do this, you will be in compliance with the requirement to put in place a food safety management system based on HACCP.”

Although the majority of EU member states have not created generally applicable national precedent HACCP plan, they have engaged in targeted advice and information campaigns to get businesses to create a HACCP plan. Such guidance may consist of general guidance issued to all businesses, or may be given individually to businesses by regulatory inspectors who visit food businesses.

Ireland has used a strategy with inspectors visiting food businesses required to implement HACCP in sector specific tranches, accompanied by “advice from inspectors, distribution of relevant materials and awareness campaigns” (Food and Agriculture Organization and World Health Organization 2005, p. 53). However, it has been

acknowledged, “in the near future, in order to tackle certain types of [Small and/or Less Developed Food Businesses], a simplified HACCP-based approach may be necessary and resources will have to be allocated for this purpose” (Food and Agriculture Organization and World Health Organization 2005, p. 53). The Food Safety Authority of Ireland has released a “user-friendly” pack aimed at helping catering businesses comply with HACCP requirements.⁶

In the Netherlands, branch associations, which have a specific legal status, represent and support specific sectors of the food industry and which food businesses are obliged to join, have played an important role in providing guidance on HACCP. Certain sector associations have produced guidance on HACCP for their food business members, which aim to “use terminology that is understandable, taking into account the level of education and cultural background of the users of the document” (Food and Agriculture Organization and World Health Organization 2005, p. 57). The Minister of Public Health approves these guides for a four-year period, after which they must be reevaluated. The legislation in the Netherlands provides two ways for a business to fulfill the requirements of Regulation 852/2004, either

...developing and implementing a personalized food safety system or implementing an approved HACCP-based hygiene guide. Food businesses not operating according to a food safety system or hygiene guide are considered to be committing a legal offence (Food and Agriculture Organization and World Health Organization 2005, p. 58).

In the Netherlands, therefore, there is an option to follow guidance propagated by a branch association, and following such guidance provides a safe-harbor against enforcement arising out of the requirement to have in place a HACCP plan. This may tend to concretize compliance, particularly among small businesses who do not feel able to develop and implement a personalized HACCP guide. Similarly, the UK Food Standards Agency has

produced guidance, entitled ‘Safer Food, Better Business’ which business in certain sectors can follow and use to comply with the requirements of Regulation 852/2004.

Each of these approaches has the tendency to suggest that there is a right and a wrong plan, or that particular elements must be present within a HACCP plan. This often leads to routinized food safety management systems, with similar approaches taken across similar (or even dissimilar) food businesses.

The risk that compliance becomes routinized and mechanical, more concerned with performance of compliance than reduction of risk, is an acknowledged risk of process-oriented regulation (Calcott 2010). Routinization may undermine the potential benefits of a HACCP approach, with firms failing to engage in the reflective assessment of the risks within their business, and instead focusing on risks identified in guidance and policy, and taking steps suggested by the guidance, rather than taking steps to manage the risk which involve the best fit for their business (Calcott 2010). In the health and safety context, businesses have been observed using policies developed for different firms without attempting to customize these to reflect the risks of their operation (Dawson, Willman et al. 1988). The routinization engendered by the requirement of HACCP in the EU is somewhat different. The small-scale mechanical application of other firms policies does not have the potential to give rise to routinized modes of compliance throughout sectors, whereas centrally mandated policies can give rise to widespread routinization and standardization, with similar HACCP plans adopted across an entire sector.⁷ The flexibility of HACCP is lessened as each business adopts the guidance, rather than critically engaging with the risks of their business, and the steps that can be taken to manage them.

Comparing HACCP Regulation in the EU and US: Enforcement Perspectives

The trend to routinize requirements for HACCP plans and to make them uniform, also impacts, and is driven by another identified trend, the difficulty of enforcement as described by one interviewee in the EU:

Unfortunately, food safety regulators (and I am one of them) may sometimes take a narrow view of what is acceptable in terms of HACCP and fail to have regard to the extensive flexibility that is permitted.⁸

It is very difficult to know whether a HACCP plan is adequate, as such an assessment requires a detailed understanding of a food business and this takes time. Where HACCP is compulsory, regulators argue that it is easy to enforce in cases where the food business does not have a plan, but difficult where a plan is in place, but it may be inadequate. A dilemma that officers face is that there are multiple HACCP plans that are acceptable, but the officer may have a preference for particular approaches which constitutes best practice. The food business may have a preference for a different approach. The diversity of possible plans allowed by HACCP should mean deference to the plan put in place by the food business, unless it fails to adequately control the risks presented by the hazards identified by the food business operator. Separating a plan that complies with the regulatory requirement, but is not how the enforcement officer would have done it, from a plan that does not comply with the regulatory requirement, is difficult for officers. Further, such an assessment takes time and has important resource implications, because tailoring inspections involves similar burdens to tailoring plans, which we have noted above provide a barrier to the adoption of HACCP. Creating a uniform model on which HACCP plans are based ameliorates this dilemma.

The enforcement of breaches of HACCP requirements was criticized by the Pennington II Inquiry into an E Coli 0157 outbreak in South Wales where one child died. Pennington (2009) identified the need to “selecting one or more Critical Control Points and examin[e]... the implementation of those aspects of the plan in some detail” (Pennington 2009, p. 144). This was not generally the approach prior to the outbreak, and is time and

resource intensive for regulators. Also, enforcement made more difficult by the disconnect between procedure and reality, with regulators arguing, “as much you look at the plan, you cannot tell if it being complied with.” Many interviewees echoed similar concerns with the suggestion made that there was a need for great microbiological sampling programs by regulators to ensure that the microbiological aspects of HACCP were being complied with.

Although things like daily diaries are intended to allow monitoring, interviewees suggest that it is difficult to ensure that these diaries are being filled in on the correct day. This is seen as a problem particularly in small businesses, which may not have the management systems in place to ensure confidence in compliance with a HACCP plan.

Comparing HACCP Regulation in the EU and US: Perceptions of HACCP

Overall, interviewees were positive about HACCP as a system for the management of food safety risk. In the EU, it was variously described as “great,” “easy to use,” and “sophisticated.” In the US, interviewees identified HACCP as a “tremendous tool,” and, when used in the correct environment, a system with “no real disadvantages.” Interviewees in both contexts identified the flexibility and process-wide view as central strengths of HACCP.

However, some interviewees from both EU and US felt that the effectiveness of HACCP could be over exaggerated. They thought that it was sometimes viewed by businesses as a form filling exercise, with the HACCP plan created and then put on the shelf and forgotten about. Training was seen as a necessary component, and the importance of ensuring that plans are followed was emphasized. The important role played by regulators in ensuring that a HACCP plan was translated into safe food was emphasized. The inspector’s role was seen as more central in the EU compared to the US, where businesses have greater freedom to choose to use HACCP.

EU interviewees expressed that HACCP in primary production was a necessary and important part of ensuring that the safety of food. Mandating HACCP is seen as a business-

friendly alternative to traditional command and control regulation, giving businesses a wide discretion to take action they deem necessary. The constraint imposed by mandating HACCP as the vehicle for achieving foods safety management is frequently seen as ‘the cost of doing business’ and the inevitable result of regulatory activity.

The US interviewees took a more market-oriented approach, with the businesses afforded greater freedom to organize the management of food safety with their businesses. Mandatory HACCP in primary production was seen by some as an imposition on a business’s freedom to manage its business in a way that it sees fit. Market forces will compel a business to ensure that the food that they produce is safe.

One US interviewee suggested that the lack of more mandatory approach to HACCP was a result of political and regulatory reluctance, rather than reluctance from scientific staff within the regulatory agency. This is in contrast to the legal interviewees within the EU who expressed satisfactions with mandatory HACCP, while articulating concerns regarding the scientific and enforcement challenges posed by the implementation of the HACCP requirements within the primary production sector.

However, respondents agreed there was a challenge in utilizing HACCP in uncontrollable environments. It is challenging to build critical control points that take into account the vagaries of the weather, and, particularly, the chemical and biological contaminants that this can introduce into food production. Interviewees felt that this meant that there was no clear point of control in the system.

Within the EU these are not seen as insurmountable problems preventing the eventual use of HACCP within agriculture. One reason for this is the amount of produce cultivated in a more controllable environment, such as greenhouses or polytunnels. Further, policy makers have faith in the ingenuity of businesses and those involved in the management of food risks, with many interviewees expressing confidence that the challenges posed by agriculture are

surmountable (see also Soon et al 2012). This confidence was supported by the current experience with HACCP within agriculture, with safety management systems (usually based on HACCP) required by major purchasers of produce, and is also a component of certification schemes operating in a number of EU jurisdictions.⁹

In contrast, US interviewees expressed greater skepticism about the applicability of HACCP within the produce sector. One interviewee expressed the possibility that a quasi-HACCP system would be more appropriate, with the environmental challenges factored into the planning.

Businesses have to consider carefully the way that HACCP works in agriculture, and identify control points differently than in a factory-based process. In particular, businesses need to monitor inputs and outputs, rather than focusing on the growing stage. Others emphasized the monitoring of inputs (particularly water) for microbial contamination. They also emphasized the need for food safety management to take into account the processing of the food subsequent to production, and suggested that HACCP plans for produce should be integrated into the plans required for the subsequent processing of the food, turning it into the final product that appears on the ‘supermarket shelves.’

Part IV – HACCP in the EU and US as a pragmatic response and a technocratic experiment

The preceding analysis demonstrates a number of themes that united and divide the interviewees attitudes to HACCP and this section attempts to provide a unifying theoretical account of the findings of the research, before discussing whether such an approach is normatively justified, or whether a more unified approach to food safety management should be adopted.

Whilst significant research has been conducted identifying the drivers of HACCP implementation, with scientific and political factors clearly noted, from the perspective of the

interviewees the adoption of HACCP as a regulatory tool was pragmatic. The decision to impose or not impose HACCP is a pragmatic one, based on a practical assessment of both the risks to consumers caused by unsafe food and of the best methods of managing those risks. Pragmatic judgments are made at two levels, both by policy makers and by food businesses.

The different approaches to HACCP in the US and EU can be seen as an example of experimentalism in action. In contrast to much of the literature, which has focused on the competing policy preferences of sub-units within federal states, and particularly the US, the experimental testing of HACCP as a tool to manage food safety risks takes place on a transnational scale, with different judgments made about the utility of HACCP as a risk management tool, and national and international knowledge-transfer designed to improve the management of food risks.

HACCP as a pragmatic response

Pragmatism posits, in part, that steps should be taken if they will bring about demonstrably good consequences, rather than because they fit with a preconceived philosophy of governance and statehood. The rise of pragmatism as a phenomenon in the design of regulatory, and particularly self-regulatory, action has been noted in a number of areas (Rees 1994; Rees 2008). HACCP can be seen as a pragmatic response on two levels; at the policy level and the practice level.

Policymakers, who choose to require HACCP systems as a management tool, and businesses who voluntarily implement such a system, do so on the basis of a practical judgment about the best method to adopt. Interviewees rejected politicized accounts of HACCP implementation, suggesting the malleability of the standard renders it attractive to policy makers of all political persuasions. Pre-existing regulatory cultures can accommodate a malleable regulatory tool such as HACCP, demonstrating its utility as a pragmatic response. Businesses identify the value of utilizing and standardizing a management system that allows

them flexibility to fit regulation to their businesses; policy-makers recognize the utility of using a food safety management system that requires the businesses to tailor the management of risks to their business, allowing risks that are unforeseen at the time of drafting to be governed by the regulatory regime. The ‘color’ of HACCP as a ‘scientific’ risk management response allows regulatory and business decision-makers to shape HACCP to what is desired, reflecting pre-existing preferences.

US businesses pragmatic decision to adopt HACCP can be compared to the self-limiting decision to adopt regulation in the US Nuclear Industry (Rees, 1994). Whilst Rees describes a collective decision to build a regulatory bureaucracy, the decision to adopt HACCP is less co-ordinated, but similarly driven by a concern to manage the risk arising from food-borne micro-organisms. Large business who choose to adopt HACCP are more adept at perceiving these risks, and have more resource to devote to tailoring HACCP to prevent such risks. HACCP works within their existing business structure, and provides a standardizing methodology for the management of risk that can be used across multiple staff members and sites. Smaller businesses, who perceive that they pose less risk, choose, where possible to use other methods for managing risks consequent on their operations as a food business.

EU businesses also use HACCP pragmatically, although against a backdrop of a requirement to manage food safety risks through a plan based on HACCP methodology. Smaller businesses choose to rely on precedent plans issued regulators or industry bodies, as these will satisfy regulators that the business is complying with its obligations, whilst minimizing the commitment of resources to creating the plan. Relying on precedents works for the purposes of the business, but may result in routinization, damaging the ability of HACCP to achieve tailored food safety management. Larger businesses also act pragmatically, designing HACCP plans to existing business practices, and adopting HACCP

to repetitious practices, with critical control points placed in places that are clear and simple to monitor.

The pragmatic judgment made by policy-makers in the EU is to require all food businesses to manage food safety risks on the basis of HACCP principles. Adopting HACCP removes the need for command and control style rules. The flexibility frees policy makers from the need to intervene in response to innovations in food technology. Risks arising from such innovations must be managed by businesses rather than by policy makers. A judgement is made that businesses are best placed to judge the risks of their businesses, although the discretion given to businesses in the form of management action is limited by the requirement that HACCP is imposed. HACCP is seen as working better than any other option for all business, even though it may fit more easily with the practices of certain sizes and types of businesses. The benefits in a unified method of managing food safety risks are seen as outweighing the benefits of allowing particularised approaches, and the difficulties that may arise when the HACCP is used to manage food safety risks in a business to which it is not perfectly suited.

HACCP in the US and EU as a technocratic experiment

The link between pragmatism, which focuses on ‘what works,’ and democratic experimentalism, which seeks to discover ‘what works’ by comparing differing approaches to similar issues is clear. Putnam (1995) describes pragmatists as “a group of inquirers trying to produce good ideas and trying to test them to see which ones have value.” One method of judging whether policy ideas ‘have value’ is to examine experiments, to see what works. The adoption of HACCP can be seen as an unintended technocratic experiment, with different policy-making regimes approach the issue of managing food safety risks from different socio-regulatory standpoints, and observing effects on the achieved policy goals, with tweaks made in the light of observed ‘findings.’

Like most technocratic experiments, the differential approaches to HACCP adopted in the EU and US were not intended as parallel approaches, but instead reflect the judgment of policy-makers about the best ways to reduce food safety risks to consumers. However, the competing pragmatic approaches allow an assessment of the utility of top-down and bottom-up approaches to the adoption of HACCP, and for lessons to be applied by other states. Therefore, the current situation has utility for those considering the appropriate way to manage food safety risks, with the experience of the US and EU providing important lessons for implementation. Further, as HACCP is increasingly emphasized at the international level, national governments have evidence that may assist them in designing appropriate regulation.

Consensus exists between the US and EU that HACCP works to manage food safety risks in a flexible manner. It is seen as an effective and worthwhile regulatory technology, and is the shared preferred method of managing food safety risks. In particular in the processing of animal products. Businesses in this sector, which are usually large and have the repetitive processes, are required to adopt HACCP to manage food safety risks in both the US and Europe. There is also consensus that HACCP doesn't work in primary production settings, given the state of scientific knowledge on risk management in primary production. In other sectors, the approaches of the EU and US can be seen as an experiment, with competing judgments regarding the effectiveness of HACCP in reducing food safety risks when mandated, compared to situations where HACCP is adopted voluntarily. Therefore, what does the data obtained in this study tell us about the utility of HACCP in those situations where there is not consensus?

This work is begun above with the preliminary trends identified set out in Part V. However, it must be questioned whether it is normatively justifiable for the EU and US to have different approaches to their management of food safety risks. If HACCP works to manage food safety risks, should it not be rolled out in the same way in all jurisdictions? This

research suggests that mandatory imposition of HACCP is not a one-size fits all solution to the problems of food safety risks. The prevailing cultural conditions in a state deciding whether to implement HACCP may influence the judgment of which approach has the greater practical utility (Echols, 1998), even where the judgment is a pragmatic one. Jordana and Levi-Faur argue that the shape of the regulatory state, and therefore the shape of regulation, varies “dependent on national institutions and state traditions” (Jordana & Levi-Faur, 2004). Cultural differences may provide a normative justification for the different judgements on what works which have been reached in the EU and US. Therefore, the quasi-experiment of comparing US and EU is only the beginning of the exploration of the approaches to the management of food safety risks,

Part V – Preliminary conclusions

At the beginning, we stated that the purpose of this paper is to conduct a comparative study of the HACCP implementation in the EU and US and answer the following questions: 1) Does ‘self-regulation’ in this context mean different things in the US and EU?, and 2) What do our findings tell us about the different regulatory approaches of the EU and US? The answer to the first question is a resounding yes. HACCP is viewed as self-regulation in both the EU and US despite the different regulatory frameworks that apply, with the US interviewees using the term to mean true self-regulation with the US interviewees meaning enforced self-regulation. The features of HACCP that allow “design and management of... operations... [and] controls” (Parker and Gilad 2011) are attractive in all regulatory systems. On question two, four main conclusions can be drawn from this research.

First, there are different drivers behind the implementation of HACCP in the EU and the US. Briefly stated, in the EU, governments are mandating implementation and, in the US, industry is the primary driver behind its implementation. Both policy-makers and business are drawn to HACCP because it is seen as effective and efficient. Increased autonomy given

to businesses is a factor in favor of HACCP, as is the ability to monitor throughout the process, rather than just at the end point.

A second conclusion that can be drawn is that regulators must be flexible in designing and enforcing HACCP systems. HACCP is flexible, but individuals in the EU and the US emphasize the difficulties for small food businesses seeking to produce plans appropriately tailored to their business needs, particularly in harsh economic times. This reflects the findings of previous researchers that HACCP compliance is cheaper for large firms. Therefore, a standardized approach is adopted, universalizing methods of compliance through guidance and precedent policy. This increases the potential of HACCP as a transnational governance regime. However, it also reflects the general trend for small businesses to demand resources and other aid to enable compliance with regulatory requirements. The Food and Agriculture Organization and the World Health Organization (2005) argue that in regulation requiring HACCP to be adhered to by such businesses “the system should not be too rigidly described as it hampers flexibility and the ability of [a small business] to apply the system to their business” (Food and Agriculture Organization and World Health Organization 2005, p. 14).

A third conclusion is that the mandatory nature of HACCP in the EU tends to require greater consideration be given to enforcement than in the US. Enforcement officers are required to evaluate HACCP procedures put in place by a food business. In the US enforcement, alongside the greater push for HACCP, is likely to stem from businesses themselves, looking for verifiable ways to ensure food safety in their business, and by the businesses at the top of the supply chain, seeking to ensure food safety from farm to fork in their produce procurement.

A final lesson from this foray into HACCP as a self-regulatory mechanism in the food industry is that over time, especially in the EU, a self-regulatory mechanism can evolve into

one of command and control through guidance. Businesses, especially small and medium-sized enterprises, express a desire to understand what type of HACCP plan will be seen as acceptable when they subject to regulatory inspection. In order to assist these businesses in creating an acceptable plan, regulatory bodies create precedents and guidance, which embody best practices. Businesses follow this guidance, rather than creating their own plan, and inspectors expect to see HACCP plans containing the elements set out in the guidance documents that have been created. If a HACCP plan used by a business does not conform to the contents of the guidance, regulators advise businesses to modify their plans to match the guidance. The guidance becomes the norm, and the regulator created HACCP plans have to be adopted. Rather than HACCP being the flexible tool intended, regulation becomes driven by the precedent plans, and businesses must follow them, routinizing *one* particular way of managing risk in a business as *the* way that risk must be managed. The flexible HACCP plan turns into a rigid requirement, routinizing the method of compliance in a similar way to command and control regulation – only the method of compliance is determined by regulators rather than politicians. This is built into regulation 852/2004 with good practice guides contemplated in articles 7 and 8.

A clear implication of this study is the need for further investigation of HACCP in the EU and US. Two areas in particular should be studied further. First, the effect on the implementation of HACCP of the difference in regulatory culture between the EU and the US should be considered. Second, whether the different regulatory regimes in the EU and US contribute or detract from effectiveness should be considered, and, in the event that the regulatory regime is not a driver of effectiveness, the factors that are must be explored. In order to answer this question it is necessary to consider for whom HACCP must be effective (business? consumer? regulator?), and to consider whether the answer is the same or different between the US and EU.

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¹ This contrasts with recital 13 of Regulation 852/2004 which states “the HACCP system should not be regarded as a method of self-regulation.”

² Considered under a host of terms; ‘management-based regulation’ (Coglianese and Lazar, 2003; May, 2007); ‘systems-based regulation’ (Kagan and Scholz, 1984; Gunningham and Johnstone, 1999); ‘principles-based regulation’ (Black, 2008); ‘process regulation’ (Gunningham, 2007).

³ Defined in Regulation 178/2002 as “the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter” and “hunting and fishing and the harvesting of wild products.”

⁴ See the list of such guides found at

<http://ec.europa.eu/food/food/biosafety/hygienelegislation/register_national_guides_en.pdf> (last visited 2/13/2014)

⁶ See <http://www.fsai.ie/food_businesses/safe_catering.html> (last visited 2/13/2014)

⁷ This risk is increased where the guidance is published on a sectoral basis, like the UK Food Standards Agency Safer Food Better Business pack, with separate packs aimed at, *inter alia*, caterers (with separate packs for caterers producing Chinese and Indian, Pakistani, Bangladeshi and Sri Lankan cuisine), retailers, care homes and childminders.

⁸ Matthew Morris, Comment to Food and Drink: Safety Requirements available at <http://www.redtapechallenge.cabinetoffice.gov.uk/food-and-drink-safety-requirements/> (last visited 2/13/2014).

⁹ E.g. Red Tractor.