



HAL
open science

Why regulators assess risk differently. Regulatory style, business organisation, and the varied practice of risk-based food safety inspections across the EU

Olivier Borraz, Anne-Laure Beaussier, Mara Wesseling, David Demeritt, Henry Rothstein, Regine Paul, Michael Huber, Marijke Hermans

► To cite this version:

Olivier Borraz, Anne-Laure Beaussier, Mara Wesseling, David Demeritt, Henry Rothstein, et al.. Why regulators assess risk differently. Regulatory style, business organisation, and the varied practice of risk-based food safety inspections across the EU. *Regulation & Governance*, 2022, 16 (1), pp.274-292. 10.1111/rego.12320 . hal-02958579

HAL Id: hal-02958579

<https://sciencespo.hal.science/hal-02958579v1>

Submitted on 25 Oct 2022

HAL is a multi-disciplinary open access archive for the deposit and dissemination of scientific research documents, whether they are published or not. The documents may come from teaching and research institutions in France or abroad, or from public or private research centers.

L'archive ouverte pluridisciplinaire **HAL**, est destinée au dépôt et à la diffusion de documents scientifiques de niveau recherche, publiés ou non, émanant des établissements d'enseignement et de recherche français ou étrangers, des laboratoires publics ou privés.



Distributed under a Creative Commons Attribution 4.0 International License

Why regulators assess risk differently: Regulatory style, business organization, and the varied practice of risk-based food safety inspections across the EU

Olivier Borraz , Anne-Laure Beaussier , Mara Wesseling

Centre de Sociologie des Organisations (CSO), Sciences Po-CNRS, Paris, France

David Demeritt , Henry Rothstein 

Department of Geography, King's College London, London, UK

Marijke Hermans, Michael Huber , Regine Paul 

Law and Society Unit, Department of Sociology, Bielefeld University, Bielefeld, Germany

Abstract

This article advances scholarship on comparative regulation by moving beyond the conventional focus on formal law and EU comitology to assess the extent of ‘practice convergence’ in the implementation of EU regulation. Drawing on 50 key informant interviews, a survey, and policy document analysis, we compare how regulators in England, Germany, France and the Netherlands have implemented EU requirements that food safety inspections be ‘risk-based’. Focusing on a clear dependent variable – risk-scoring methods – we find important differences in the conception and targeting of risk-based inspections; with starkly different implications for what kind of food businesses they need to target to ensure safety within an ostensibly harmonized single market. We attribute variation in the implementation of risk-based inspection to the ways that EU requirements were filtered through long-entrenched regulatory styles and modes of food business organization in each country, reinforcing preexisting inspection practices in the design of new risk-based tools.

Keywords: EU, food safety, harmonization, inspections, risk-based regulation.

1. Introduction

Without many of the conventional tools of state for forging an imagined national community, like an army or *lingua franca*, the European Union has put considerable effort into creating a single market through the adoption of common regulatory frameworks and technical standards. Yet, while much is known about EU comitology and the transposition of regulation across member-states, comparative studies of Europeanisation tend to focus on formal discourse and decisions and to disregard implementation. For example, much of the debate about national differences in the stringency of environmental regulation hinges on comparisons of black-letter law across countries (e.g. Hammit *et al.* 2013). Such measures, however, only capture what regulatory systems aspire to achieve; they provide little insights on actual practices, that is ‘the law in action’, or outcomes. In the case of occupational health and safety regulation, for example, leading EU member-states achieve broadly similar rates of workplace injury despite striking differences in the levels of protection promised by their headline law (Rothstein *et al.* 2019).

If we wish to explain whether and why regulatory outcomes differ, then we must move beyond formal decisions to consider how regulation is actually implemented. However, as Pollitt (2001, p. 479) explains, comparing regulatory practice “is a tougher challenge than identifying formal decisions”. This methodological challenge is perhaps greatest when it comes to regulatory inspection, which involves comparing the various organizational

Correspondence: *Olivier Borraz, Centre de Sociologie des Organisations (CSO), Sciences Po-CNRS, 19 rue Amélie, 75007 Paris, France. Email: olivier.borraz@sciencespo.fr

Accepted for publication 24 April 2020.

practices and proclivities of street-level bureaucracies that are far removed from negotiations in Brussels, but critical to achieving their aims.

This article responds to that challenge by examining the degree of “practice convergence” (Pollitt 2001) in the organization of official food safety controls across England, Germany, France, and the Netherlands. These geographically and politically proximate countries are subject to common EU regulation of their closely integrated agri-food systems. Yet these four countries use starkly different models for assessing the risk of food safety violations and targeting regulatory controls by inspectors. In France, the risk assessment model focuses on the inherent hazardousness of food processes, which results in inspectors targeting large food business operators (FBOs). By contrast, the Dutch risk assessment model ignores hazard in favor of the compliance history of FBOs; accordingly, inspectors rarely target large businesses that participate in voluntary assurance schemes. English and German risk assessment models consider both hazard and FBO behavior and thus inspectors target a wider range of FBOs than their French and Dutch counterparts.

This variation in inspection practice is surprising for two reasons. First, a series of high-profile food safety scandals in the 1990s, most notably Bovine Spongiform Encephalopathy (BSE), highlighted significant “deficiencies in national systems of control” (EC 2000, pp. 29–30), which led to food safety becoming arguably the most harmonized policy domain in the EU (Havinga 2014). In contrast to other policy domains, where the subsidiarity principle grants member-states latitude about how to enforce EU regulations, the 2004 Food Hygiene Package not only sets out strict safety standards, but it also specifies how states must organize regulatory inspection of FBOs to uphold those standards. In particular, EC Regulation 882/2004 requires that “Member-states shall ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency” (art. 3–1). Given the concerns that led the EU to exert this unusual degree of control, it is surprising that member-states vary so widely in their methods for assessing the risks of non-compliance.

Second, this variation is also surprising because proponents of ‘better regulation’ typically insist that organizing regulatory controls on a risk basis will not only make them more efficient and effective but also more consistent and accountable, insofar as inspection priorities are set in proportion to the anticipated likelihood as well as the adverse consequences of regulatory non-compliance (OECD 2010). Yet the varied organization and targeting of regulatory inspections amongst member-states suggest that, far from being universal, risk ideas can support significantly different national approaches.

The aim of this article, therefore, is to explain why, given the strong pressures for regulatory convergence in food safety regulation around ideas of risk, there is so much variability in the practice of risk-based inspection across our four countries.¹

2. Why risk-based approaches to regulatory inspection might vary

While the EU’s requirement for member-states to introduce risk-based food safety inspections was a direct response to the BSE crisis, it mirrored the promulgation of risk-based approaches to regulatory inspection more widely across policy domains and countries by the ‘Better Regulation’ programs of the 2000s. Dating back roughly 30 years to their original development by the UK occupational health and safety inspectorate (Demeritt *et al.* 2015), risk-based approaches aim to rationalize the organization of regulatory inspections by optimizing the outcomes they seek to achieve. Rather than trying to prevent all possible harms, risk-based approaches are designed only to prevent those that exceed acceptable levels by targeting regulatory inspections according to the probability and consequence of non-compliance by regulatees (Rothstein *et al.* 2006; OECD 2010a; Black 2010). By “directing regulatory resources where they can have the maximum impact on outcomes”, as the landmark *Hampton Review of Administrative Burdens on Business* (Hampton 2005, p. 4) put it, the belief is that risk-based inspection would become more efficient, effective, and consistent. Indeed, since 2008, almost all UK regulators have a statutory duty to take a risk-based approach to regulatory inspection and enforcement (BERR 2007); and international organizations have done much to promote its adoption elsewhere (OECD 2010a).

Risk-based inspection has much in common with Ayres & Braithwaite’s (1992) concept of “responsive regulation”, which seeks to match regulatory interventions with the likelihood of non-compliance by regulated firms. Indeed, Baldwin & Black’s (2008, 2010, 2016) idea of “really responsive regulation” explicitly integrates the two by focusing on the ways in which risk tools can respond to the broader institutional environment of, and

competing pressures on, regulatory inspection. In that context, risk-based approaches to inspection do not just have a decision-making function; they also have a disciplining function by controlling how inspectorates should act, not least when merging regulatory bodies or in federated structures where central government or oversight bodies have only limited levers for control (Black 2010). Moreover, risk-based approaches also provide, at least in principle, a means for regulators to mitigate blame for not preventing the most unlikely and least consequential adverse outcomes.

Promulgators of risk-based approaches to regulatory inspection argue that its utilitarian focus on optimizing regulatory outcomes should lend it universal appeal, and thus, by implication, the adoption of risk-based approaches should lead to practice convergence across countries. However, there are relatively few comparative studies on the extent to which regulatory inspection practices of any form – let alone risk-based approaches – are converging (e.g. Falkner *et al.* 2007). The limited literature that does exist, however, suggests at least six broad reasons why the organization of risk-based regulatory inspection might vary across countries, even when – as in the case of food safety – it is mandatory.

First, the conventional definition of risk (hazard \times probability of occurrence) provides scope for varied interpretations. The problem is that the science of assessing the consequences and likelihood of non-compliance is in its infancy and struggles across many regulatory domains: be it predicting the next hedge funds crisis, harm from contaminated land or the provision of poor-quality healthcare by hospitals (Mackenzie 2003; Swartjes 2002; Beaussier *et al.* 2016, 2020; Griffiths *et al.* 2017). Indeed, demands to protocolize regulatory risk assessments can often conflict with the need for more flexible and adaptive approaches in the face of endemic uncertainty (Kuhlicke & Demeritt 2016). More generally, there is no consensus in the risk analysis literature on how to optimize the management of frequent but low-consequence non-compliance vs. low probability but high-consequence failures (Stirling 2010; Black & Baldwin 2012; Rothstein & Downer 2012).

Second, institutional studies have long shown how coordination and control become more difficult as hierarchies become larger and more complex (e.g. Hood 1986). EU attempts to control regulatory inspection are likely to be no exception given the significant ‘institutional distance’ between Brussels and frontline inspectorates in member-states and the consequent difficulties in ensuring common understandings and avoiding policy drift and shirking. For example, it may be harder to ensure effective implementation of EU-wide enforcement policies in countries with federal state structures or fragmented local inspection architectures, than in those with unitary structures and national-level enforcement bodies.

Third, and relatedly, such control problems may be exacerbated by the demands that risk assessments can make on inspectors, which they may be ill-equipped to meet, go beyond their mandate, or threaten their expertise and autonomy (Black 2010). Where there are conflicts, inspectorates may resist changes to the way that they work by adapting risk assessments in ways that suit their own professional concerns (Rothstein *et al.* 2006). At the same time, one might expect such problems to arise less in Anglo-Saxon countries and the Netherlands, which have been global leaders in putting risk ideas at the center of their ‘Better Regulation’ strategies (Black 2005; Oostendorp *et al.* 2016), than in other advanced capitalist economies such as Germany and France, which have proved more resistant to such reforms (OECD 2010b, 2010c).

Fourth, local political salience can also influence the inspection practices of national regulators. Thus Versluis (2007), in analyzing the tension between “even rules” and “uneven practices” in chemical regulation between the UK, Netherlands, Germany and Spain, concluded that high profile policies are more likely to be enforced than low profile ones. Lodge & Wegrich (2011) have likewise shown how food safety scandals pushed both Danish and German meat inspections toward protocolization and system performance.

Fifth, EU member-states have distinct regulatory traditions and institutional administrative arrangements that ‘fit’ EU demands to varying degrees (Knill & Lenschow 1998). As Treib (2014, p. 30) has noted in other contexts, EU “laws requiring a vast change of behavior on the part of target actors are harder to implement in practice than laws that only require gradual changes of behavior.” Consequently, EU regulation can be readily filtered through Member-states’ long-standing regulatory styles, which are well known to vary in their legalism and formality (Brickman *et al.* 1985; Vogel 1986; van Waarden 1995). Thus, Germany and France typically take quite prescriptive and legalistic approaches to regulatory enforcement; while Dutch and British regulation tends to stress discretionary and pragmatic styles of enforcement. Bastings *et al.* (2017), for example, have shown that even though German and Dutch inspectors have taken a relatively legalistic approach to the implementation of

the EU Packaging Waste Directive, the former do not hesitate to sanction regulatees for non-compliance whilst the latter maintain a more pragmatic approach in their interactions with industry.

Indeed, recent research has shown that issues of fit may be particularly important in terms of the compatibility of risk-based approaches to regulation and hard-wired legal and constitutional constraints of governance. Most notably, the utilitarian logics of risk-based regulation, which seek to optimize regulatory outcomes, can conflict with rights-based constraints on regulatory interventions, such as constitutional commitments to equality or high legal thresholds for justifying state interference in the negative rights of individuals and businesses (Rothstein *et al.* 2013). For example, constitutional obligations in France and Germany make it difficult for regulators to reconcile the absolute legal duty of employers to “ensure the safety and health of workers in every aspect related to the work” with the risk-cost-benefit trade-offs inevitably involved in workplace safety; issues that do not arise in the UK or the Netherlands in the absence of strong constitutional protections of rights to safety (Rothstein *et al.* 2017, Rothstein *et al.* 2020).

Finally, the organization and power of regulatees *vis-à-vis* the state may also shape the way in which regulators undertake risk assessments. Thus, countries with strong traditions of corporatism – such as Germany and the Netherlands – tend to support close and high-trust interactions between regulators and businesses; since well-organized and powerful sectoral associations can negotiate regulatory rules with the state and coordinate sectoral self-regulation. By contrast, countries with more pluralist traditions – such as England and France – tend to rely on the preeminent role of the state to ensure collective interests, given that their economies are marked more by intra-sectoral business competition than by strong institutions for sectoral representation, coordination, and governance (Berger 1983). Havinga (2014) illustrates such issues through nationally contrasting regulatory responses to the BSE crisis, finding that Scottish food safety inspectors – having only limited trust in FBOs – preferred to “keep things in their own hands” (Havinga 2014, p. 48), while Dutch inspectors – more trusting of FBOs – were more relaxed about sharing regulatory responsibilities with them. This finding suggests possible cross-country variations in the extent to which inspectorates might use membership of a trade association as an indicator of likely regulatory compliance or use more objective measures to assess FBO behavior.

The literature thus suggests a number of reasons why the risk assessment tools used by regulators in different countries might vary. In the following sections, we set out our methodological approach to identifying such variety for food safety inspection across the EU, and we then go on to present and discuss our findings.

3. Comparative case-study design and methods

This article explores variety in risk-based approaches to regulatory inspection across Europe by comparing the risk-scoring methods used by food safety regulators to determine FBO inspection frequencies in England, Germany, France and the Netherlands. Those four countries were selected to provide sufficient variety to test the hypotheses above. Thus, Germany and the Netherlands have long-standing corporatist traditions that accord business associations strong sectoral governance roles, while England and France have more pluralist traditions that are marked by intra-sectoral business competition. Our countries’ regulatory styles cut across that division, however, with Germany and France having typically juridified regulatory styles, and England and the Netherlands taking more *ad hoc* and discretionary approaches to regulatory action (Richardson 1982). Moreover, while France and the Netherlands have centralized food safety inspectorates, they are institutionally fragmented in Germany and England across *Länder* and local authorities respectively.

We used source, method and investigator triangulation to trace the development and use of risk-based methods for targeting food safety inspections of FBOs in each country. Readers should note, however, that we excluded meat and slaughterhouse inspections, which are governed by separate – and not risk-based – obligations to control all animal carcasses that leave slaughterhouses. Our research included documentary analysis of 26 national reports of the European Commission’s Food and Veterinary Office (FVO) directly related to food products (e.g. eggs and egg products, fishery products, primary production of food of non-animal origin, milk, and milk products) over a period of 10 years (2009–2019) and 50 semi-structured interviews with policymakers, food professionals and regulatory inspectors (England-7; Germany-8 plus a *Länder*-wide survey; France-17; Netherlands-15; and at EU-level FVO-1, DG Sanco-1 and EFSA-1). Finally, we organized a workshop bringing together two senior inspectors from each country to discuss our initial findings. In the following section, we set

out the background to food safety regulatory inspection and the introduction of risk-scoring FBOs and then examine each country in turn.

4. The implementation of food safety risk-scoring methods

4.1. Background

The history of food safety regulation and enforcement is very similar in our four countries. During the 19th century, local authorities organized police forces to inspect food markets and producers in response to adulteration and fraud scandals that accompanied the industrialization of food production (Stanziani 2005; van Waarden 2006; Hierholzer 2010). It was only later that food safety and hygiene laws were introduced in England (1875), Germany (1879), France (1905) and the Netherlands (1919) to protect consumers from unsafe food. New government inspectorates were also created to enforce these laws, whose goal of safety remains unchanged today despite now being set down by EU Regulation. Organized at the local level to match the often locally varying nature of the food industry, inspectorates were either field services of the state (France, Netherlands) or part of local government (Germany, England). Over the course of the 20th century, they became increasingly professionalized, developing their own distinctive national regulatory styles and practices (Self 2017).

In response to the BSE crisis, the 2004 Food Hygiene Package synthesized a complex array of prior EU food safety Directives and imposed standard operating procedures on national inspectorates. Amongst these, article 3 (1) of EC Regulation 882/2004 requires member states take a risk-based approach to setting inspection priorities using four parameters. The first (a) relates to the inherent hazard posed by a food product or business activity and thus the consequences of any food safety violation, while the other three (b–d) relate to the probability of violation by regulatees:

- a** identified risks associated with animals, feed or food, feed or food businesses, the use of feed or food or any process, material, substance, activity, or operation that may influence feed or food safety, animal health, or animal welfare;
- b** feed or food business operators' past record as regards compliance with feed or food law or with animal health and animal welfare rules;
- c** the reliability of any own checks that have already been carried out; and
- d** any information that might indicate non-compliance.

However, the Regulation does not define how those parameters should be assessed or combined in order to calculate the risks posed by FBOs; member-states are free to devise their own scoring systems. Nevertheless, teams from the European Commission's Food and Veterinary Office (FVO)² periodically audit member state compliance with 882/2004, through thematic audits of national controls of particular foodstuffs and products. In the following sections, we provide an overview of how each of our four countries have designed their scoring systems to risk-rate individual FBOs in order to prioritize their inspections.

4.2. England

Food safety enforcement in England has long been entrusted to local government environmental health officers (EHOs). This professional group emerged from 19th century Sanitary Inspectors with a dual role as both law enforcers and technical advisors to FBOs on complying with hygiene standards. Over the last 30 years, however, food safety enforcement has been subject to increasing central government oversight, most notably with the creation of the Food Standards Agency (FSA) in 2000 following the BSE crisis. The FSA is responsible for food safety regulation and oversees local government inspectorates through its Local Authority Enforcement Monitoring System.

Local authorities target their inspections using a food hygiene scoring system that scores individual FBOs according to their inherent hazardousness and their probability of non-compliance with regulatory requirements (Table 1). The higher the total summed score, the higher the risk and the more frequent the inspection (from once every three years to twice a year). Hazard-based criteria about the potential consequences of regulatory non-compliance account for more than half the total score. But professional judgements of 'level of compliance' and

‘confidence in management’, which both measure the probability of something going wrong, are also important in determining risk scores and thus inspection priorities.

Table 1 Risk-scoring parameters and weightings for determining food safety inspection targets and frequency in England

Factor	Points
Hazard	
Type of food and method of handling	5/10/30/40
Method of processing	0/20
Consumers at risk	0/5/10/15
Establishments involved in the production or service of food intended specifically for consumption by consumers which are likely to include a vulnerable risk group of more than 20 persons	0/22
Significant risk of food being contaminated with <i>Clostridium botulinum</i> , and the organism surviving any processing and multiplying; or Significant risk of ready-to-eat food being contaminated with micro-organisms or their toxins that are pathogenic to humans	0/20
Probability of compliance	
Level of (current) compliance with food safety regulations	0/5/10/15/20/25
Confidence in management/control procedures	0/5/10/20/30
	Total: 5–172

Source: FSA (2017)

Our interviews with inspectors suggested that they broadly support the risk-scoring system, not least because it was developed by local authority EHOs in the 1990s – well before 882/2004 – borrowing from a similar approach for organizing occupational health and safety inspection (Demeritt *et al.* 2015). Risk-based approaches in both regulatory domains suited the need of EHOs to prioritize scarce inspection resources and defend their autonomy and professional judgment against regulatee complaints and meddling from elected politicians. As one inspector argued:

You take an area like H..., [where] the population is growing and there is lots of investment in the commercial economy. ...The political leaders have to be seen to be promoting economic growth ... So if that sort of thing is the political will, then it's very difficult for those same people to support and promote strict enforcement for breaches in the law.

The success of these local initiatives eventually stimulated central government to incorporate local authority approaches to priority planning into the first national codes of food safety enforcement practice in the mid-1990s (DoH 1996). Indeed, this local authority experience significantly influenced the Hampton Review's (Hampton 2005) key recommendation – later made a statutory requirement (BERR 2007) – that all regulatory inspection and enforcement across most policy domains should be risk-based. While FVO audits have broadly supported the food hygiene scoring system, they have found some problems in the implementation and calculation of the risk score. For example, one audit complained that inspection frequencies established by the scoring system for egg product establishments were not always respected (FVO 2015-7502, p. 10), while another audit found that “microbial hazards in primary production of [food of non-animal origin] were not systematically considered in the risk analysis” (FVO 2015-7456, p. 8).

The FSA has attempted to address such problems by providing EHOs with extensive guidance on the scoring system in its Food Law Code of Practice (FSA 2009/2010), which has assumed particular importance in the wake of austerity-driven budget cuts that have reduced local authority capacity to provide effective controls. That guidance, however, has spurred tensions with local EHOs, in particular over the requirement for inspectors to give better ‘confidence in management’ scores to FBOs participating in approved third-party assurance schemes. Ministers insisted on allowing business to ‘earn recognition’ and free themselves from state oversight, as part of a wider drive to deregulate and roll back the state (Escobar & Demeritt 2017). However, local inspectors expressed doubts during interviews about the effectiveness of commercial assurance schemes, which are designed to reassure consumers about animal welfare and food quality rather than to ensure compliance with detailed food safety

regulations; a point reinforced by recent scandals at firms participating in such schemes (House of Commons 2017).

Some FSA officials share such concerns, having struggled to persuade the schemes to disclose their detailed requirements for third-party certification, and FBOs to share information on their safety management systems. Nevertheless, under pressure from ministers to lighten regulatory burdens, the FSA has debated giving more weight to management behavior and compliance than inherent hazardousness in the scoring system. As one FSA official commented:

I think the challenge of the future is to move away from the system that we have, which tends to be rather more hazard-based than risk-based. [...] There are certain types of businesses that can never come out of the highest risk category, no matter how very, very good they might be. If you're supplying a hospital kitchen, you would always be the highest risk. I think I would say actually that's all about the hazards. That isn't about risks. A hospital kitchen under very, very good control is not a premise that you would expect to be going and seeing a tremendous amount.

This suggests that risk-scoring is having to reconcile the distinctively different agendas of the FSA, inspectors and ministers; the FSA being concerned with consistency, inspectors with targeting their scarce resources while defending their autonomy, and ministers with lightening administrative burdens on business.

4.3. Germany

While the German federal government transposes EU food safety requirements into domestic law, the 16 Länder are responsible for organizing official controls; with food safety inspectors, as in England, organized at the level of municipal districts and free city administrations. Unlike England, however, food safety enforcement was historically a police role, with training of FBOs even today lying with trade associations that FBOs must join to receive their license to operate. Nevertheless, over the 20th century, the police were gradually supplanted by veterinarians, food chemists, and personnel recruited from the food trades; and since 1977, these inspectors have been overseen by a Federal Association of Food Inspectors (BVLK), which has also played an important role in developing federal law (Self 2017). These developments, however, have not made Germany immune to periodic food safety scandals such as the fatal foodborne *Escherichia coli* outbreak in 2011 (DW 2017).

While inspection practices have historically varied across Länder, 822/2004 afforded an opportunity to make those practices more consistent. All Länder now follow a jointly negotiated General Administrative Decree (*Allgemeine Verwaltungsvorschrift – AVV*) specifying the basic parameters for determining inspection frequency of FBOs according to their inherent hazardousness and probability of non-compliance. Survey responses from 14 out of 16 heads of the Länder association of food inspectors suggest the scoring system used by inspectors in North Rhine-Westphalia and Lower Saxony are indicative of how the Federal guidelines have standardized the risk rating of FBOs by inspectors on the ground (Table 2).

Table 2 Risk-scoring parameters and weightings for determining food safety inspection targets and frequency in Germany

Factor	Points
Hazard	
Hazard inherent to product	0–100
Producer type (sizes, direct consumer contact etc.)	0/10/20
Probability of compliance	
Legal compliance record of producer	0/1/2/3/5
Traceability/documentation of product chains	0/2/3
Staff training system	0/2/4/6/7
Use of hazard analysis and critical control point principles	0/3/6/9/12
Own sampling and controls	0/1/2/3/5
Temperature control and cooling	0/2/4/6/8
Architectural features (walls, surfaces etc.)	0/1/2/3/5

(Continues)

Table 2 Continued

Factor	Points
Cleaning/disinfection systems	0/2/4/6/8
Staff hygiene (during illness, work suits etc.)	0/3/5/8/11
Production process hygiene	0/4/7/10/13
Bug/pest monitoring and control	0/2/3
Total	0–200

Source: North Rhine-Westphalia *Leitfaden für die Risikobewertung von Lebensmittelbetrieben* and Lower Saxony *Anwenderleitfaden*.

This long list of individual parameters is summed to determine risk levels and consequent inspection frequencies, which can range from daily to once every three years for FBOs with the lowest risk scores. Out of a maximum of 200 points, 120 are clearly hazard-related, while 80 deal with the likelihood of risk materializing due to FBO non-compliance.

Our interviews with inspectors suggested they were broadly supportive of the scoring system. Likewise, in the food sectors it has audited, the FVO has been satisfied with the organization of official controls, concluding that inspections of food of non-animal origin, for instance, have been “carried out regularly and on a risk basis as required by Article 3 of Regulation (EC) No 882/2004” (FVO 2013-6664, p. 7; see also FVO 2016-8682, p. 12; FVO 2016-8842, p. 13).

The design of the scoring system reflects some distinctive challenges for Germany in using risk-based regulatory instruments. On the one hand, quantitative risk scoring helped inspectorates defend themselves against FBO complaints about inconsistent and subjective inspection practices, particularly from large FBOs with facilities across the country. As one inspector recalled:

FBOs did not accept inspections as objective ... and would say ‘the inspector just does not like my face’.

Such complaints have great force in Germany given the legal opportunities for FBOs to assert their constitutional rights against unwarranted state interference by challenging inspection decisions in the courts as capricious or arbitrary (Self 2017). Codified risk-scoring parameters made it harder to challenge inspectors in administrative law courts.

On the other hand, Germany’s federalist decision-making processes resulted in a lowest common denominator approach to defining risk-scoring parameters, which were negotiated by joint federal-Länder technical working parties with substantial industry participation as well. Geographical and inter-sectoral variability made it difficult to agree on universally applicable parameters that did not unfairly disadvantage the particular agri-food sectors of different Länder. As one participant explained to us:

...risks are different across the Länder. But we can of course get to a joint assessment, that probably a small firm with 3-5 staff members constitutes a bigger risk in general compared to a certified producer. And then one has to make a statement, does everybody agree on that point? And if we arrive at the conclusion that one is riskier than the other across many Länder, then we can think about writing this down as a principle in the general administrative decree on inspections.

In fact, the need for full agreement has impeded the adoption in Germany of a ‘confidence in management’ parameter, as used in England, despite the widespread belief among inspectors that:

Big food producers, ... professionals like Kraft-Foods, Unilever, Nestlé, I would say feature almost no risk at all ... At the same time, you have small Döner Kebap producers with plenty of tiny stalls in the middle of Berlin, and there you DO have a hygiene problem!

Another unresolved issue is about whether FBO membership of a sectoral quality assurance scheme should be taken as an indicator of reduced likelihood of non-compliance. That omission is surprising, because Germany’s strongly corporatist traditions – which in the case of food safety have left training and licensing in the hands of trade associations – might be expected to favor such an indicator. Certainly, there are high membership rates of

private schemes, and as the FVO (2017-6072, p. 1) observes, there is evidence that identification of non-compliance by German accreditation schemes is ‘comparable’ to official controls. Accordingly, many inspectors are sympathetic to the idea of rewarding assurance scheme membership. As one inspector commented:

[We] need to discuss whether in case of large production lines and trade chains, which are well certified [and] apply systems of quality assurance, we can give them a certain bonus from the viewpoint of inspections. ...

The Länder, however, have failed to reach legal agreement on integrating private certification into the scoring system because of the potentially compromising financial relationship between FBOs and certification bodies (FVO 2017-6072). Consequently, local inspectorates only informally consider scheme membership according to their preferences, though inspectors are likely to score smaller FBOs as higher risk where schemes are considered.

4.4. France

French food safety inspectors were first established in 1905 as a body within the Ministry of Finance to combat food fraud and adulteration. They joined the Ministry of Agriculture’s field services in 1984, but became a separate entity when the BSE crisis and subsequent scandals over *Listeria* in unpasteurized cheese and catered goods in 2000 exposed conflicts of interest with the parent ministry’s responsibility for supporting farmers and food production (Besançon *et al.* 2004; Bonnaud & Coppalle 2010). In 2010, however, food safety inspectors were remerged with the Ministry of Finance’s fraud inspectorate as part of a comprehensive reorganization of French public administration, but they still remain within the remit of the Ministry of Agriculture.

The French scoring method differs from the English and German ones in two important respects (Table 3). First, it focuses predominantly on hazard. Three of the four risk parameters concern intrinsic hazard, exposure, and vulnerability, while only one parameter rests on inspectors’ subjective judgment of operators’ overall regulatory compliance. Second, the individual parameters are multiplied, rather than summed as in the other countries, to generate overall FBO risk scores for determining inspection frequencies, which can range from once every six months to once every three years.

Table 3 Risk-scoring parameters and weightings for determining food safety inspection targets and frequency in France

Factor	Points
Hazard	
A: Theoretical risk related to the type of activity or process	10–40
b: Production volume	1/2/3/4
S: Sensitivity of the consumer	1/2
Probability of compliance	
M: Past evaluation	A/B/C/D (1/2/3/4)

Source: French Ministry of Agriculture.

The method was devised by the inspectorate as part of a larger strategy following past food safety scandals for which they had been blamed. An assurance scheme that set standards for inspections was elaborated (becoming ISO 17020 in 2003), which quickly expanded to include a risk-scoring system in response to Regulation 882/2004. As one representative from the French inspectors’ union explained, quantitative scoring helped justify inspection priorities in case of failure:

It gives you a point of reference. Before, the local head of services was really alone when he had to determine where to inspect, the choice was partly random. The risk score didn’t bring about a revolution, but it provided some comfort, including judicially.

While such protocolization is a common institutional response to legitimacy pressures (Porter 1995), the particular emphasis of the French risk-scoring system on hazard was shaped by constitutional commitments to equality. Whereas the hazard scores for individual FBOs could be generated automatically according to the type of

business and customer, inspectors were conscious that attempts to assess operators' will and capacity to comply might lead to accusations of discrimination. As one inspector put it:

In the beginning, everyone did it his way. But now, you know that wherever you are in the country, you will be inspected with the same rhythm, the same method, and there is equality.

FVO audits have consistently supported the French scoring system, concluding that "France has established a risk-based system for official controls in line with the requirements of Article 3 of Regulation (EC) No 882/2004" (FVO 2015-7496, p. 11; see also FVO 2014-7172, p. 8). At the same time, however, the FVO also complained that despite "the comparatively high number of major non-compliances" (FVO 2014-7172, p. 8) on farms, the emphasis on hazard in the French scoring system meant that in practice those farms attracted "quite low" numbers of inspections.

Concern that actual inspections are not sufficiently sensitive to non-compliance in part reflects the constraints imposed by the weight given to hazard compared to past compliance. That bias, however, is further amplified by the reluctance of inspectors to use the full range of grades and discriminate sharply between FBOs on the basis of past compliance (row M). As one inspector told us:

- *We rarely give an A. A means that everything's OK, that there's no problem. It's rare that we don't find something.*
- *So you give a majority of Bs?*
- *Yes.*
- *And Ds?*
- *That's rare. And it's mostly in direct sales.*

Consequently, the design of the scoring system and scoring practices leads inspections to focus on larger FBOs, in striking contrast with Germany where smaller operators are inspected more often. Indeed, the French formula is not used for restaurants, caterers, and small retailers, which are only inspected during two annual, heavily publicized campaigns in the summer and Christmas holidays that target businesses flagged by customer complaints or informal intelligence of non-compliance. That focus on larger FBOs reflects the professional proclivities of inspectors, who claim that focusing on larger operators creates benefits that cascade down the food chain. As one argued:

There are more risks because more people are affected [by a large FBO]. ... While in a restaurant, you only get 40 persons affected. It's not a million persons. And also because behind a problem [in a large FBO], there are economic consequences, and eventually border closings.

Such concerns are illustrated by a 2018 scandal in which 37 babies across Europe contracted salmonella infections from contaminated baby milk, leading a French dairy giant to withdraw 12 million boxes of the product.

Moreover, we found inspector resistance to redressing that bias by lessening the inspection frequency for FBOs participating in private assurance schemes. While such schemes are welcomed as a measure of FBO professionalism, inspectors are skeptical of their value as a measure of FBO safety. As one inspector commented:

These private systems rest on two assumptions. One, the operator is competent. But that's not always the case. ISO standards are all about repeatability, not relevance. Two, the operator is honest. That's the difference between an audit and an inspection. In the Anglo-Saxon logic, you presume that the operator is honest. But that's not always true!

Inspectors' views of private systems are not just driven by skepticism but also by being blamed for past leniency with private operators in the aftermath of food safety scandals (Besançon *et al.* 2004; Muller 2008). As one inspector observed:

I think that as an inspector, we also have our share of responsibility, if we control and miss a dysfunction, don't put our finger on it, and afterwards, finally, it turns into a health problem, we probably could have avoided if we had been more vigilant.

As a consequence of these concerns for equality, skepticism of private assurance schemes, and fear of blame, the French scoring system's bias toward hazard makes it distinctively different to England and Germany.

4.5. Netherlands

Historically, food safety inspections in the Netherlands were conducted by a patchwork of municipal, provincial, and central government agencies, each responsible for regulating different parts of the food chain. During the 2000s, a series of wider reform programs across government prompted the nationalization of local inspectorates and their merger with other agencies to create one central authority – the NVWA (Food and Consumer Product Safety Authority) – in charge of enforcing regulation, risk assessment, and risk communication (WRR 2009). Supervised by the Ministries of Economic Affairs and of Public Health, the NVWA's responsibilities go beyond food safety to include tobacco, alcohol, consumer products, animals and animal products, and plant health.

Historically, the planning of inspections resulted from a combination of inspectors' professional judgments, thematic programs – for example in the aftermath of scandal – and the NVWA's own intelligence about particular activities. In 2007, the NVWA first introduced a risk-based approach that formally quantified how often individual FBOs should be inspected, which was based on FBO compliance behavior but ignored hazard. Called the “risk pyramid” (Fig. 1), the Dutch scoring method echoed Ayres & Braithwaite's (1992) ‘tit for tat’ approach to responding to regulatee non-compliance, classifying FBOs according to four ordinal colored categories dependent on inspection findings over the previous two years (NVWA 2015b). Green FBOs were compliant and only required biannual inspections; amber FBOs had committed one or more offenses and required annual inspections; red FBOs require close supervision or closure after three or more non-compliances. New businesses or those not inspected for two years were left white pending an urgent inspection to update their classification.

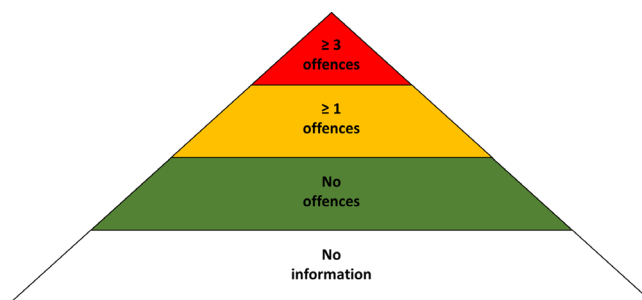


Figure 1 Risk-scoring pyramid for determining official food safety inspection frequency in the Netherlands.

The NVWA introduced this approach in response to 882/2004 and the government's new “vision on inspection” – *Minder last, meer effect* (Less burden, more effect) (MBZK 2005). That new vision – which was part of a wider neoliberal reform program of the Balkenende and Rutte governments for reducing the size of the state and regulatory burdens – built on the Dutch corporatist traditions of business self-regulation. The NVWA put that into practice by encouraging the food sectors to develop private certification schemes in exchange for reduced inspection frequency. The NVWA has formally recognized 11 systems of self-control, with six more under assessment in 2017 (FVO 2017-6071), and signed agreements with nine firms or industry associations to certify their own control systems (Havinga & van Waarden 2013). Meanwhile, NVWA inspectors could concentrate on FBOs outside of those schemes and those with a history of non-compliance, following the engrained principle of Dutch legal culture of “lenient whenever possible, tough when required” (NVWA 2018, p. 6; Van Rossum 2016). The NVWA justified that focus on compliance history to the exclusion of hazard by arguing that fully compliant businesses should not pose a risk to consumers (NVWA 2018, p. 6). As one inspector explained to us:

We consider the inherent risk of a product or a process as a given, which should not be dominant in the risk-based approach.... By applying HACCP [Hazard Analysis and Critical Control Point] in the right way and taking sufficient control measures to mitigate the risks, a food business operator is in compliance with legislation. ... Generally speaking, risks only occur in case FBOs are NOT in compliance.

As the FVO summarized the Dutch approach: “the risk is more related to the FBO than the product” (FVO 2013, p. 33).

The NVWA, however, struggled to use the risk pyramid to prioritize inspection based on individual FBO risk scores because the agency lacked up-to-date information on the compliance history of too many FBOs. In part, this problem arose because NVWA inspection volumes were reduced quite dramatically because of reductions in staff; falling by some 25 percent between 2010 and 2017 (NVWA 2014; 2017b). According to a discussion with senior inspectors, more than 50 percent of all FBOs were classified as white in 2020. Moreover, third-party certification made only a limited contribution to offsetting the decline in inspections. While the FVO reported that the NVWA was confident that “certified FBOs show overall a better level of compliance with the legal requirements on food hygiene” (FVO 2017-6071, p. 17), scheme membership varied widely across sectors: from 90 percent of food manufacturers, to less than 10 percent in storage, transportation and brokerage, and less than 3 percent of the hospitality, restaurants, and catering FBOs (FVO 2017-6071). The problem, as the FVO observed, was that in the absence of customer prerequisites, smaller firms had little incentive to join costly and burdensome certification schemes when it was likely to “take several years for an FBO to be selected for inspection” by the NVWA for free (FVO 2017-6071, p. 5). As NVWA officials pointed out:

That is one the problems we have in the Netherlands: [FBOs] have to make higher costs for scheme membership, so if it doesn't pay off in less inspections, why should they join the scheme?

The NVWA's problems were compounded by a series of food-related scandals, notably salmonella in salmon (2012) and the horsemeat food fraud (2013), while its approach to inspections was the subject of several critical reports (NVWA 2015a). This led to the adoption of new frameworks and policies for supervision of FBOs between 2015 and 2017 which introduced, amongst other things, tougher sanctions for non-compliant businesses (NVWA 2015b, 2016; 2017b). During the same period, FVO audit reports variously complained amongst other things, that fishery product FBOs were not inspected with the stipulated frequency (FVO 2014-7140); that feed chain FBOs that had never been inspected were classified as white irrespective of the hazards they posed (FVO 2013-6753); and that the prioritization of egg FBO inspections – which was the responsibility of the *Netherlands* Controlling Authority for Eggs (NCAE) – did “not take into account all the factors required in Article 3(1) of Regulation (EC) No 882/2004” (FVO 2015-7501, p. 13). In response to that latter audit, the NCAE pledged that their “planning of official controls will be more risk based”, that is “dependent on the findings of earlier performed inspections and risks related with the activities performed by the establishments” (NVWA response to FVO 2015-7501). As a result, between 2014 and 2017 the number of warnings issued by NCAE increased three-fold. But in 2017, confidence in Dutch eggs was undermined by the discovery of widespread contamination with the pesticide Fipronil.

These problems prompted the NVWA to stop using the pyramid as its primary method for setting inspection priorities. Instead of risk-rating individual FBOs, the agency developed an entirely new approach to priority-setting based on strategic risk assessments of entire food chains. Its new program – NVWA 2020 – has identified 12 major integrated food production chains and, by drawing on inputs from various government and research bodies, professional sectoral associations, and the scientific literature, the NVWA is now conducting high-level analyses of all the potential problems with food safety and hygiene, fraud, animal health and welfare, and other regulatory concerns within their remit along those chains. This new campaign style of inspection identifies the parts of the food chain that inspectors need to pay attention to, but in stark contrast to the other three countries, does not provide a risk-rating formula for prioritizing individual FBOs for inspection. Instead, inspectors continue to use their professional discretion and – as one inspector phrased it – “gut feeling” to decide which FBOs to visit in carrying out the campaign.

5. Explaining divergence in national definitions of risk

All our case study countries claim to be compliant with the requirements of EC Regulation 882/2004 that food safety inspections be risk-based. Yet, they have implemented this requirement using starkly different risk-scoring methods. As Table 4 shows, only the English and German inspectorates use all four risk-rating parameters (columns a–d) set out in 882/2004, though the Germans define those parameters using more numerous and tightly

codified measurement criteria than the English. By contrast, the French method risk-rates FBOs largely according to hazard parameters to assess the consequence of food safety violations (column a), while probability of FBO non-compliance is just derived from past compliance records rather than inspector judgements of internal FBO controls (column b). The Dutch approach initially ignored hazard completely (column a) and only considered past compliance record (column b), but attempts to risk-rate individual FBOs have now been abandoned in favor of high-level analyses that identify problem areas of food production chains, leaving prioritization to the professional discretion of inspectors.

Table 4 Food safety risk-rating parameters used by national inspectorates to prioritize inspections vs. requirements of EC Regulation 882/2004, art. 3-1

	Consequence of food safety violation	Probability of food safety violation		
	a – inherent hazardousness of food products and processes	b – compliance record	c – inspector confidence in FBO's own checks	d – informal intelligence and other information on non-compliance
England	X	X	X	X
Germany	X	X	X	X
France	X	X		X
Netherlands		X		X

FVO audit reports have expressed various concerns about the implementation of 882/2004 by our case-study countries. Most notably, the reports have identified lower rates of inspections than stipulated by the methods used in England, France, and the Netherlands. The FVO has also complained that insufficient attention was paid to particular hazards in both England and the Netherlands. However, the FVO has not questioned the design of the scoring methods used in each country; having only complained about the formula used for risk-rating egg-related FBOs in the Netherlands. Although FVO officials acknowledge some differences between scoring methods, they justify such variation on the grounds that some flexibility is required. As one commented:

You have to give member-states the flexibility to adapt their control systems to what they identify to be the biggest risks because, frankly, they're best equipped to do it... Basically you have to have confidence in the member-states that they have the ability and the local knowledge to identify how best to deploy their resources and how best to target risks.

The FVO's position is puzzling, because it is not just differences in the practices, but in the scoring methods themselves that result in the four countries targeting very different kinds of food businesses in what is meant to be a single market. In France, for example, a high-hazard, high-production volume business serving sensitive consumers but with a perfect compliance record scores 320 and is thus regarded as riskier than a high-hazard FBO with the worst possible compliance record, which would only score 160 if it is low volume and does not serve sensitive consumers. In England and Germany, the reverse is the case. The Netherlands started by being indifferent to hazard; only differentiating between businesses according to their compliance history, not according to their products or their customers. Now, however, the Netherlands has effectively abandoned even its compliance-based formula in favor of high-level risk analyses of food chains that allow local inspector discretion about which FBOs to inspect. How then can we explain this variation in implementing 882/2004, which has now persisted for well over a decade?

One explanation is that – like many regulatory domains – there is no scientific consensus on how to assess the likelihood and consequence of non-compliance with food safety regulation. While hazard assessment draws on well-established disciplinary traditions, such as chemistry, microbiology, and epidemiology, there is no agreement on how to consider other factors such as the size and characteristics of the consumer base that

might be affected by non-compliant FBOs. Likewise, while certain behaviors by FBOs are known to produce unsafe food, there is no agreement on how best to predict the likelihood of regulatory non-compliance, be it using actuarial data on compliance history or professional judgements of regulatees' willingness and/or capacity to comply (Yapp & Fairman 2006; Ipsos-Mori 2017). The interpretative flexibility afforded by such methodological uncertainties helps explain the opportunities for divergence between our case-study countries' risk scoring systems; but it is of less help in explaining the different ways those systems measure, weigh, or even ignore the four risk-rating parameters mandated by 882/2004. To address those questions, we need to consider other explanations.

Another conventional explanation for variety in regulatory implementation is institutional centralization, insofar as member states with centralized inspection regimes might be expected to implement EU requirements for risk-based approaches more completely and consistently than member states with fragmented regimes where local inspectorates have more autonomy. However, our findings suggest the opposite pattern. In France and the Netherlands, which have centralized food safety inspectorates, risk-based tools were imposed top-down by central government but diverge the most from EU requirements. By contrast, the inspectorates that follow EU requirements are those in England and Germany, where the food safety inspectorates are institutionally fragmented across English local authorities and German Länder; the latter notably exhibiting only minor variation despite their jealously guarded constitutional autonomy.

A related explanation for our observed variety might be that countries with prior experience of risk-based regulation are better placed to implement 882/2004 more completely. However, our cases suggest otherwise. Thus, officials in both England and the Netherlands were familiar with risk-based approaches to regulation prior to the implementation of 882/2004 and have keenly embraced such ideas for reforming regulation in general, but only England fully complies with 882/2004. Likewise, risk-based approaches to regulation were unfamiliar in both France and Germany prior to the implementation of 882/2004, and Germany has struggled to implement Better Regulation doctrines in general (OECD 2010b). Yet, Germany fully complies with 882/2004, while France does not.

Nor can these differences be explained easily by varied political salience (Treib 2014). All four countries have suffered from food safety scandals over the years and have, at least nominally, put food safety high on their policy agendas.

We can get further in explaining our observed variation, however, by considering the institutional fit between the demands of risk-based inspection on the one hand, and particular national regulatory styles on the other. Tellingly, inspectors in all four countries admitted that implementing 882/2004 did not fundamentally change how they determine inspection priorities, but rather formalized their tacit ways of working. That process of formalization filtered ideas of risk through two distinctive institutional commitments in each country.

The first concerns the extent to which inspectors must work within strict legal constraints when determining inspection priorities and frequencies. In France, constitutional principles of equality lead to a quasi-automatic set of criteria from which inspectors cannot depart and preclude subjective judgements of FBO behavior; while in Germany, detailed lists of criteria are set out within administrative law as a defense against inconsistent inspection practice across Länder. In the less juridified contexts of England and the Netherlands, inspectorates have more discretion in determining inspection priorities and frequencies depending on pressure from politicians.

The second factor concerns the organization of business and its relationship to the state insofar as regulatory tasks can be delegated to corporatist structures or retained by the state as the preeminent means for ensuring collective interests. In the highly corporatized contexts of the Netherlands and Germany, we found close and high-trust interactions between regulators and business, with membership of private assurance schemes central to the Dutch scoring system, and good alignment between private schemes and official controls in Germany. In the more pluralist context of France and England, the state continues to play a more important role given the fragmented organization of the food industry, which has been unable to develop best practice standards, codes of practice, or private assurance schemes that sufficiently align with regulatory demands or command the trust of regulators. These two factors lead to significant differences in the definition of risk and, by extension, the kinds of FBOs most frequently targeted for inspections (Table 5).

Table 5 Approaches to risk-based food safety inspection by regulatory style and agrifood industry structure

	Agrifood industry structure	
	Corporatist	Pluralist
Legal constraints on enforcement		
Low (discretionary)	Netherlands <i>Risk</i> = probability <i>Target</i> : food-chain sectors/ parts with high levels of non-compliance	England <i>Risk</i> = consequence × probability <i>Target</i> : all FBOs but pressure to reduce scores of well-run FBOs in the absence of private assurance schemes comparable to official controls
High (legalistic)	Germany <i>Risk</i> = consequence × probability <i>Target</i> : all FBOs but pressure to recognize membership of private assurance schemes that are comparable to official controls in order to reduce score	France <i>Risk</i> = largely consequence <i>Target</i> : larger FBOs

Thus, the English regulatory context, which has historically valued the professional judgements of inspectors in both educating and sanctioning regulatees, facilitated the original development of risk-based food safety inspections based on indicators of probability and consequence of non-compliance that drew on inspector expertise. That discretionary approach to risk-rating survived later pressures to ensure consistency across local inspectorates, reduce regulatory burdens on business, and cope with budget cuts by narrowing the focus on the riskiest FBOs. However, the FSA has struggled to compensate for austerity and accommodate ministerial demands for still further deregulation by giving greater weight to confidence in management scores and relying more heavily on private assurance as an indicator of food safety; the pluralistic English food sector is just too poorly organized to create and enforce private assurance schemes that align with regulatory requirements.

In the Netherlands, inspectors have also historically enjoyed a high degree of discretion and have also faced austerity measures in recent years. Unlike England, however, Dutch corporatist traditions provided an opportunity for the NVWA to manage those deregulatory pressures by encouraging the development of private assurance schemes for managing the inherent hazardousness of food products and processes, leaving the agency to just use non-compliance records to risk-rate FBOs. However, that approach to prioritizing inspections was undermined by diminishing state inspection resources and poor take-up of private schemes in catering and other less well organized food sectors, which left too many FBOs unclassified. The NVWA was consequently forced to abandon priority-setting based on the risk-rating individual FBOs in favor of identifying problems in food production chains whilst leaving inspectors to decide which FBOs to visit.

Germany – like England – considers both probability and consequence of non-compliance, but its more legalistic regulatory style has both led it to codify its measurement parameters within administrative law and, unlike the Netherlands, prevented it from capitalizing on corporatist self-governance. Under pressure from big business to standardize inspection practices across Länder, Germany's rule-based regulatory approach lent itself to a proliferation of indicators because, as Diver (1983) has observed, while precise rules help ensure legal consistency, as they become narrower, so their number has to increase to match the variety of circumstances that they must meet. At the same time, while Germany's corporatist polity has seen its well-organized professional trade associations develop private certification schemes that are comparable to official controls, doubts about their reliability have prevented necessary legal agreement amongst Länder on including private certification into the scoring system. As our interviews suggest, however, many inspectors are still likely to score smaller FBOs as riskier than big FBOs insofar as they are more out of reach of the trade associations and are, thus, less trusted to comply.

Finally, the French emphasis on inherent hazardousness to assess non-compliance reflects a legalistic regulatory style within a pluralist polity. In contrast to Germany, French risk-scoring is less constrained by administrative law than by strongly entrenched constitutional principles of equal treatment. In that context, the inspectorate is reluctant

to make judgements about confidence in management that could be regarded as arbitrary, preferring instead to rely on objective measures of hazardousness. That approach is also aligned with a fragmented and poorly organized food business sector whose own private controls cannot be trusted to uphold the 'general interest' and thus require strong state policing. Those factors, combined with the multiplicative algorithm for risk-scoring, focus attention on large FBOs because it emphasizes the consequences of any failure for their large customer base. That targeting stands in stark contrast to the other three countries, which either focus on smaller or a broader range of FBOs.

6. Conclusions

While studies of regulatory enforcement in EU member states have long pointed to strongly-entrenched and distinctive national regulatory styles across policy domains, the mandatory requirement that they should all organize regulatory inspections through the concepts, tools, and methods of risk provides a rare test case of the extent to which it is possible to bring consistency to member-state enforcement practices. Our study of four member states, however, found significant differences in how they assess risk, to the extent that some are reaching diametrically opposed conclusions about what kind of FBOs to target and how often. This finding is surprising because: the use of risk-based policy instruments has been widely heralded as a universal approach to Better Regulation that can improve the efficiency, effectiveness, and consistency of regulation; food safety is a case of a regulation, not a directive, imposing that inspections be risk-based; and a European agency, the FVO, conducts regular audits of national inspectorates. We draw three conclusions from this study.

First, risk concepts have sufficient interpretive flexibility for risk-scoring methods to be constructed in ways that reflect the organization of political economies and nationally specific legal constraints that have long shaped the very enforcement practices reformers seek to standardize. Thus, while risk-scoring can be made to favor operators that belong to professional associations in the well-organized corporatist political economies of Germany and the Netherlands, such memberships carry less value in terms of trustworthiness in the poorly organized pluralist political economies of England and, particularly, France. At the same time, in the juridified regulatory settings of France and Germany, risk-scoring methods are strongly constrained by constitutional and administrative law, while in the less juridified English and Dutch contexts, risk-scoring methods are shaped more by inspectorates' professional preferences and contingent political pressures.

Second, risk-based approaches to regulatory reform are unlikely to make much impact on enforcement practices without more reflection on the assumptions, conceits, and institutional contexts that shape how risk is understood and used by regulators from country to country. As Lascoumes & Le Galès (2007) have argued, policy tools embody particular ideas about the purposes of governance and relationships between "governors" and "governed". Our case shows that risk-based tools are no exception. Instead of challenging regulatory practices, risk-based instruments are sufficiently malleable for inspectorates to codify preexisting practices in ways that preserve their predilections and institutional commitments. The consequence is that far from stimulating regulatory convergence, risk-based approaches can sustain entirely incompatible and mutually contradictory regulatory practices in different countries. Indeed, if better regulation reformers want to argue risk-based regulation can improve regulatory efficiency, effectiveness, and consistency, then they need to reflect more on what efficiency, effectiveness, and consistency mean in different national contexts. Moreover, the Dutch case suggests that better regulation reforms to slim down and consolidate regulatory agencies in the name of efficiency undermines the evidence-gathering capabilities required for effective targeting of inspections.

Finally, this paper raises interesting questions for current debates about Europeanisation (Thomann 2019). Whereas one might expect the Commission to be concerned with regulatory convergence across countries, the case of food safety suggests a greater concern with how closely member states follow their own internal control policies than whether their regulatory practices are externally consistent with each other. Further research would be required to determine why this might be. It could be, for example, that FVO concern with internal consistency is simply a first step toward later efforts to promote greater convergence across countries. Or it could also be that in the absence of much more detailed and prescriptive EU guidance on what a risk-based approach to food safety regulation actually means, *ad hoc* FVO audit teams tend – perhaps unsurprisingly – to evaluate the consistency of local practice with national policy, not least because of member-state sensitivities to scolding from Brussels. Indeed, the cross-national variation highlighted by this paper is relatively invisible given the focus of audits is on

national compliance. Or finally, it could be that Europe's embrace of risk-based instruments and other approaches to 'Better Regulation' is as much about improving transparency and accountability of regulatory practices within member-states as convergence between them.

Acknowledgments

This research was funded under the Open Research Area (ORA) for the Social Sciences program by the Economic and Social Research Council (No. ES/K006169/1), the Agence Nationale de la Recherche (ANR, France), Deutsche Forschungsgemeinschaft (DFG, Germany), and the Nederlands Organisatie voor Wetenschappelijk Onderzoek (NWO, Netherlands).

Declaration of conflict of interest

The authors declare the absence of any conflict of interest with the organizations mentioned in the paper.

Endnotes

- 1 As food safety is a devolved responsibility in the UK, we focus on England, which has 84% of the population and tends to set the pattern for the rest of the UK. Food safety is a responsibility of the Länder in Germany, but in this case, we focus on the whole country rather than a specific Land, given the joint efforts of local and central authorities in harmonizing food safety inspections across the country.
- 2 FVO was replaced in 2015 by the Health and Food Audits and Analysis Directorate, part of DG Health and Food Safety, but for reasons of brevity, we will continue to refer to it as FVO in this article.

References

- Ayres I, Braithwaite J (1992) *Responsive Regulation: Transcending the deregulation debate*. Oxford University Press, Oxford.
- Baldwin R, Black J (2008) Really Responsive Regulation. *The Modern Law Review* 71(1), 59–94.
- Baldwin R, Black J (2016) Driving Priorities in Risk-Based Regulation: What's the Problem? *Journal of Law and Society* 43(4), 565–595.
- Bastings L, Mastenbroek E, Versluis E (2017) The Other Face of Eurolegalism: The Multifaceted Convergence of National Enforcement Styles. *Regulation & Governance* 11(3), 299–314.
- Beaussier A-L, Demeritt D, Griffiths A, Rothstein H (2016) Accounting for Failure: Risk-Based Regulation and the Problems of Ensuring Healthcare Quality in the NHS. *Health, Risk and Society* 18(3/4), 205–224.
- Beaussier A-L, Demeritt D, Griffiths A, Rothstein H (2020) Steering by their Own Lights: Why Regulators across Europe Use Different Indicators to Measure Healthcare Quality. *Health Policy* 124(5), 501–510.
- Berger S (ed) (1983) *Organizing Interests in Western Europe: Pluralism, Corporatism, and the Transformation of Politics*. Cambridge University Press, Cambridge, MA.
- BERR (2007) *Regulators' Compliance Code: A Statutory Code of Practice for Regulators*. London HMSO, Department for Business, Enterprise and Regulatory Reform.
- Besançon J, Borraz O, Grandclément-Chaffy C (2004) *La sécurité alimentaire en crises. Les crises Coca-Cola et Listeria de 1999-2000*. L'Harmattan, Paris.
- Black J (2005) The Emergence of Risk-Based Regulation and the New Public Risk Management in the United Kingdom. *Public Law*, (Autumn) 510–546.
- Black, J. (2010). Risk-Based Regulation: Choices, Practices and Lessons Being Learned. In: OECD, *Risk and Regulatory Policy. Improving the Governance of Risk*, pp. 185–236.
- Black J, Baldwin R (2010) Really Responsive Risk-Based Regulation. *Law and Policy* 32(2), 181–213.
- Black J, Baldwin R (2012) When Risk-Based Regulation Aims Low: A Strategic Framework. *Regulation & Governance* 6(2), 131–148.
- Bonnaud L, Coppalle J (2010) Les inspecteurs vétérinaires face aux normes privées. *Revue d'Etudes en Agriculture et Environnement* 90(4), 399–422.
- Brickman R, Jasanoff S, Ilgen T (1985) *Controlling Chemicals: The Politics of Regulation in Europe and the United States*. Cornell University Press, Ithaca, NY.
- Demeritt D, Rothstein H, Beaussier AL, Howard M (2015) Mobilizing Risk: Explaining Policy Transfer in Food and Occupational Safety Regulation in the UK. *Environment and Planning A* 47(2), 373–391.
- Diver CS (1983) The Optimal Precision of Administrative Rules. *The Yale Law Journal* 93(1), 65–109.
- DoH (1996) *Code of Practice No. 8 on Food Standards Inspections (second revision)*. London HMSO, Department of Health and Ministry of Agriculture, Fisheries and Food.

- DW (2017) *Food scandals in Germany*. Available from URL: <https://www.dw.com/en/food-scandals-in-germany/g-39973278> (last accessed May 8 2020)
- EC (2000). *White Paper on Food Safety* Brussels, European Commission.
- Escobar MP, Demeritt D (2017) Paperwork and the Decoupling of Audit and Animal Welfare: The Challenges of Materiality for Better Regulation. *Environment & Planning C: Government and Policy* 35(1), 169–190.
- Falkner G, Hartlapp M, Treib O (2007) Worlds of Compliance: Why Leading Approaches to European Union Implementation Are Only ‘Sometimes-True Theories’. *European Journal of Political Research* 46(3), 395–416.
- FSA (2009/2010). *Framework Agreement on Official Feed and Food Controls by Local Authorities*. Food Safety Agency, London.
- FSA (2017). *Food Law Code of Practice (England)* London, Food Safety Agency.
- FVO (2013). *Netherlands Country Profile. Organisation of official controls*.
- Griffiths A, Beaussier A-L, Demeritt D and Rothstein H (2017) ‘Intelligent Monitoring? Assessing the Ability of the Care Quality Commission’s Statistical Surveillance Tool to Predict Quality and Prioritise NHS Hospital Inspections’ *British Medical Journal Quality and Safety*, 26(2):120–130
- Hammit, J., Rogers, M., Sand, P. & Wiener, J.B. eds. (2013) *The Reality of Precaution: Comparing Risk Regulation in the United States and Europe*. Earthscan, New York.
- Hampton P (2005) *Reducing Administrative Burdens: Effective Inspections and Enforcement*. London, HM Treasury, London.
- Havinga T (2014) National Variations in the Implementation and Enforcement of European Food Hygiene Regulations: Comparing the Structure of Food Controls and Regulations between Scotland and The Netherlands. *Recht der Werkelijkheid* 3, 32–53.
- Havinga T, van Waarden F (2013) *Enforcing Compliance with Food Regulation: Modalities in the Relationship between Public Enforcement Agencies and Private Parties*. Bordeaux, ECPR General Conference, Sciences Po.
- Hierholzer V (2010) *Nahrung nach Norm: Regulierung von Nahrungsmittelqualität in der Industrialisierung 1871–1914*, Vol. 190. Vandenhoeck & Ruprecht, Göttingen.
- Hood C (1986) *Administrative Analysis: An Introduction to Rules, Enforcement and Organizations*. Wheatsheaf Books, Brighton.
- House of Commons (2017). *2 Sisters and Standards in Poultry Processing*. First Report of Session 2017–19. Environment, Food and Rural Affairs Committee.
- Ipsos-MORI (2017) *Research on the Modernisation of the Risk Intervention Rating Systems for UK Food Establishments*. Report FS517009. London: Food Standards Agency.
- Knill C, Lenschow A (1998) Coping with Europe: The Impact of British and German Administrations on the Implementation of EU Environmental Policy. *Journal of European Public Policy* 5, 595–615.
- Kuhlicke C, Demeritt D (2016) Adaptive and Risk-Based Approaches to Climate Change and the Management of Uncertainty and Institutional Risk: The Case of Future Flooding in England. *Global Environmental Change* 37, 56–68.
- Lascombes P, Le Galès P (2007) Introduction: Understanding Public Policy through its Instruments. *Governance* 20, 1–2.
- Lodge M, Wegrich K (2011) Governance as Contested Logics of Control: Europeanized Meat Inspection Regimes in Denmark and Germany. *Journal of European Public Policy* 18(1), 90–105.
- Mackenzie D (2003) Long-Term Capital Management and the Sociology of Arbitrage. *Economy and Society* 32(3), 349–380.
- MBZK (2005). *Minder last, meer effect. Zes principes van goed toezicht*.
- Muller S (2008) *A l’abattoir*. Paris, Editions de la MSH.
- NVWA (2014, 2017a). *Multi-annual National Control Plan*. Utrecht, Nederlandse Voedsel- en Warenautoriteit.
- NVWA (2015a). *Annual Report*. Utrecht, Nederlandse Voedsel- en Warenautoriteit.
- NVWA (2015b). *Guiding Principles for Supervision and Enforcement*. Utrecht, Nederlandse Voedsel- en Warenautoriteit.
- NVWA (2016). *General Intervention Policy*. Utrecht, Nederlandse Voedsel- en Warenautoriteit.
- NVWA (2017b). *Specific Intervention Policy for the Inspection of Foodstuffs*. Utrecht, Nederlandse Voedsel- en Warenautoriteit.
- NVWA (2018). *The First Food Safety Statement*. Utrecht, Nederlandse Voedsel- en Warenautoriteit.
- OECD (2010a). *Risk and Regulatory Policy: Improving the Governance of Risk*. OECD Publishing, Paris.
- OECD (2010b). *Better Regulation in Europe. Germany*. OECD Publishing, Paris.
- OECD (2010c) *Better Regulation in Europe. France*. OECD Publishing, Paris.
- Oostendorp Y, Lemkowitz S, Zwaard W, van Gulijk C, Swuste P (2016) Introduction of the Concept of Risk within Safety Science in The Netherlands Focussing on the Years 1970–1990. *Safety Science* 85, 205–219.
- Pollitt C (2001) Clarifying Convergence. Striking Similarities and Durable Differences in Public Management Reform. *Public Management Review* 3(4), 471–492.
- Porter T (1995) *Trust in Numbers: The Pursuit of Objectivity in Science and Public Life*. Princeton University Press, Princeton.
- Richardson J (1982) *Policy Styles in Western Europe*. Routledge, London.
- Rothstein H, Borraz O, Huber M (2013) Risk and the Limits of Governance: Exploring Varied Patterns of Risk-Based Governance across Europe. *Regulation & Governance* 7(2), 215–235.
- Rothstein H, Demeritt D, Paul R, Beaussier A-L, Wesseling M, Howard M, de Haan M, Borraz O, Huber M, and Boudier F. (2017) ‘Varieties of Risk Regulation in Europe: Coordination, complementarity & occupational safety in capitalist welfare states’. *Socio-Economic Review* 17(4), 993–1020.
- Rothstein H, Demeritt D, Paul R et al. (2019) Varieties of Risk Regulation in Europe: Coordination, Complementarity and Occupational Safety in Capitalist Welfare States. *Socio-Economic Review* 17(4), 993–1020.
- Rothstein H, Downer J (2012) ‘Renewing Defra’: Exploring the Emergence of Risk-Based Policymaking in UK Central Government. *Public Administration* 90(3), 781–799.
- Rothstein H, Irving P, Walden T, Yearsley R (2006) The Risks of Risk-Based Regulation: Insights from the Environmental Policy Domain. *Environment International* 32, 1056–1065.

- Rothstein H, Paul R, Demeritt D (2020) The Boundary Conditions for Regulation: Welfare Systems, State Traditions and the Varied Governance of Work Safety in Europe. *Governance* 33, 21–39.
- Self, D. (2017). *Risk Managing Food Safety: Comparing the Enforcement of Food Safety Regulation in the UK and Germany*. PhD, King's College London.
- Stanziani A (2005) *Histoire de la qualité alimentaire: XIXe-XXe siècles*. Paris, Seuil.
- Stirling A (2010) Keep it Complex. *Nature* 468(7327), 1029–1031.
- Swartjes FA (2002) *Variation in Calculated Human Exposure: Comparison of Calculations with Seven European Human Exposure Models*. RIVM Report 711701030. Bilthoven, RIVM.
- Thomann E (2019) Customized Implementation of European Union Food Safety Policy. *United in Diversity?* Palgrave Macmillan, London.
- Treib O (2014) Implementing and Complying with EU Governance Outputs. *Living Reviews in European Governance* 3 (5), 1–30.
- Van Rossum W (2016) Dutch Legal Culture. In: Chorus J, Hondius E, Voermans W (eds) *Introduction to Dutch Law*. Alphen aan den Rijn, Kluwer Law International B.V.
- Van Waarden F (1995) Persistence of National Policy Styles: A Study of their Institutional Foundations. In: Unger B, van Waarden F (eds) *Convergence or Diversity? Internationalization and Economic Policy Response*. Aldershot, Avebury.
- Van Waarden F (2006) Taste, Traditions, Transactions, and Trust: The Public and Private Regulation of Food. In: Ansell C, Vogel D (eds) *What's the Beef*, pp. 35–59. MIT Press, Cambridge, MA.
- Versluis E (2007) Even Rules, Uneven Practices: Opening the 'Black box' of EU Law in Action. *West European Politics* 30(1), 50–67.
- Vogel D (1986) *National Styles of Regulation: Environmental Policy in Great Britain and the United States*. Cornell University Press, Ithaca, NY.
- WRR (2009) *Uncertain Safety: Allocating Responsibilities for Safety*. Amsterdam University Press, Amsterdam.
- Yapp C, Fairman R (2006) Factors Affecting Food Safety Compliance within Small and Medium-Sized Enterprises: Implications for Regulatory and Enforcement Strategies. *Food Control* 17(1), 42–51.