# From chasing violations to managing risks: origins, challenges and evolutions in regulatory inspections.

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# 2. Inspections, risks and circumstances – historical development, diversity of structures and practices

> *41. An inspector under this Act shall have power to do all or any of the following things ; namely,*
>
> *(i.) To make such examination and inquiry as may be necessary to ascertain whether the provisions of this Act (…) are complied with in the case of any mine :*
>
> *(ii.) To enter inspect and examine any mine, and every part thereof, at all reasonable times by day and night, but so as not to impede or obstruct the working of the mine (…)*
>
> *42. (1.) If in any respect (…) any inspector finds any mine, or any part thereof, or any matter thing or practice in or connected with any such mine, to be dangerous or defective, so as in his opinion to threaten or tend to the bodily injury of any person, he may give notice in writing thereof to the owner agent or manager of the mine (…) and require the same to be remedied; and unless the same be forthwith remedied shall also report the same to a Secretary of State. (…)*
>
> *(3.) If the owner agent or manager fail to comply (…) the time of making the award (as the case may be), he shall be guilty of an offence against this Act, and the notice and award shall respectively be deemed to be written notice of the offence.*
>
> *United Kingdom* Coal Mines Regulation Act*, 1887*[11]

Inspections are so much a part of modern economic life – and the expectation of safety regulations and their enforcement acting as a "backstop" to our daily life so anchored in assumptions of developed countries' citizens – that it is worth remembering that this is a relatively recent development. Indeed, the first inspectorates looking at *safety* were created not earlier than the second half of the 19th century. Looking briefly at the historical emergence of inspections is an essential introduction to a broader consideration of what these inspections are supposed to achieve, and more broadly of how risk, regulations and compliance are connected, and of the limits of these connections.

The history of the emergence of formal (in particular written) law has generally been given more prominence than the question of how laws were enforced and implemented (and how much they were complied with) – both for "ideological" reasons (traditional priority given to formal rules and official decisions over the more "menial" issues, one could say the "logistics" behind the laws) and for practical ones (sources on written, official laws are *relatively* abundant – finding out about enforcement and compliance is considerably more difficult).

[11] Full text available at: http://www.scottishmining.co.uk/256.html and a contemporary commentary and full text at: https://archive.org/details/coalminesregula00peacgoog

In addition, while historians have in fact covered "economic regulations" (when they were adopted), though rarely as much as other legislation (covering civil or criminal issues, say), there is no real body of historical knowledge specifically looking at the "history of regulations" – i.e. when, why and how certain economic activities or fields came to be covered by specific rules. When this has been covered in existing literature, this was mostly by economists and political philosophers, but their work has tended to look only at some examples that were relevant to the theory being developed, or were known to them. There has not really been a systematic investigation of the issue over time and space.

The reason why this is relevant to this research is that the basic premise of our work here is to question the existing enforcement structures and practices. Doing so leads us also to wonder since when they have existed, in which forms, regulating which areas – and also why they came about, what was expected from them, what they replaced. Thus, even though this can only be a short and partial overview, and there is no easy body of research to use, we have attempted this modest and partial summary.

## 2.1. Controlling compliance, controlling safety – the early history

### a. Tracing the earliest examples of "inspections" from Egypt to Greece and Rome

To understand better what are the specificities of inspections and inspecting institutions, it is worth considering their emergence, and looking at when and how were first created structures specifically mandated with controlling and enforcing specific rules. "Regulation" of human activities, in its broadest meaning, may be at least as old as the earliest urban societies. As activities specialized in a way that we could now name "economic activities", different "regulatory" measures and instruments were introduced. Morris Kleiner (2006) thus suggests that "among the oldest evidence of rules governing occupations is the existence of the Babylonian Code of Hammurabi, dating to around 1780 B.C.E. This body of codes stipulated both the fees patients were to pay for medical services and the punishments practitioners were subject to for negligent treatment" (p. xiii). This earliest example already featured the multiple purposes of regulation: safety ("negligent treatment") but also other considerations, in particular costs, affordability etc. ("fees"). We do not have indications of the Code being enforced through "inspectors", but rather it seems to have been used in judicial rulings, though not necessarily with direct references to its text (Charpin 2010). Thus, right from the origins of regulation, we can witness the decoupling of *rules* and *enforcement.* Not every rule (far from it) has its implementation inspected and enforced by a specific institution. In fact, historically most regulations (and even today many of them) can be said to have been left entirely to "reactive" and "private" enforcement, i.e. only by judicial decisions when litigation happened[12].

Nonetheless, efforts to promote and ensure better implementation of policy directives, and compliance with rules, started early on. Ancient Egypt in the New Kingdom era (16th-11th centuries B.C.E.) already had a complex administrative system with technical staff at the lower levels that were in charge of making sure that central directives (e.g. relating to irrigation systems etc.) were properly followed (Moreno Garcia 2013). Specialized institutions or officials in charge of *control* of compliance with rules probably first came into

[12] Indeed, even though police forces often have broad jurisdiction and notionally could (and in some countries effectively do) control compliance with some (or many) regulations, this is a relatively recent development. Development of police forces itself was gradual and came relatively late compared to the establishment of urban societies, with Classical Athens (the "rod-bearers") and Augustean Rome (the vigiles) among the first reported to have had significant numbers of officers tasked with maintaining public order and fighting street crime and other hazards. Police forces were mostly small in numbers for many centuries, and clearly focused on violent crime and threats to the state authority. Even though there are some indications that there was some enforcement of weights and measures in Athens, any such activities were quite limited.

existence to supervise payments of customs duties and taxes[13] - being gradually developed in ancient Greek city-states, Hellenistic kingdoms and Rome. Officials in the ports controlled ships to ensure proper payment of trade duties. Still, these administrations underwent only limited development in staffing, professionalism and methods (at least as far as we can make out) – republican and imperial Rome relied on *publicans* (contractors) to make an advance on the product of taxes to the state treasury,[14] and then collect actual taxes – thus, tax collectors were in fact private contractors. Tax farming remained, if not the norm, at least a very common method, until the 19th century C.E. (one of the most important examples remaining France's *Ferme Générale,*[15] which was abolished by the Revolution).

Looking more closely we can, however, find some real examples of direct state control, for instance in Athens. In the *Constitution of the Athenians* attributed to Aristotle one can thus read that among the magistrates to be chosen by lots were 10 *agoranomes* (whose tasks included checking that goods on the market were not falsified), ten *metronomes* (verifying weights and measures) and ten (and later thirty-five) *sitophylakes* (checking that sales prices of wheat were in proportion of grain prices and weights, etc.) (Austin and Vidal-Naquet 1972, pp.326-327). While Athens is likely to have been "ahead of its times" in terms of how organized and specialized the city offices were, we should also remember how thoroughly incomplete and partial our knowledge of ancient times is. It may well be that such magistrates were far more frequent than the traces we have. This would thus suggest that the importance of securing the truthfulness of market transactions, but also to some extent the safety of consumers, and (more importantly considering the number of magistrates allocated) the fact that consumers were not "gouged", were very early concerns, and among the first gave rise to active state control.

A few more remarks on these early examples. First, we are not absolutely sure to which extent these controls (early "inspections") were based on clear "regulations", or enforced far more diffuse "acceptable practices" relying more on experience, customs etc. – and clearly on the question of "fair prices" at least, and of falsification, it is unlikely that rules (if they existed) were very detailed (weights and measures being one issue where, on the contrary, the rules were certainly clearer). This means that the question of inspectors *discretion* was already very relevant. Second, the Athenian magistrates were (as for most other functions) selected randomly – the idea of *professional* inspectors was one that was not yet present.

Still, while these functions undoubtedly related to enforcement, control and inspections, the structures in place did not necessarily look very similar to what we would nowadays understand as "inspections". These developed gradually, over a number of centuries – both in terms of scope, professionalism and methods. Some important steps can be sketched out as "landmarks" in this emergence of "inspecting institutions"[16] – from the Middle Ages to the 19th century.

### b. The developments of the Middle-Ages and Pre-Modern times – and their relevance

The relatively simple character of fiscality – and of accounting, at least until the 14th century – in pre-modern times means that the complexity of operations needed to assess taxes and duties was limited – and inspectors were not really distinct from collectors. These collectors did not really constitute a corps of "inspectors" that would have looked in details at operations of economic agents. It is in other fields that we can trace some of

[13] See Asakura 2003, Austin and Vidal-Naquet 1972

[14] See e.g. Badian 1983

[15] See e.g. Pion 1902

[16] This outline is clearly done from a Western European perspective as, institutionally, this is where the model of modern inspecting institutions comes from. This is, of course, not to say that other regions did not develop their own approaches to problems of safety, compliance, market regulation etc. – only to focus on what is the most relevant for our present study.

the origins of modern, "professional" inspectors – and in ways that often show a very strong link between "risk" and "control".

### *i. Food Scares and Food Controls – unity of concerns, diversity of approaches*

There were, however, other aspects to economic activities than taxes and levies, some of which were deemed very important by populations and rulers. This is the case of the "quality" of goods, works and services, in particular (the notion of "quality" is a highly problematic one, but this was the term that was most frequently used at the time). As Madeleine Ferrières has managed to sketch out (in spite of the fragmented nature of sources) in her ground-breaking book on the history of food fears (Ferrières 2002), an increasing number of control measures were brought in from the late 12th century onwards, as cities again started to grow in Western Europe, in order to alleviate "fears" about the "safety" of animals being brought into the city, slaughtered and sold. While the contents of regulations imposed, the way in which controls are implemented, were grounded in the conceptions held at the time about what was "healthy" or "unhealthy", "safe" or "unsafe", and had nothing to do with modern science (except by some chance overlaps between the two) – they still manifested a concern that is very much akin to what now drives the development of food safety regulations and inspections. The intellectual background for regulation of food was very different then from what it is now. Bacteria and other germs were unknown, as were the real mechanisms of contamination. Food, however, had a centrally important role in medieval medicine and beliefs on health. The existence of animal diseases was of course known, some parasites were, if not understood, then to some extent identified, and there were many fears, that drove the demand for regulation. Because medical conceptions were so different, and understanding of biological mechanisms was yet to be developed, many of the rules and practices imposed at the time would not make sense from our perspective[17] – but the question here is not whether rules were appropriate to control diseases (they often were not), but how they were enforced.

The number of cities regulating the sale of meat, in particular, kept increasing over the 12th-15th centuries (Ferrières 2002 pp. 43-45)[18]. Very early on, too, emerge crucial differences between what we would now call "regulatory approaches". While cities in Southern France and the Mediterranean region more broadly (Italy, Spain) relied on municipal regulations, detailed written law (these were Civil Law regions) , and officers appointed by municipal authorities to control the "safety" of meat, Northern France (and England, or the Low Countries) had a different model. There, professions such as butchers were "self-regulated" by guilds, they were "sworn trades" and swore to obey the guild's charter. Rules are less detailed in this case, the prohibition of selling "unsafe" or "unsuitable" meat is meant to be implemented by professionals who have the knowledge and "know how". Guilds themselves control compliance (*ibid.* pp. 45-46). There is no evidence of a marked difference in effectiveness between the two, but it is noteworthy that two models existed from the onset, based more on inherited legal, social and political differences between these two areas, rather than on considerations of how effective the control may be – and worth noting that this difference has, to a significant extent, endured, with a stronger reliance on self-regulation and involvement of professionals in England or Germany, and more emphasis on state control and written rules in France or Italy, say.

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[17] Even though everyday experience did yield some practices, such as thorough cooking, that do make sense from a bacteriological perspective, many other requirements would be more questionable from a "modern" view. For instance, in pre-modern Europe, rules generally mandated animals to be killed in view of all, i.e. on the markets themselves, with corresponding hygiene issues – but thus avoiding fraud on the actual state of the animals being slaughtered (see Ferrières pp. 48-51 and 348-356). It should be noted that this concern and belief that animals killed "in sight" are safer is still widely spread in developing countries around the world today, and thus probably corresponds logically to a situation where consumers have no other trusted sources of information about products than their own eyes.

[18] It is notesworthy that regulation at this time is essentially done at the municipal level. National, rather than local, regulation came in much later.

While the control of animals "imports" (into the city), slaughter, and sale of meat were the earliest food-related regulations and "inspections", successive centuries saw additional types of foods and food trades increasingly regulated – in line with epidemics and "food scares", i.e. in our modern language real and perceived risks. To these traditional forms of control was added some supervision of street vendors (*ibid.* pp. 222-223 for the example of *pâtés* and their regulation in the 16th century) and food shops in large cities by police forces (e.g. in Paris), that gradually developed and indicated an increased concern on the side of political authorities – because food scares could rapidly degenerate into unrest. This was the case with disputes about new bread baking techniques that led to royal intervention and regulation in Paris (*ibid.*, pp. 158-163). Major epizootic crises gradually contributed to a more organized and constant involvement of central state authorities (necessary to enforce quarantine), but this happened only slowly, and with a number of reversals, over the 17th-19th centuries (*ibid.,* pp. 294-311 and 392.402). Slaughterhouses, along with state-run enforcement, were introduced in France in the early 19th century, and thus live animals removed from the food markets. In 1906, sanitary inspections were made mandatory in slaughterhouses in France and the US adopted the Pure Food and Drugs Act (*ibid.,* p. 431) but it is only well into the 20th century (Ferrières. pp. 428-432 – see also Blancou 2000), long after Pasteur's work gave the scientific foundation for modern food safety control, that food safety services were systematically organized[19].

Food-related "scares" or, to use a modern term, "risks" were not, however, the only application of early efforts at regulatory control. Much as today we can still see a nuance between some types of inspections focusing strictly on safety and physical threats, and others looking at consumer protection and other "economic interests", early examples of regulation also included interventions aiming at safeguarding consumers from fraud and deceit. The food-related controls we discussed above had a dual purpose – protection against "unsafe" foods, and fight against adulteration and fraud (e.g. the purported use of cat instead of rabbit meat in pies – see Ferrières pp. 216-225). This was, however, not the only area where rules and processes existed with the aim of protecting consumers. Just as guilds were involved in the food trade, the craftsmen guilds that emerged in a number of cities from the 11th-12th centuries onwards covered most of the significant crafts and trades in Western Europe, and a major part of their functions was to control the way their members worked, and the "quality" of their wares, works and services.[20] Guilds were also found in non-European contexts and played an important role[21] in what could be called early examples of "self-regulation" or "regulated professions" or "enforced self-regulation" (depending on the specifics of each case).

In many jurisdictions and in many aspects, one could thus say that "enforced self-regulation[22]" preceded "regulation". Guilds regulated their members (often with a limited amount of details in written rules, and more emphasis on practice) – and authorities (municipal, state or otherwise) provided an "enforcement backup" for whoever would try and operate outside of the guild and its rules. In this perspective, it could be interesting to study more closely whether the liberalisation of entry into economic activities and the abolition of guilds' monopolies (e.g. in France with the *Loi Le Chapelier* adopted in 1791) had an influence (even delayed) in the gradual emergence of more direct state regulation. It would not be absurd to imagine that states that more thoroughly eliminated the old guilds system (e.g. France) would rely less on professional regulations than others (such as Germany) where changes were slower and less radical – and this could have reinforced a

[19] See e.g. overview of the United States FDA's history: http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm124403.htm
[20] See e.g. Martin Saint-Léon 1922.
[21] See Lucassen *et al.* 2008
[22] We are here using in a deliberately anachronistic way an expression borrowed from Ayres and Braithwaite 1992 – see pp. 102 and 118.

difference in regulatory approaches that, as we have seen above, has some origins in the Civil Law/Common Law "divide"[23].

### *ii. The French Manufactures Inspection – an early example of "inspectorate"*

One of the most interesting early examples of regulatory inspections, however, involved direct state intervention to ensure an adequate level of "quality" for the era's most important consumer goods – textiles. The story of textile manufacturing inspections bears striking resemblance to many of our time's inspections and enforcement logics, challenges and reform attempts. It also features England following up in France's regulatory footsteps, which does not fit with today's stereotypes on the two countries. Covering this case in some detail is worth the insights it can give us on how issues we tend to see as "contemporary" are in fact further developments of long-present trends and challenges.

One of the first "inspectorates" defined as such was created in 17th century France to supervise textile manufacturing. In August 1669, Louis XIV enacted the *Règlement Général des Manufactures et Teintures*, on the recommandation of Jean-Baptiste Colbert, *Contrôleur Général des Finances* – his chief minister. Further to this major regulatory act, in april 1670 Colbert (who was also "*Surintendant des Bâtiments, arts et manufactures de France*") issued an instruction on its implementation[24] (Lenoble 1908 pp. 1-3). The regulation included rules to ensure raw materials (wool, primarily) were not damaged, detailed mandatory prescriptions on the way weaving and dyeing should be done for different types of cloth, requirements to check the cloth for conformity and mark it with a lead seal – as well as serious sanctions for those who would violate these rules (*ibid.,* pp. 2-3). This initial regulation was followed by subsequent additions, amendments and reforms: first, aiming to strengthen and complement it and then, later, trying to make it more flexible to accommodate market demand for more diversity and lower prices, more "segmentation" as we would now say (Lenoble 1908 p. 2 and Minard 1997 p. 490). The inspection itself underwent gradual development over several decades, with inspectors appointed throughout the kingdom, then "inspector generals" created in 1727 (Lenoble 1908 pp. 3-4) – reaching a staffing level of 50-60 (Minard 1997 p. 488) – modest by modern standards, but far from insignificant for states in the 18th century, and considering the limited number of manufacturing facilities to be controlled.

Even though the inspection was to be abolished quite suddenly (Minard 1997 p. 487, Lenoble 1908 p. 9) in 1791 by the Constituent Assembly (in the same year that it also abolished all guilds and corporations, and forbade trade unions and strikes, by the *Loi Le Chapelier*), the inspection was not only well established but, to an extent, imitated elsewhere. Building further on the policies of successive Tudor monarchs who "used protectionism, subsidies, distribution of monopoly rights, government-sponsored industrial espionage and other means of government intervention to develop England's woollen manufacturing industry" (Chang 2007 pp. 40-41), in the 1720s Robert Walpole and his cabinet went further. Not only was Walpole's 1721 legislation adopted to "protect British manufacturing industries from foreign competition, subsidize them and encourage them to export" – in addition, "regulation was introduced to control the quality of manufactured products, especially textile products, so that unscrupulous manufacturers could not damage the reputation of British products in foreign markets" (*ibid.*, p. 44). While "Walpole's protectionist policies remained in place for the next century" (*ibid.*, p. 45), state-imposed quality controls were also phased out in the 19th century as part of a broader wave of free-trade reforms.

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[23] A number of regulatory features have origins as far back as the French Revolution – for instance, the way French building safety regulations are primarily enforced through a 10 year liability on builders dates back in essence to the 1804 *Code Civil* – see World Bank Group 2013 b, pp. 82-87.

[24] Full text available at: https://www-persee-fr.bibliopam-evry.univ-evry.fr/web/ouvrages/home/prescript/article/corr_0000-0002_1863_cor_2_2_928_t1_0832_0000_5 .

Cursory information suggests the system was imitated also in other countries, but since information available is limited, we will focus on the original French example in order to briefly describe some of the main goals, characteristics, challenges and lessons of the "manufacturing inspection" experience. The overall goal of the regulation of manufactures (primarily textile, but with coverage of rules and inspections also extending to other sectors) was the economic development of the country through an increase in manufacturing production (both for import substitution and exports), aiming at capturing more of what was not yet called "added value" (see Lenoble 1908 p. 1). Inspectors are supposed to help achieving this goal first by improving the consumers' confidence and trust in the products being sold to them – meaning both domestic consumers and foreign consumers, with French products supposed to gain market share, and maybe also with the idea that trust will help "grow the market" by increasing overall demand (Minart 1997 p. 489-490). In addition, inspectors also provide (or are expected to provide) advice to manufacturers (or would-be manufacturers) and to local officials such as the *intendants* on where to set up their facilities, how to source raw materials, which products are more in demand, which markets they could target, which technologies they could use etc. (Lenoble 1908 p. 6) They also collected statistics for the government.

The corps of manufactures inspectors reportedly "survived" an early "temptation" by Louis XIV who, cash-strapped after the Spanish Succession War, decided in 1704 to sell offices of inspectors and controllers of manufactures, and let them levy a duty on cloth. Petitions by manufacturers and traders led to this decision being repealed, and the corps increasingly became what Minart (*ibid.,* p. 488) calls a "laboratory" for a new type of "*Ancien Régime* Civil Servant" – with "all the elements" (or at least many) typical of the "modern civil servant": hierarchy, entrance examination[25], status, career profiles, discipline, obligation to reside in duty station, pension. The inspectors were under a clear vertical hierarchy reporting to the minister (*Contrôleur Général des Finances*) though they also coordinated to a large extent with the local *intendant* (whose role was close to the modern French *préfet*).

We do not have sufficient information (and even less data) to attempt an assessment of the inspectors' effectiveness, even more so considering that their purpose (increasing production) was one where their role would evidently be (at best) very minor compared to other factors (geography, trade, geopolitics, technology, overall institutional and political framework etc.). Nonetheless, Minart (*ibid.,* p. 489) suggests that manufacturers and traders in fact, to a large extent, supported the system because of the trade facilitation effect it created (through increased trust). The excessive complexity brought by ever-increasing detailed prescriptions, the heaviness of the limitations on innovation or lower-cost production (and the undercutting of compliant producers through cheaper, "informal" production) led to series of reforms, in particular under the ministries of Turgot (1770 – see Lenoble 1908 p. 2) and Necker (1779 – see Minart 1997 p. 490). In particular, the latter issued instructions to inspectors to "clarify and narrow down the scope of regulation", accommodate more "freedom of creation, flexibility in implementation of norms" and "quality-price oriented consumption" (*ibid.*).

In spite of this, the regulation and inspection of manufactures was increasingly seen by the French liberals as a "*carcan gothique*[26]" (*ibid.* p. 489) – and it was abolished, as mentioned, during the Revolution. What is fascinating for the student and practitioner of modern inspections, is the number of aspects where this system reminds us of contemporary product market regulations and their enforcement – and their challenges.

First, the tension between the need to enable market development through trust, and the barriers to innovation and growth imposed by excessively detailed and strict regulation. Defining precisely what certain product names should mean, and imposing specifications and certification, are still methods that are in use

[25] Though Lenoble 1908 reports famous cases of nepotism in appointments – which is not necessarily contradictory with a practice of examinations for most cases and/or at a later stage (p. 5)

[26] A "gothic straightjacket" – a qualification at least as harsh as those used by modern-day "regulatory reformers"

today – however, in the EU for instance, these are generally voluntary (i.e. to be complied with only if one wishes to sell a product using this specified controlled denomination – alternative products, named differently, are allowed) and certification is not done by state inspectors (but by accredited and authorized conformity assessment bodies)[27]. However, many countries around the world (e.g. most former Soviet countries) have systems where most products are subject to mandatory certification, alternative product types and production methods are not allowed, and certification is done directly by state bodies which also conduct inspections.

Second, the arguments used to create the institution, propose its reform and its abolition, as well as the ways in which it was reformed (and then abolished), all remind us of modern situations as well. Developing an industry and protecting consumers are oft stated goals in developed and developing countries alike when it comes to introducing regulations and creating inspection institutions. Removing barriers to innovation, reducing prices and allowing diversification are frequent reasons why reform is advocated. Introducing more flexibility compared to a more rigid initial practice is a common reform approach – just as the "radical" approach to free up markets fully from restrictions that are not necessary for safety but only aim at ensuring "quality" is another option that is just as present in contemporary reform situations.

Finally, the ways in which the inspectorate developed – an initial decision to regulate, the recognition that inspectors were needed, gradual build-up of staff without a very clear initial plan, and progressive formalization, are close to what often is seen to happen in modern times. The decision to regulate is taken quickly based on goals that seem undisputable but with a "theory of change" that is not fully thought through and excessively optimistic. The need for implementation and enforcement resources emerges quickly, but there is no initial vision of how to structure it, and it progresses in a partly "unplanned" way. Path dependence is a strong factor.

In conclusion of this small case of "pre-modern" inspection, we can say that the historical study of regulation and regulatory enforcement appears to hold much promise in order to better put our own contemporary problems in perspective, and comparisons of countries with different regulatory approaches and reform decisions could be even more enlightening. What is clear, in any case, is that our modern issues are far from being uniquely novel. There are relatively few studies of institutions that (under whichever names) could be considered as forebears of "inspectorates", but it is noteworthy that the intent to create institutions to both foster and control specific industries is not new, and neither are the tensions between these different missions, and the many questions of institutional structure, resources and methods. Further research on historical roots of inspections and enforcement regimes may yield valuable insights on today's differences between countries, as well as on the strengths and weaknesses of different institutional models.

## 2.2. The emergence and development of modern inspectorates

What this brief overview shows is first that control activities existed (and were seen as necessary) already in the Middle Ages in most of Western Europe (and possibly beyond), and were created at that time primarily in response to "fears" (often but not always corresponding to real hazards) related to food "quality" or "safety". Protecting a trade from competition was also an important function of guilds, but for the public, safeguarding "quality" was seen as their role. Further development of inspections in the 17th and 18th centuries were linked to "quality" again, this time of manufactured goods, with a view to strengthening trade opportunities for domestic producers.

[27] Note that, interestingly, the quickly-reversed 1704 reform that aimed at selling the offices and letting them recoup their costs through a duty on textiles would have had some features of the "private" modern system of conformity assessment.

The second notable point is that several models existed, one based on self-regulation, another on control by public authorities (municipal), and (later on) a third on inspectors appointed by the central government. The adoption of one or another model (at least between the first two) appears to have been the result not of an "effectiveness evaluation", but of institutional structures, social, legal and political dynamics. The development of more systematic control, led often (but not always) by central authorities (or at least by municipal ones), was very gradual (at least for food) – and spurred by the combination of the general growth of modern states, major food-related crises (e.g. epizootics), advances in scientific knowledge, and changes in mentalities. In contrast to this gradual process, the manufactures inspection provides the example of how a centralized institution could be created due to a deliberate government decision.

This suggests is that there is nothing self-evident in what is or is not inspected, and with which structures. Medieval cities introduced supervision of food trade, but it did not exist everywhere in the same form, and many other issues were left without a specific "inspection", even when in fact they were submitted to many rules (such as the different forms of pollution, including noise, that could arise in cities – rules were often adopted at various stages in the medieval and pre-modern times, but there was no "environmental inspection" nonetheless). It is also far from clear that these inspections were actually effective, or useful, in most cases. Ogus (1994) summarizes regulation in the "Tudor and Stuart Periods" as "often over-inclusive, incurring the hostility of those unintentionally caught by the provisions, or under-inclusive, leading to avoidance behaviour by those intended to be caught" (p. 6) and adds that "enforcement was a matter for local administration and often ineffective".

Most of the control exerted by the state (or by non-state actors with regulatory functions, such as guilds) in pre-modern times applied to the trade angle: ensuring that buyers were not defrauded, and that the quality of goods sold abroad was high enough to sustain high levels of exports against the competition. Just as weights and measures were a core prerogative of the sovereign, avoiding deceit on markets was seen as an issue worthy of rules, and enforcement. Other issues, which to us would appear as high priorities, were on the contrary mostly left without specific enforcement (if not necessarily without rules), such as safety in the workplace[28], fire and buildings safety, "environment" (even understood in a pre-modern context), etc.

Thus, while manufactures were inspected in France (and some other countries) from the 17th century at least (and most crafts in Western Europe subject to enforcement by guilds), workers safety only became an area of state control in the 19th century. Regulations and enforcement centering on health and safety appeared in connection to large-scale industry and in particular mining, and what contemporaries started to perceive as the horrifying conditions workers (and in particular children and juveniles) had to endure. Ogus suggests that the interesting and specific aspect of the new regulations appearing in the 19th century, compared to the previous period, was "the large number of measures dealing with public health and the conditions of employment" (Ogus 1994 p. 8).

As Ogus rightly points out (and as we have illustrated above), "state intervention did not result from any abrupt shift (…) but rather emerged gradually" (*ibid.,* p. 7) – and indeed regulation had been around for far longer. The new situation was "the emergence of administrative structures capable of diagnosing the problems and formulating solutions to deal with them" – as "the existence of specialist bodies served to inject an almost unstoppable momentum into the growth of regulatory law." As administrators found shortcomings while implementing existing rules, "to correct the defects, they would demand amendments to the provisions or an extension to their own rule-making powers" (*ibid.,* pp. 7-8). As we have seen above, France's Inspection of Manufactures was in many ways a prefiguration of this trend, and thus "specialist bodies" were maybe not as

[28] Lenoble (1908) specifically indicates that the manufactures inspectors did not look at safety and related issues at all – though they monitored social situations, occasionally organizing assistance for manufacture workers in times of crisis, more often warning about the dangers of strikes (p. 9).

novel as Ogus states – but the ways in which the Inspection indeed constantly prodded the further development of regulations surely validates Ogus's claim that this institutionalization was a key cause for the growth of regulatory law.

In Britain, at least, the emergence of new regulatory areas and institutions often started with "*ad hoc* commissions to investigate social conditions", which often led to the creation of "boards" and "inspectorates" to implement new legislation, but with often an unclear relationship to Parliament and state structures (*ibid.*). Eventually, criticisms led to the "decline of the independent regulatory agencies" – with, for some, powers "transferred to central or local government", for others, "more formalized arrangements regarding (…) the legislative definition of their powers and their accountability" (*ibid.*). Such trends, to an extent, can be seen in other countries, but with different degrees of speed and resilience of "independent" structures (e.g. these seem to have often survived far longer in the Netherlands[29]).

When "inspectors" were appointed or "inspections" set up, it was also often to look at the state administration itself, rather than at the private sector. This was particularly important in France, and in countries that imitated (to varying extents) the French model (or "inherited" it later through colonization). Gogol's "inspector general" was one of these. Looking at these "internal" state inspections would be the subject of a whole other research, but it is striking that Gogol's work shows issues that are still salient today: the fear of the inspector (not universal certainly, but frequent), the misconceptions about him – and the risk of corruption.

Looking at the gradual emergence of modern inspectorates in a number of countries would be a task far beyond the scope of this research, and would add little to our purpose of understanding the *problems* that inspections face, and to which extent risk-based approaches can remedy them. What is, however, helpful is trying to get a glimpse of the mechanisms that have led to the current structures and resource allocations – and, to this aim, some history "snapshots" are useful. To this aim, we will look at examples taken from the two inspection functions that were formalized in a "modern" way earliest: occupational safety and health (OSH) (in some depth), and food safety (briefly). We will describe at some length the example of OSH in the UK, a country that is often considered now among the most representative of the practice of risk-based, "smarter" inspections, with some shorter summaries of the experience of other major economies (France, the Netherlands, Germany and the United States). The consideration of food safety will be considerably shorter, for the amount of available research on the history and development of regulatory institutions in this sphere is much smaller (a point we will discuss at the beginning of that section). The idea is to look for an *illustration* (and not, at this point, for models or regularities) of how institutional structures and resources came about, and in what relation to risk, and for this purpose one case and a few "snapshots" should be sufficient – and not take up an excessive part of this research.

The cases were selected based on a combination of criteria. First, because the development of modern public administration structures largely proceeded first in a small number of major powers, which were the earliest industrial economies and wielded the most influence in the late 19th and early 20th centuries, we sought to select these in priority. This meant a long-list of Britain, France, Germany and the United States (with Britain and France having had major influence through their colonies, France and Germany having significant influence in Continental Europe and Japan, and the United States in many Latin American countries, and the Philippines). Second, we focused in particular on "prime movers", i.e. the countries that were the first to establish inspectorates in the fields selected for study (e.g. again Britain, France and Germany for OSH). To this list, for the particular case of food safety, we decided to add the Former Soviet Union, as its institutional and policy model was both relatively "advanced" for the time of its creation (1930s), taking place as it did in a

[29] Food safety supervision for dairy and eggs is still conducted in the Netherlands by private, independent bodies, which are commissioned by the central government (and can be revoked, changed etc.) – see Blanc (2012) p. 85 and websites: www.ncae.nl and www.cokz.nl

crisis context and in a situation of *tabula rasa* of earlier institutions – and as it still influences contemporary structures not only in successor states of the USSR, but in all countries that were under its influence. Third, where there are significant differences in timelines and approaches concerning the establishment of inspections and enforcement legislation and institutions, we have sought to present cases that illustrate the different paths taken (e.g. United States and European Union in food safety, or Netherlands in OSH as a "late mover" example, or Britain, France, Germany and United States as four very different models in OSH). Fourth, it was particularly important to discuss the impact of the European Union in food safety, where it has had a major impact not only on Member States but as an international model that is being imitated far and wide (even, to some extent, by the United States). Finally, there was an element of opportunity in some of the choices, as the development of inspectorates and inspections has been the object of far more studies in some countries than others, e.g. Britain and the United States. As a result, the list of countries includes Britain, France, the Netherlands, Germany and the United States for OSH. For food safety, it comprises Britain, the United States, France, the Former Soviet Union and the Netherlands.

These examples will enable us to understand better the contexts in which inspectorates have been created and have developed, the different paths taken in terms of institutional models and approaches to fulfilling their missions, the role of path dependency in explaining differences that still hold true today, and to start exploring the degree to which these historical differences may explain contrasts in practices and results today.

Finally, the reason we decided to focus specifically on OSH and food safety, and to treat them separately, is that it would be impossible in practice to try and cover the emergence and development of *all* inspection functions, and that these were both historically the first "new inspection functions" (as distinct from earlier ones such as tax or weight and measures) to emerge, and functions that were seen as so centrally important that such inspectorates ended up being created practically everywhere. They also typically represent institutions of a significant size today, with important resources and staff. Other functions (e.g. environmental protection) emerged much later (late 20$^{th}$ century), or are not present everywhere "as such" (e.g. fire protection), and/or have much smaller staff (e.g. environmental protection in many countries) etc. For all these reasons, we concluded that OSH and food safety could meaningfully serve as examples and as the richest and most insightful cases we could consider from a historical perspective. Studying them separately allowed to compare specific historical trajectories between different countries for a given function, which was our key purpose here. It is worth noting that these cases (countries and regulatory functions) do not fully match those selected in chapter 4 to investigate the implementation of risk-based approaches in practice. To the extent possible, we did cover some of the cases in both chapters (e.g. Britain, Germany, France and the United States in OSH, Britain and the Former Soviet Union in food safety), but we did not do so *systematically*. First, because the purpose was different – in chapter 4, we selected cases specifically to look at the results of risk-based vs. non-risk-based approaches. Second, because our selection in chapter 4 was to a large extent driven by the availability of strong "examples" (i.e. practices clearly representative of risk- or non-risk-based approaches) and – most crucially – the availability of data. Since data on inspections burden and outcomes is (as we will discuss further in chapter 4) frequently unavailable, the selection of this second set of case studies was consequently far more constrained, and could not in any case fully match those that we will now consider from a historical perspective.

## a. The emergence and development of modern inspectorates - Occupational Safety and Health[30]

### *iii. Why did Occupational Safety and Health come first?*

Perhaps surprisingly, considering that the "safety" and "quality" of food (or whatever was then understood behind these terms) had been probably the issue on which most of the early regulatory efforts were made (looking at the Middle Ages onwards), the first modern inspectorates created did not aim at improving it. Nor did they cover any of the other long-standing market issues (like weights and measures) that had been a key domain of state intervention. Rather, they targeted a problem that was "brand new" – maybe not in its substance, but in the way it was perceived: the way workers were treated in the newly developing factories and mines, and in particular the fate of women and children.

Let us pause for one instant and challenge what may seem obvious to modern readers who know well the picture of terrible abuse and horrific conditions painted by Dickens, Zola and others. While the way workers in general, women and children in particular, were treated in textile factories, coal mines and other industrial establishments was indeed horrific – it is not self-evident that this was the "greatest risk" of the time, nor is it absolutely clear that this abuse was a shocking novelty.

Looking only at the magnitude of risks, and at the impact that prevention could have had, hygiene, water and sanitation would probably come first (at least in retrospect). The time of the creation of the first labour inspectorates was also the time of the great cholera pandemic. In France, in 1832, 20,000 persons are thought to have died in Paris – and researchers estimated that mortality in affected regions doubled – and in the 1854 epidemic, mortality even quadrupled in a large swathe of Eastern France (Raulot *et al.* 1978, p. 140). In London, as late as 1866, a major cholera outbreak killed "nearly four thousand people there between the end of July and the beginning of November" (Luckin 1977 p. 32). Though the reason the epidemics did as much damage as they did was the new development of exchanges and trade, and increased mobility of people across and within countries (Raulot *et al.* 1978, p. 140-141), the direct causes of these outbreaks were (theoretically) preventable, and caused by poor hygiene.

For London in 1866 "it was the action (or, more accurately, the negligent inaction) of the East London Water Company which decisively determined the dissemination and scale of the outbreak" (Luckin 1977 p. 32). However, even in 1866, "it was only a minority within what may be loosely characterized as the *avant-garde* in the nascent profession of epidemiology which gave unqualified support to the view that the outbreak (…) was decisively carried by water" (*ibid.* p. 33). Indeed, even though the bacterium causing cholera had in fact been discovered in 1854 by Filippo Pacini[31], this discovery had been ignored, and most "experts" still clung to the old "miasma theory" of epidemics causation (which explained why the discovery was ignored). Pasteur's and Koch's[32] works were still to come. Thus, to an extent, people (including policymakers) at the time simply had too little understanding of the disease to act effectively. However, some understood the fact that clean water was important to epidemics control, even without a correct explanation for how the diseases were caused. In fact, "the [water] company had clearly contravened a clause of the Metropolitan Water Act of 1852 which outlawed uncovered reservoirs within five miles of St. Paul's" (*ibid.* p. 34). The impossibility to demonstrate the link between contaminated water (since one did not then know what contamination to look

[30] The reader may be surprised that in the historical account below we very rarely mention the EU (only for the German case), and do not cover the International Labour Organization (ILO). The reason is that these have had at most quite a late and relatively marginal impact on the countries we are discussing, which were among the first to have an OSH inspection system, and thus took part in defining the standards to be followed rather than being "standard takers". This does not mean there was, of course, no impact at all – but that for our issue, which was understanding the different paths taken by OSH systems in these countries, the ILO convention (n. 81) on labour inspections (1947) and the EU Directive 89/391 (1989) both came quite late and, at least for the ILO, added little to the framework already existing. Where the EU additions had significant effects (i.e. at least in Germany), we shall discuss them.

[31] See http://en.wikipedia.org/wiki/Filippo_Pacini and http://www.ph.ucla.edu/epi/snow/firstdiscoveredcholera.html

[32] Whose "re-discovery" of *Vibrio Cholerae* in 1884 was, this time, fully acknowledged

for, and how) and the epidemic, however, made action impossible. “Both during and in the immediate aftermath of the virulent epidemic, the company retaliated against the accusations of the "progressives" by citing authoritative miasmatic and "sociological" theories of disease (…)The company was also able to rely on the open or tacit support of a majority of the metropolitan medical officers of health.” (*ibid.* p.35) Even though there already existed “inspectors” and “Rivers Pollution Commissioners” (*ibid.* p.38), their inability to understand cause and effect in the epidemic doomed them to ineffectiveness.

Still, in 1866, the level of understanding of epidemics mechanisms (if not of their causes) had improved enough to lead gradually to change: “it was Netten Radcliffe's persuasively commonsensical, although almost excessively non-doctrinaire advocacy of the detailed analysis of each epidemic (…) which eventually superseded its rivals. According to this approach, it was imperative to act as though unsafe water was likely to have been the primary medium during any wide-ranging outbreak of cholera or typhoid, and in the thirty years following the epidemic of 1866 it provided the ground rules for an increasingly efficient surveillance of the metropolitan water supply.” (*ibid.,* p. 42). For most of the 19th century, however, this level of knowledge and understanding had simply been missing. Addressing a major risk requires to at least understand its most basic parameters, at least some of its nature and causes. Public health, until the end of the century, was thus not a field where it was possible to create credible, effective inspecting institutions.

Returning to the origins of the first labour inspectorates, it is clear that, by contrast, poor treatment of human beings by other human beings, and malpractice in industrial installations, were problems that were both understandable, and could be addressed in practice. What remains striking is why this started to become a problem that society decided to address at this precise moment. After all, children and women had been working for centuries on farms and, in times of hardship, their lives had been in serious jeopardy. In England, in fact, the “enclosures[33]” and the rapid development of sheep breeding for wool, and of the wool industry (strongly supported by the state from the Tudors onwards) had led to a growing number of urban poor from the 16th century, and to many of them working in very unsafe conditions in “proto-factories” (including women and children). The reaction to this had not been labour inspections targeting the employers, but the “poor laws[34]” that, while organizing some scarce assistance, mostly aimed at controlling the poor – the “Overseers of the Poor” were in a way “labour inspectors in reverse”. A number of parameters, however, had changed by the first half of the 19th century.

First, one could argue, the democratisation of politics and the overall effects of the Enlightenment, suggesting slowly that poor people were also people, whose lives deserved at least a modicum of concern – and, possibly, the French Revolution had shown the risks of letting the social situation deteriorate too far. As Eves (2014) puts it: “memories of the disturbingly radical ideas of the French Revolution of 1789 were fresh in the uneasy minds of British political leaders. Amid widespread unrest, demands were being made for Parliamentary reform and fairer representation of the people.”

Second, “shocking evidence was emerging of serious physical and moral harm suffered by children and young persons in the cotton textile mills (…) as the result of an entire system for exploitation of cheap labour (the ‘Factory System’). Skilled workers employed by a ‘cotton master’ would themselves pay unskilled women and children to help them”. Beyond this, new technologies created new hazards and new harms. We could be seeing here an early illustration of what Slovic *et al.* describe as “the selective nature of attention to different sources of risk or danger” (Slovic and Weber 2002, p. 18). To the extent that modern industry and mining were, precisely, “modern”, i.e. new and radically different from the traditional activities and trade of an hitherto mostly rural society, they could have carried what Slovic calls a “dread” factor[35] - “an accident that takes many

[33] See http://en.wikipedia.org/wiki/Enclosure

[34] See http://en.wikipedia.org/wiki/English_Poor_Laws

[35] And indeed the very negative ways in which modern industry is generally described in Romantic-era literature may point to this – beyond the actual harms, industry was seen as something as “dreadful” as nuclear power or GMOs are today for many

lives may produce relatively little social disturbance (beyond that caused to the victims' families and friends) if it occurs as part of a familiar and well-understood system (…). However, a small incident in an unfamiliar system (…) may have immense social consequences if it is perceived as a harbinger of future and possibly catastrophic mishaps" (*ibid.*, p. 13).

A last point may help explain why regulating manufacturing industry and mining became a priority at that point in time. Regulation of industry by state inspectorates (e.g. HM Factories Inspectorate in the UK) intervened in a context where modern industry had developed in parallel (possibly partly thanks to) the weakening or dissolution of craftsmen's guilds hold. Modern workers were mere wage-labourers, with a very weak bargaining power, and hence without regulation extremely harsh and hazardous working conditions arose. On the contrary, in a guilds-controlled economy, freedom of establishment (and innovation, and growth) were seriously limited, but workers had a considerably higher power and state supervision was not seen as needed. There may thus be a sort of trade-off whereby less stringent conditions on establishment (partial or complete freedom) tend to lead to more supervision role for the state, and more stringent self-regulation ("sworn trades") and limits to establishment may correspond to a (real or perceived) lesser need for state supervision. Our practical experience suggests that this is a (real or imaginary) trade-off that is visible today in a number of countries, where an abundance of restrictions to entry (licensing and others) coexist with overall weak inspection and enforcement practices.

The creation of the institutions in charge of labour protection (what later became known as "occupational safety and health" in the narrow sense, as well as regulations on working hours, women and children at work etc.) was gradual. In Britain, Her Majesty's Factory Inspectorate was created in 1833, the Mining Inspectorate in 1843, the Quarry Inspectorate in 1895 – but one had to wait until 1956 for OSH provisions covering agricultural workers[36], even though all studies repeatedly show that this is a high hazard occupation[37]. For a long time, the focus was exclusively on activities that were *perceived* as high risk by the public and policymakers – as indicated above, and as suggested by Slovic *et al.*, it is likely that agriculture was deemed too "normal" to let its high level of hazard be really acknowledged. Similarly, most services (including retail warehouses and retail trade, however large etc.) were considered low risk and remained for a long time outside of the OSH net. From 1974, they have been covered by legislation, but as we will see enforcement has remained separate (under Local Authorities) as an inheritance of earlier situation and vision.

### *iv. OSH in Britain – from the Factory Inspectorate to the HSE*

#### The gradual extension of the scope of control in Britain

The circumstances that led to the creation of the first inspectorate (Factory Inspectorate) were ones of broad social tensions and reform – including political (extension of suffrage and change of constituencies' boundaries): "By 1831 the Prime Minister, Earl Grey, judged the pressure for Parliamentary reform to have become irresistible and he persuaded King William IV that a Bill to widen the franchise should be introduced into Parliament. Although the Bill was passed by the Commons, it was defeated in the Lords, whereupon serious rioting broke out in several towns. (…) Another Bill was introduced by Grey in 1832. This time Parliament narrowly passed the Representation of the People Act (or 'Great Reform Act').The general election that followed and the arrival of new Members of Parliament soon led to further reforms, some the result of pressure from philanthropists such as Lord Shaftesbury, whose campaign against slavery led to its abolition in the United Kingdom in 1833. Grey also set about reforming the Poor Laws." (Eves 2014) By that same time, the need for reform of industrial conditions was also perceived as urgent, as "the 1831 census indicated that

[36] For a timeline of OSH institutions and legislation in the UK see: http://www.hse.gov.uk/aboutus/timeline/index.htm
[37] See e.g. US BLS news release for September 11, 2014 available at: http://www.bls.gov/news.release/pdf/cfoi.pdf – p. 4

among the country's population some three million people worked in manufacturing industry of various kinds, including almost a quarter of a million in cotton mills, most of which were in Lancashire. A significant percentage of these textile workers were women and children" (*ibid.*). Reform focused on conditions for children: "A Royal Commission (the 'Factory Commission') was set up (…). Its inquiries swiftly exposed the exhausting working conditions and long hours endured by children (…) [and] prompted Parliament to pass the landmark Factory Act of 1833, its full title being 'An Act to regulate the Labour of Children and Young Persons in the Mills and Factories of the United Kingdom'." In it, section 17 read: "…the Laws for the Regulation of Labour of Children in Factories have been evaded, partly in consequence of the want of the Appointment of proper Visitors or Officers whose special Duty it was to enforce their Execution" (*ibid.*).

Thus, a combination of factors was required for the inspectorate (however small at the time, with only four inspectors initially, for 3,000 textile mills) to be created: strong public concern about an issue considered as a "dread risk", favourable political conditions, and experience of implementation problems in previous reforms. A similar combination was often found in later reform steps, and successive creations of new inspectorates.

Whereas "the 1833 Act dealt principally with restrictions on the employment of children and young persons less than 18 years of age" in factories (*ibid.*), "in 1840 a Royal Commission was established to investigate working conditions in the mining industry. The Commission's findings published in 1842 made shocking reading. Accidents, brutality, lung diseases, long hours and highly dangerous and adverse working conditions were found to be the norm. Public outcry resulted and the Mines Act 1842 was brought into force. The Act allowed for the appointment of an inspector of mines and collieries and the first inspector (…) had only limited powers under the Act but undertook many prosecutions, investigated the condition of the mining community and made recommendations (…). In 1850 inspectors were allowed to enter and inspect mine premises and Tremenheere's plans for a dedicated mining inspectorate began to be realised[38]." The concern about health and safety also led to the adoption of new legislation for factories: the "landmark Factory Act of 1844 extended the law's coverage to all textile factories (except lace-making) and took a first significant step towards improvement of workers' safety. Under Section 20, children, young persons and women were prohibited from cleaning shafting and other transmission machinery while this was 'in motion for the purpose of propelling the manufacturing machinery' and from working between fixed and moving parts of machines" (Eves 2014).

Successive "Factory Acts were passed in 1861, 1864 and 1867 (…) Step by step, the scope of the law was widening. (…) The 1867 Act further extended the law's cover to some other specified trades and to 'any premises in which fifty or more persons were employed in any manufacturing process'. (…) A Royal Commission was appointed in 1875 to review the law's numerous amendments since the Act of 1802. Their report in 1876 led to major consolidation of the laws and removal of anomalies by the Factory and Workshop Act, 1878. (…)bringing almost all of manufacturing industry within scope of the law, in three clearly defined classes of Textile Factories, Non-Textile Factories and Workshops (…). Non-Textile Factories included certain specified premises such as shipyards for the first time. Greater protection was afforded to women and children: from now on children under the age of ten could not be employed anywhere and between the ages of ten and fourteen they could be employed only for half days (and must attend school). Women were allowed to work only up to 56 hours per week. The law with respect to secure fencing of dangerous parts of machinery and reporting of accidents remained much the same but children were no longer allowed to clean machinery while it was in motion and women and young persons were not allowed to clean mill gearing in motion" (*ibid.*). The 1891 Factory Act then gave power to the Secretary of State to adopt "Special Rules", which greatly accelerated the development of technical secondary legislation. Another Act in 1895 strengthened several provisions, in particular relating to health. In addition, "the Quarries Act 1894 extended the powers of the Metalliferous Mines Regulation Act 1872 to give inspectors the power to enforce provisions of notifying

[38] Quoted from: http://www.hse.gov.uk/aboutus/timeline/index.htm

accidents, undertake prosecutions and make Special Rules. This led to the establishment of the Quarry Inspectorate[39]."

During the 20th century, successive consolidations of legislation, improvements, additions (e.g. covering electricity) etc. were made. Occupational health gradually took more importance as well. Major additions came with "the Factories Act 1937, which had the effect of providing for the first time a comprehensive code for safety, health and welfare applicable to every factory, irrespective of whether it was a textile or non-textile factory and whether or not mechanical power was used (…) [and] included safety provisions for lifting machinery, floors and stairs" – and in the "Factories Act of 1948 (…) at long last, regulations were introduced for safety, health and welfare at building operations" (Eves 2014). For a couple decades, most of the focus in improving health and safety then centered on the development of the National Health Service. Still, "yet another Factories Act was passed in 1959. This improved provisions for precautions against fires, prompted in no small part by a disastrous fire in 1956 at a Keighley mill" (*ibid.*). In addition, the Offices, Shops and Railway Premises Act 1963 extended OSH protections to "a further 8 million employees[40]" – in the transportation, trade and services sectors – with enforcement left to local authorities[41].

The transformative step that was the creation of the Health and Safety Executive (HSE) in 1974 came about on a background of increasing risk overall (at least of fatal accidents), and of the emergence of new risks due to new industries and technologies: "Chief Inspectors' annual reports throughout the 1960s had frequently drawn attention to concerns over rising fatal and major injury rates" and accidents were "by no means confined to industries regulated by the Factory Inspectorate", which repeatedly "exposed a serious regulatory gap". As a result, "it was becoming increasingly obvious that the narrow, prescriptive approach of Factory Law and the limited powers of Factory Inspectors were no longer sufficient for the effective regulation of modern industry". As an additional stimulus, in 1970 "the USA passed its Occupational Safety and Health Act and created a new federal agency (OSHA) to enforce it" (Eves 2014). In 1970, the new Government "decided to invite Lord Robens, the Chairman of the National Coal Board who had experienced the tragic Aberfan tip disaster, to carry out a fundamental review. A Committee on Safety and Health at Work was formed and took evidence over the next two years, reporting in July 1972.

Their findings became known as 'the Robens Report' (…) [and] recommended that a National Authority for Safety and Health at Work should be established to replace Whitehall's existing fragmented administrative arrangements and bring together the several Inspectorates scattered between Departments." Robens "believed that a broader and more flexible framework would enable statutory inspection services to be used more constructively in advising and assisting employers and workers. At the same time, it would enable their resources to be concentrated more effectively on serious problems where tighter monitoring and control might be needed." (*ibid*.) While the 1974 Act established a Health and Safety Commission (vested with analytical functions and regulatory powers) and a Health and Safety Executive (in charge of implementation, inspections, enforcement), later reforms finally ended up with the merger of the HSC functions into the HSE (in 2008), fulfilling the original vision of the Robens Report.

The consolidation initiated in 1974 and continued in 2008 is, however, still incomplete – with a duality in enforcement between the HSE and local authorities. Löfstedt's *Reclaiming health and safety for all* report (Löfstedt 2011) lays out the problems this creates: "by allowing each enforcing authority to only consider the workplaces within their area of control" this duality generates a barrier to the most efficient targeting of enforcement activity across the board. Premises that are considered relatively low risk amongst the workplaces overseen by HSE (and which are therefore not inspected) may nevertheless be riskier than many of those under local authority control, resulting in too many inspections by local authorities of relatively low-

[39] Quoted from: http://www.hse.gov.uk/aboutus/timeline/index.htm

[40] See: http://en.wikipedia.org/wiki/Offices,_Shops_and_Railway_Premises_Act_1963

[41] See full text of the Act at: http://www.legislation.gov.uk/ukpga/1963/41/pdfs/ukpga_19630041_en.pdf

risk workplaces" (p. 5). While he does not recommend fully eliminating local enforcement of H&S rules, not to risk "losing the synergies with other local authority enforcement responsibilities" (*ibid.*), he advocates to "give HSE the authority to direct all local authority health and safety inspection and enforcement activity, in order to ensure that it is consistent and targeted towards the most risky workplaces" (*ibid.,* p. 83). Following up on this recommendations, the following changes have been introduced in the past couple of years: "HSE published a National Local Authority Enforcement Code (May 2013) that sets out the risk based approach to targeting occupational safety and health interventions that Local Authority (LA) regulators should follow. HSE has also published (…) a list of higher risk activities in specific LA-enforced sectors suitable for proactive inspection (…) [and] supplementary guidance to assist LAs (…). HSE has consulted on the implementation of the Code (ended October 2014) and has reviewed the 2013/14 LA annual returns. The conclusion was that LAs have been implementing the Code and are now more risk based in their targeting[42]." To the extent that further developments verify these claims, the "consolidation" process will have been largely completed, as well as the spread of risk-based targeting approaches for all OSH inspections. We will come back to these questions in more detail, but it is worth looking first very briefly at some markers in the development of resources, methods and powers in OSH inspections in Britain.

### Evolution of resources over 180 years

While the Factory Act's enforcement was initially left to only four inspectors, "were authorised to appoint Superintendents (called Sub-Inspectors after 1844) to assist them in their duties" (Eves 2014). Numbers rose gradually, and in 1871 "the Inspectorate numbered 35 Inspectors and sub-inspectors" (*ibid.*). Nearly a century later, there were over ten times more: "By the end of 1961 the Inspectorate had 426 inspectors in post, including specialists at headquarters, with the majority working in 13 divisions spread over England, Scotland and Wales. Divisions were headed by a Superintending Inspector and generally contained six or seven small teams, each led by a District Inspector, working from 100 or more local district offices." (*ibid*.) Of course, these over 400 inspectors now had a broader remit, and a considerably larger population and economy to supervise.

The 1974 merger resulted in a much larger organization: "As well as the staff of HM Factory Inspectorate, the staff of a number of other regulatory organisations were transferred to HSE in 1975, including the Explosives Inspectorate (from the Home Office), the Employment Medical Advisory Service (with its doctors and occupational nurses returning from the Department of Employment), the Nuclear Installations Inspectorate and the Mines and Quarries Inspectorate (from the Department of Energy), the Safety in Mines Research Establishment, the British Approvals Service for Electrical Equipment in Flammable Atmospheres (BASEEFA) and the Alkali and Clean Air Inspectorate (from the Department of the Environment.)" (*ibid.*)

In 2002, the HSE and Health and Safety Laboratory had 4282 staff[43], out of which 2794 in operations (inspections and enforcement, including management and "operational policy" etc.). In 2006, the same figures were 3811 and 2497. In 2009, only 3591 and 2253 respectively. In 2014, the HSE had 3081 staff in total and (having moved to another classification method) numbered 1294 staff in "frontline roles"[44]. After the "spin-off" of the Office for Nuclear Regulation[45], these went down to 2621 and 1059 respectively – and as of 31 March 2015, 2575 and 1047 respectively (a relative stability). In 12 years, thus, HSE staff was reduced by around a quarter (comparing with the data pre-ONR spin-off, so as to have comparable scope of work).

The point here is not to try and discuss whether these numbers are "sufficient" or not, which would require to define "sufficient for what?", to have reference points, comparators etc. We will discuss later in this

[42] See Health and Safety Executive, *A progress report on implementation of health and safety reforms – March 2015* (draft presented to HSE Board), pp. 9-10, available at: http://www.hse.gov.uk/aboutus/meetings/hseboard/2015/250315/pmarb1525b.pdf
[43] This and subsequent figures from HSE statistics and annual reports – see: http://www.hse.gov.uk/aboutus/reports/staff06.htm
[44] HSE Annual Report 2013-2014 available at: http://www.hse.gov.uk/aboutus/reports/1314/ar1314.pdf
[45] On this, see: http://en.wikipedia.org/wiki/Office_for_Nuclear_Regulation and http://www.onr.org.uk/

research the question of how well the HSE performs in terms of effectiveness. The notable fact at this stage is that staffing levels have clearly never (or at best rarely) been set based on any serious analysis of the scope of work and necessary work time, but rather based on whatever seemed "appropriate" at a given time, and increased or decreased depending on the prominence of OSH issues among public concerns, on the availability of funding, on other budget priorities (increasing spending elsewhere, or reducing the deficit) etc.

### Methods and powers

Powers, methods, and approaches to planning and targeting all evolved constantly over the nearly 200 years of OSH inspections and enforcement in Britain. While, initially, inspectors were only able to bring prosecutions against violators of the applicable regulations, the 1844 Factory Act gave them power "to give written notice to a factory occupier that dangerous parts of machinery should be immediately fenced, an important addition to their ability to improve machinery safety (and a fore-runner of the powers to serve improvement and prohibition notices that were given to Inspectors 130 years later)" (Eves 2014). Formalization of how notices worked, and in which circumstances penalties could be applied, was also gradual.

There may have been some forms of targeting in the early days (as staffing levels were so low), based on whatever information was available, and probably also on material constraints. By the 1960s, "the inspection programme laid down by the Chief Inspector required every factory to be inspected on a four yearly cycle, regardless of whether risks were high or low. Larger factories were usually divided into units that could be inspected in half a day" (*ibid.*) This may have appeared appropriate in an era of concentrated, large facilities, with well-known production techniques – and when the inspectorate's mandate was still relatively narrow. This approach was to prove its relative lack of effectiveness – "the 1974 Flixborough disaster (…) prompted the swift establishment of a Major Hazards Branch, a Risk Assessment Group and a Major Industrial Hazards Advisory Committee. Meanwhile the Chief Inspector had introduced a system of priority inspections of major hazard premises, over-riding the conventional four-yearly cyclical pattern of planned inspections and encouraging Inspectors to spend as much time as was necessary to improve controls at these sites" (*ibid.*). As we will discuss more in depth in a later section, risk-based targeting has now become one of the "hallmarks" of the HSE, but this does not mean there are not important challenges remaining on this front.

Another evolution was the degree of liability and responsibility for health and safety resting on operators themselves. The question of what could or could not be prosecuted and give rise to sanctions was rather unclear in the early days of the Factory Inspectorate, as was the question of compensation (since the Act anyway had little to say about safety issues). Case law and written law both gradually evolved to strengthen the liability of employers in case of work-related injuries: "The case of *Priestley v Fowler*[46] in 1837 had been the first known civil action in which an employee successfully sued his employer. It seemed to establish the principle that an employer owed a common law duty of care to his employee which was actionable if a breach of that duty resulted in injury. Under Section 24 of the 1844 Act the Secretary of State could empower a Factory Inspector to bring an action for damages on behalf of any person who had been injured by machinery. Reports indicate that many such actions were successfully taken by Inspectors. Later in the century, (…) the Employers' Liability Act 1880 gave a worker the right to sue the employer, but the worker had to prove that the injury suffered was the employer's fault. However, under the Workmen's Compensation Act of 1897 it became necessary for a worker only to prove that the injury had occurred at work" (Eves 2014). It is, in retrospect, fascinating to see that it took over 60 years after the first Factory Act for the law to put clear liability (in a tort law perspective) on the employer – considering that this is (at least potentially) one of the strongest incentives

[46] See Stein 2003 – "*Priestly v Fowler* is the first known recorded decision of an employee having sued an employer for work-related injuries" (p. 689) but is a very confusing case and precedent is highly disputed – Stein concludes that "Priestley v. Fowler is best understood within the framework of the emerging independent tort of negligence as a failed effort to extend master/servant liability" (p. 730)

to improving occupational safety (at least if there is a reasonable likelihood that courts will award guilty verdicts and significant damages)[47].

What one could call the logical consequences of employers' liability were only drawn nearly a century after the Employers' Liability Act, with the 1972 Robens Report and the 1974 Health and Safety Act. "Believing that the primary responsibilities lay with those who created risks and those who worked with them, Lord Robens' Committee concluded that a more self-regulating system of provision for safety and health at work was needed and that the traditional approach based on ever-increasing, detailed and prescriptive statutory regulation was outdated, over-complex and inadequate. Reform should be aimed at creating the conditions for more effective self-regulation[48] by employers and workpeople jointly. (…) Much greater use should be made of agreed voluntary[49] standards and codes of practice to promote progressively better conditions." The Act "imposed general duties to ensure health and safety 'so far as is reasonably practicable' not only on employers but also on the self-employed, designers, manufacturers and suppliers of equipment and materials. For the first time, the safety of the public was to be protected when put at risk by 'the conduct of an undertaking'" (*ibid.*). As we will discuss later, this approach to defining obligations and compliance led the HSE to develop a strong "enforcement management model" in order to clarify what this requirement meant in practice, and give a transparent (and risk-based) framework to its officers' discretion.

### A Medium-term perspective on methods and structures

Some of the most significant research on the HSE's work, culture and approaches has been conducted by Keith Hawkins, and it has spanned both the 1980s and 1990s (see Hawkins 1992 and 2002 in particular). Hawkins's primary focus is to understand how the HSE (and, by extension, an inspecting institution) functions in practice, what structures, frames, heuristics etc. shape decisions taken by inspectors – beyond and below the official policy documents. In so doing, he gives us important perspective on how the HSE's structures and methods evolved over the past couple of decades, since the HSE was set up following the Robens report and HSW Act 1974.

First, Hawkins shows how the culture of HSE staff, the approaches taken both officially and in practice reflect the underlying philosophy of the HSW Act. Indeed, "the Robens Committee adopted a rather benign conception of the problem of enforcing" OSH regulation "shaped by an assumption that not only the workforce but also management had an identity of interest" (Hawkins 2002, p. 144)[50]. The structure and mandate of the

[47] See Ogus 1994 pp. 81-87 for a general (theoretical) discussion of the use of criminal justice and liability in regulatory matters. Liability (civil and criminal) is a powerful tool (see e.g. its use in the French building safety system in World Bank Group 2013 b pp. 82-87), but it has of course limitations, in particular when (a) the risks of permanent damage (incl. death) are too high given current practices and (b) potential victims are likely to be in an unfavourable position to sue (lack of resources, fear etc.) – both of which clearly applied to occupational safety and health a century and a half ago (and to an extent still do).

[48] Technically, this is not really "self-regulation" but rather a form of "enforced self-regulation" or, more correctly, of regulation with loosely defined performance requirements, the enforcement of which relies on codes of conduct and other "soft law" developed by the industry itself (both employers and employees). A similar practice can be observed in other countries and domains, e.g. in the French construction safety system the *Documents Techniques Unifiés* are developed by the different industry stakeholders, but compliance with these can be made enforceable in court as they constitute the equivalent of the 'so far as reasonably practicable' standard, i.e. the obligation of due diligence by the builders.

[49] As per previous note, "voluntary" but in fact likely to be used in enforcement when the need arises to define what is "reasonably practicable".

[50] A note is needed here on this assumption of (at least significantly) converging interests. While it is generally accepted by many practitioners (see e.g. World Bank Group 2014 a) that there is an alignment of interests between food business operators and food safety regulators (safe food is good for business, because consumers come back), it is far less often thought to be the case in OSH, which is rather commonly seen as a "trade off" field – businesses seek to save money by cutting back on OSH expenses, and gain little by complying. The Robens report took a different view, assuming that there were clear benefits of OSH for employers (less liability and court cases, better image for the company, better workers' motivation and effectiveness, less disruptions due to accidents etc.). Interestingly, while some well-publicized food scandals (see further in the US food safety case) show that the expected "alignment" is

Health and Safety Commission (since then merged with the HSE) "embodies a theory of assent in the formulation of regulation" (*ibid.,* p. 149) aiming at making compliance more likely (and easier). The HSE (and HSC) were clearly positioned from the onset not at bodies functioning in an abstract, aloof independence, but working "at the centre of an intricate web of political relationships" (*ibid.,* p. 157) - balancing different interests, priorities, needs, with negotiation as central activity (*ibid.,* p. 158). This builds a sharp contrast to France, for instance, where the Labour Inspection is seen as being (and *having to be*) fully independent (and even impervious to) any interests on the side of businesses (clearly less so on the side of trade unions), and any political pressures (whether it is so in practice is another question). While this difference is clearly linked to deep (and historically long-term) divergences in industrial relations, the role and posture of trade unions and businesses, it is likely that different approaches taken in legislation have also played a significant role in strengthening and hardening these divergences.

Second, Hawkins shows how there has been a gradual shift over more than two decades in the *focus* of the HSE, and the definition of "risk" that underpins its work, targeting, and enforcement response. Significantly, the HSW Act changes the definition of what is being supervised and enforced. Rather than pinpointing specific rules and requirements, it establishes a "duty of care" to workers, and any people who may be affected – the purpose of the Act is to "ensure that safety is a pervasive value" and it requires that operations should be "safe 'so far as reasonably practicable', specifically requiring a weighing of cost and trouble against the severity of the hazard and likely benefit" (*ibid.,* p. 145). Thus, the Act is *founded* on a risk-based and approach (addressing risks to safety is the purpose, not enforcing specific statutory points *per se*, and prioritization is not only permitted, but called for). Cost-benefit analysis, in a way, is at the core of the HSW Act. In addition, the Act "brought statute law to bear on a broader range of sites and problems" – leading to a change in the range of risks covered, and in risk prioritization (increasing attention to risks to the public, and comparatively less to risks to workers[51]) (*ibid.,* p. 147). During the 1980s there were again new trends and shifts in focus of resources and interest (*ibid.,* p. 161): "shift (…) in the balance of regulatory activities towards major hazards and the protection of the public from industrial harms, and (…) a marked increase (…) in public concern for the environmental aspects" (*ibid.,* p. 162). The EU "Seveso" Directive in 1984, for which HSE was selected as responsible body in the UK, reinforced this shift (along with further national and EU legislation).

Third, this focus on hazard control and mitigation, and this modulation of inspections and enforcement based on risk, have been officially, clearly articulated for a long time – meaning current HSE practice builds on at over 30 years of experience and gradual consolidation of this approach. Hawkins thus quotes a 1978 official HSE document stating that its goal is to "ensure that management recognises its responsibilities for the control of hazards" (*ibid.,* p. 155). In another, slightly later, official document (from 1980), the HSE explains that "the frequency with which inspections are undertaken in any premises depends on need – the standards of safety, health and welfare found (…) at the last visit, the potential inherent hazard (…) and the quality of the management" (*ibid.,* p. 167). Thus, both the risk-based targeting model, and the "enforcement management model" have long and deep roots. All the HSE inspectors' actions have to contribute to "tackle root causes rather than just the symptoms of undesirable conditions (*ibid.,* p. 166) – and this leads to an approach to enforcement that is fundamentally *instrumental* (concerned with utilitarian goals) more than *expressive* (symbolizing fundamental values).

Fourth, inspectors' decisions (and HSE actions more broadly) aim at minimizing risk and, as a means to this end, at maximizing compliance. For inspectors, "the seriousness of the event and the seriousness of the risk

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not always present in food safety, the generally good OSH situation in the UK suggests that the Robens report's assumptions may well have been correct, at least to a significant extent. This is certainly a topic worthy of further research.

[51] Hawkins does not discuss whether or not this gradual shift was "appropriate" from a data-driven risk perspective, i.e. whether risks to the public created in aggregate more harm than strictly "occupational" ones, and we did not have the opportunity to research data from this perspective.

of harm" are essential in terms of "framing the prosecution decision" (*ibid.,* p. 54). In this perspective, "decisions about legal standards and their enforcement" are made in a broader setting, within a given context, with decision 'frames' "interpretive and classificatory devices" (*ibid.,* p. 48). Whereas "prosecution can provide symbolic satisfaction to the public while doing little instrumentally to gain compliance or repair problems" (*ibid.,* p. 7) – as a result, "formal enforcement is often reserved for weightier matters", including particular seriousness, visibility, harm, persistence (*ibid.,* p. 41). This is all part of a *compliance strategy* rather than a *sanctioning* one: "sanctioning is largely concerned with rule-breaking, where compliance strategy is focused on results". Hawkins notes that such an approach is most reliably achieved when there is familiarity with the business, stability of relationships between regulator and regulated entities, which means inspectors can work on improving matters – with sanctions being far more frequent in other cases (e.g. more "transient" businesses) (*ibid.,* p. 46).

Finally, while the roots of contemporary HSE approaches go back to the 19th century ("the use of prosecution as an enforcement move of last resort goes back to Victorian times", *ibid.,* p. 17), there have been considerable efforts since 1974 to create more consistency and uniformity. At the onset, and for a couple of decades, "there were markedly different cultures and traditions of enforcement within HSE" (*ibid.,* p. 19). This was the result of HSE's "birth as the progeny of several shotgun marriages", and "throughout the 1970s and 1980s HSE remained essentially a federal structure" (*ibid.,* p. 156).In 1990, a major reorganization was made to ensure more consistency, with the creation of the Field Office Directorate (FOD), which replaced the previous "legacy" inspectorates[52] (*ibid.,* p. 163). Several other institutional changes were made with the "objective of maintaining consistency of enforcement practice" e.g. the set-up of National Interest Groups (*ibid.,* p. 154). Overall, these all show a consistent "pursuit of greater uniformity of policy and practice in the operation of HSE at all levels" (*ibid.,* p. 164).

The challenge, however, that all efforts at consistency and uniformity have encountered, is that actual enforcement work does not proceed through "implementation" of official policies – but rather, that official policies are but one of the many drivers of real-life enforcement decisions (and analysing these many drivers is what Hawkins's work is about). In practice, "inspectors have routine conceptions of 'risks', 'accidents', 'problems', and so on, which assist them in making sense of the difficulties that come to light" (*ibid.,* p. 50) – and they also have values, visions of their work, experience and uses, which all contribute to their decision-making. Reforms in HSE, in recent years, have clearly aimed at bringing consistency to a further level, and at achieving a better implementation of the *Enforcement Policy*[53]. To this aim, the approach to be used in determining whether or not to take enforcement action, and which one, has been spelled out in far greater detail, and with a number of "decision trees", in a document called the *Enforcement Management Model (EMM)*[54].

The EMM reiterates and further develops an approach that was already, as we have seen, in place in the late 1970s/early 1980s – it does so, however, with more details and precision. The fundamental idea is that the inspector should use a risk-based approach at every stage of his work – and in particular when identifying violations and assessing their relevance, and when deciding on the enforcement action (or lack thereof). We will come back to the EMM later on, but fundamentally it emphasizes the importance of "risk of personal injury" and "immediacy of risk", and to assess them, as well as the degree to which the situation deviates from clearly established standards, uses an approach called "risk gap analysis" (p. 9). When determining the enforcement action, the EMM considers the overall situation in the establishment, as well as the compliance

[52] Keeping, however, some specialized ones for high-hazard establishments, e.g. the ones supervised under the "Seveso" directive.
[53] See *HSE Enforcement Policy Statement* available at: http://www.hse.gov.uk/pubns/hse41.pdf. See also explanatory page on the policy: http://www.hse.gov.uk/enforce/enforcepolicy.htm.
[54] See *HSE Enforcement Management Model* available at: http://www.hse.gov.uk/enforce/emm.pdf.

history (p. 25). By making the enforcement guidelines far more detailed and specific, and breaking them down in a number of steps, more uniformity and consistency is sought. Still, there remains a considerable degree of discretion in decision making, and the assessment of conditions and of the "risk gap" are done by inspectors, with all the experience, views, 'frames' etc. that they bring to the process. Hence, what Hawkins describes in his work is still essentially valid, even though it may be that the variation has been significantly reduced (recent research on the effectiveness of the EMM in this regard not being available).

The next step in improving consistency of risk-based approaches is thus to work on the inspectors themselves, on their culture and understanding of risk, on their "competencies". Considering the HSE's history outlined above, it is no surprise if the development of a new "common approach to competency" for regulators (and specifically inspectors) has been piloted to a large extent in the HSE, even though it applies to a number of other regulators (and is driven by the UK BRDO). We will come back to this in a later section, but it shows the pertinence of Hawkins's emphasis on the "personal" element in inspector decision making – regardless of how detailed and specific policy guidance is, achieving "better" risk-focus (as seen by the regulators' managers) and greater consistency involves working on what inspectors know, believe, think, how they see their work and analyse situations. In line with this, one of the "core competencies" identified in this "common approach" is "risk" (see BRDO 2015 and the Guidance for Regulators – Information Point Portal[55]).

### Short conclusion

Among the most noteworthy changes over the years is the *scope* of what is now understood as OSH control. First, the way the institution and its mandate were defined: originally, it was by their *object* of control – factories, mines, quarries. The definition of a type of risk, or a regulatory area, was missing. The type of object was seen as defining the scope of work.

Second, there is the question of *what* inspectors were expected to control. The 1833 Act only looked at the question of child labour, and attempted to limit both the young age at which children could be made to work, and the types of tasks they could be made to perform. The 1844 Act went further – it introduced additional restrictions of tasks allowed to assign to children, youth and women, and it also "introduced requirements for 'secure and continuous fencing' of fly-wheels, water-wheels, wheel-races, hoists and teagles (lifting machinery) near to which children and young persons were liable to pass or be employed, and all parts of 'mill gearing' (transmission machinery)". In other words, it now clearly covered occupational safety. Under this Act, "Inspectors were authorised to appoint 'Certifying Surgeons' to whom (…) any accident preventing the injured person from returning to work by nine o'clock the following day had to be reported. The Surgeon was required to make a full investigation of the nature and cause of the accident and report to the Inspector" which allowed to seriously start monitoring, investigating, understanding occupational hazards (*ibid.*). In 1850, the Ten Hours Act was voted, "reducing the maximum length of a working day for women and young persons employed in textile factories" (*ibid.*). Successive Factory Acts and other legislation in the 19th century continued to introduce safety requirements only gradually, and to mainly regulate issues in regard to children and, to a lesser extent, women. The safety of adult workers was, for long, left unregulated.

Was it, then, that the risks were *greater* for children? Purely statistically, it is unlikely – adult, male workers were the majority, and an even greater majority of those performing hazardous tasks. What counts here is however risk *as perceived by the society as unacceptable (and requiring regulation)*. For a variety of (relatively obvious) reasons, children were seen as more vulnerable, less able to understand and manage risks themselves, more in need of protection etc. – and thus, adopting regulations to protect them (but not adult workers) was seen as appropriate. Adult males were expected to be able to assess and manage their own risks.

[55] Portal available at: http://www.regulatorsdevelopment.info – see on risk: http://www.regulatorsdevelopment.info/grip/coreskills/risk

As for women, the fact that they were awarded more protection than men (but less than children) reflects both the period's mentalities and culture (women generally seen as "minors", "weaker", "in need of protection") and sociological realities (women that had to do factory work to survive were very poor, underpaid, and often in serious jeopardy, physical and otherwise).

Perception of risks continued to shape priorities and structures for a long time. Agriculture was only covered by OSH legislation, and trade and services were included in 1963, but with enforcement left to local authorities – which resulted in the "twin peaks" problem, whereby both the HSE and local authorities build *separate and unrelated* "risk pyramids", i.e. classification of objects (establishments) on the base of risk[56]. Because the scope of competence of HSE and local authorities is different, there is the possibility (and indeed this is often the case in practice) that the "peak" of the local authority's pyramid is in fact *lower* in relative risk compared ot the "base" of the HSE's pyramid. As a result, this "local peak" will be inspected frequently, whereas the (objectively riskier) "HSE base" will be inspected rarely or not at all. As the Better Regulation Executive put it, this "limits the ability of regulators to target overall inspection resource on workplaces where the risk of injury and illness is highest" (Better Regulation Executive 2008 – quoted by Löfstedt 2011 and the main basis for his recommendation to put HSE in charge of "directing" local enforcement too).

In conclusion, the question of how risks were conceived and perceived was central to the adoption of regulations, creation of inspection institutions, development of their scope of work, powers and methods. What was required in order to have regulations adopted and an inspection institution created was not just a risk, or even a major risk, it was a combination of factors. First, the risk had to be identified and understood (or thought to be understood), and perceived as something that could possibly be mitigated through intervention – a poorly understood risk, to which science and techniques were unable to respond, would not produce the same reaction, however significant its statistical impact (as the cholera example shows). Second, it has to be seen as a risk "out of the ordinary", unacceptable, what Slovic *et al.* call a "dread risk". New techniques and industries, disruptions in what was hitherto considered normal, create "dread" – but large amounts of preventable deaths in ways and occupations that have been part of everyday life's fabric for centuries often simply do not register (e.g. agriculture). Similarly, in the 19th century at least, adult men engaged in hazardous occupations was seen as "normal" – but children exposed to the same risks appeared shocking. Third, moving from "no intervention" to "some intervention" usually takes a combination of factors including "crisis events" or broader social pressure. Finally, the way in which institutions are set up, develop and grow is generally *not* thought through at the beginning, is strongly subject to path dependence, and getting towards a somewhat more "rational" set up can take a very long time indeed (and many "lessons learned").

A few more words should be said to emphasize the complex set of changes in structures, policies and (eventually) staff training and competencies involved in making an institution more "risk-focused", and inspectors' decision-making more consistent. In all these respects, as we will see in further sections, the HSE will serve as a very important example, and help us test different hypotheses.

#### *v. A brief look at other countries*

The gradual establishment in Britain of specialized inspectorates for the enforcement of labour-related legislation was to an extent paralleled in other "advanced" economies of the time, but the timeline and specifics differed.

[56] The "pyramid" metaphor conveying the idea that, by design, there should be larger number of lower-risk businesses, and a smaller amount of high-risk ones, so that there can be real *focus* of activities – this classification is the result of prioritization, and does not mean that risk is *absolutely* low or high, but that it is *relatively* higher or lower.

## France

In France, the context and timeline to some extent resembled what was seen in Britain, and so did some of the initial measures, but the two systems were to strongly diverge over time. The same social blights associated with the rise of modern industry were highlighted in France, as they were in Britain – one of the most prominent publications in this perspective being the report by Dr Villermé[57] that was commissioned by the Academy of Moral and Political Sciences and presented (for its first part) in 1839. Villermé exposes in details the living and working conditions of workers in the textile industry but, while demonstrating the hazards they create and the depth of misery, it is also very much a socially conservative account. He only criticizes "abuses" (and in particular in relation to children), otherwise puts substantial blame on the poor themselves, and calls for some remedies but clearly "no radical solutions" (Tyl 1971, Introduction). This perspective very much reflected that of the higher bourgeoisie who dominated the *July Monarchy* regime of the time – and Villermé's report led to the adoption of the 1841 law on child labour in factories, manufactures and workshops. For similar reasons to those seen in Britain, this was the issue in regard to which state intervention was seen as appropriate and urgent – safety of workers more broadly was still far from being regulated.

In the post-revolutionary context, limitation of working hours was adopted in 1848 – but further legislation had to wait for the fall of the Second Empire and the re-establishment of the Republic. In 1874, a new law further regulated child labour, as well as women employment conditions. This was also the law that effectively created a labour inspection – a full 33 years after adoption of the first law on child labour. Indeed, after some debate, the 1841 law had left the matter to the government to decide through a decree (Bouquet 1895 p. 1), and the initial decision was to have volunteer local commissions in charge of inspections. This seems to have quickly proved ineffective (*ibid.*) and, from 1847, there were repeated plans, draft laws etc. aiming to replace these by a professional inspection. All, however, failed, mostly due to far larger political events – the 1847 draft to the revolution of February 1848, a 1850 discussion was left without follow-up (in a very tense political context that led to the 1851 *coup* by then-President and future-Emperor Louis-Napoléon Bonaparte), another project in 1858 was again not followed through, and a 1870 draft was quickly side-lined by the Franco-Prussian (or Franco-German) war that started in July (*ibid.,* pp. 1-3). Even though a few local administrations (*départements*) had created their own inspections, they lacked proper powers and a clear framework and had limited effectiveness. This period seemed to demonstrate *a contrario* the usefulness of inspections, through the very limited progress in implementing the 1841 law that was observed in the absence of an inspectorate. The system created in 1874 was a kind of hybrid: it retained local discretion in hiring and appointing local inspectors (in some *départements* local authorities hired quite a few, in others none), as well as local volunteer "commissions", but added a professional, central service (with 17 inspectors) and a Central Commission[58].

In 1892[59], a new law was voted regulating employment of women (in particular minors) and children – and, crucially, this new law restructured (and strengthened) the inspection function. It got rid of local inspectors altogether, as well as of local volunteer commissions. The labour inspection now would have 11 superior inspectors, 76 departmental inspectors (in charge of a *département*) and 16 departmental female inspectors[60]. Inspectors were henceforth to be recruited via a *concours* (competitive examination) covering a range of legal

[57] See Tyl 1971 for a modern edition and presentation

[58] With representatives from industry, politics and science, and a role that in some way could be seen as a prefiguration of the UK's Health and Safety Commission created a century later: assessing problems, proposing solutions, developing recommendations etc. The commission filled a need (as the inspectorate was not endowed with the regulatory powers given to HM Factory Inspectorate in Britain), and helped "bridge the gap" between government administration and private industry (cf. Bouquet 1895 pp. 4-5).

[59] A point of context was the 1890 International Conference on Labour Law in Berlin.

[60] In line with the prejudices of the day, there were arguments against having female inspectors at all, but they were retained due to successful local experimentation in Paris and its suburbs in the earlier period – but they were confined to all-female factories and workshops, and to workplaces with no engine-powered mechanical equipment (and their entrance examination had the same topics as male inspectors, with the exclusion of mechanical engineering issues) (Bouquet 1895 p. 8).

and regulatory, chemistry, engineering, safety and workplace organization questions (*ibid.* p. 9). The profession of inspector now opened to a real career. For mining establishments, the 1892 law left responsibility of inspections to the corps of mining engineers (a long-established state body).

Like in Britain (but in a faster succession – which is understandable given much later creation of the inspectorate), the remit and mandate of inspectors gradually expanded – starting only from rules on children and under-age girls in manufacturing. In 1883 they were given authority to enforce the 1848 legislation on work duration in manufacturing industry. The 1892 law which re-organized the inspectorate added the employment of children in "peddling and itinerant trades". It was only with the 1893 law on workers hygiene and safety in manufacturing establishments, however, that their functions really came to cover "health and safety" in a broader meaning, beyond the limited provisions until then existing for children and women (*ibid.,* p. 11). This last addition, one could argue the most critical one from a "risk prevention" perspective, was however to be the most complex to translate into practice – requiring the development and adoption of specific technical norms, and requiring a relatively complex enforcement procedure (Guérard 2000 – see below).

The fact that regulations and inspections first focused on regulating children (and later women) employment (and left adult men to fend for themselves for a long time) again reflects contemporary vision and ideology – in other words, risk perceptions are mediated by what is considered normal and acceptable, or not, rather than being purely (or even mostly) driven by objective data such as injury or fatality rates. A prominent representative of that day's legal thinking, Advocate General at the Court of Cassation Louis Sarrut, put it thus: "if one can, to an extent, argue against the legislator's setting working conditions for men having completed their physical development and with full civil capacity, it is beyond doubt that the legislator has to intervene in the interest of minors and women (…) For a well-organized State, valid citizens are needed. The limitation of women employment is indispensable to the good upkeep of the household" (Sarrut 1894, pp. 16-18, author's translation). What is being seen as a risk, here, is mostly the social risk: "the withering of the race" (*ibid.*) is what could happen if the state did not intervene (and this would have, one can read between the lines, consequences in the international rivalry and contest, particularly with Germany). Still, in Sarrut's time, the view that harm to (male, adult) workers was also a risk worth addressing had prevailed (but it had not been self-evident). As Sarrut himself puts it, commenting the introduction (under discussion at the time, adopted into law in 1898) of no-fault liability for employers in labour accidents: "modern industry (…) has become by itself hazardous for the worker. (…) Accidents proceed far more from the kind of work and tools than from worker's actions. Industrial work implies risks – and this kind of work and these tools are established by the employer" (*ibid.,* pp. 20-22). The justification of no-fault liability also relies on economic reasoning: "industrial labour is the source of the master's benefits. These benefits are the risks' compensation. The worker, on the contrary, is limited to a set salary. It is thus as rational as it is equitable to (…) impose to the employer the reparation of damages" (*ibid.*). This view of risks, once again, has part of its foundation in the "dread risk" aspect of industrial employment as distinct of, say, farm work – but it receives conscious justification and elaboration, a justification that is linked to the economic question as well. Because industrial activities (unlike farming, at least at the time, and/or at least in the mind of contemporaries) involves novel techniques, arrangements set by the employer (and not, say, by tradition), and unique perspectives of profit, regulation is justified[61], which would not be possible from a classical legal perspective. Indeed, on the question of no-fault liability, Sarrut approves of the departure from "very ancient doctrine, transmitted by Roman Law (…) that the affected party can only obtain reparation of the damage in court if it can demonstrate fault" (*ibid.*, p. 20).

[61] The 1898 law excludes agricultural activities, as well as most trade and services – it covers "workers employed in construction, factories, manufactures, public works, land and water transport, loading and unloading, public warehouses, mines, quarries and any establishment (…) where are manufactured or used explosives, or machinery activated by a force other than man or animals".

Decisions on the scope and aim of legislation were thus strongly driven by ideology and perceptions, rather than be actual data on the health and safety risks presented by different activities. The same seems to have been the case for enforcement approaches and instruments. Commenting on the implementation of the 1892 law, Sarrut wrote: "sanction can seem insufficient, for violations are brought before the Police Court [*note: Minor Offences Court*], and a fine is in principle the only penalty; but fines are cumulative in case of several violations or felonies (…) Anyway the legislator, not without reason, appears to expect full compliance with the law more from the vigilance of inspectors and commissions than from penalties" (*ibid.,* p. 16). Inspecting as frequently as possible seems to have been the approach taken in practice – commenting on the pre-1892 set-up, Bouquet wrote that inspectors "saw at a maximum a little over half [of establishments under supervision] per year. The inspection of each establishment, particularly small workshops, was thus insufficiently frequent to avoid that, in the meantime, the industrialist fell again in its old errors" (Bouquet 1895, p. 7, author's translation).

Unfortunately, little can be said about these inspections' effectiveness. Statistics of the time, and later articles, have focused mostly on the volume of enforcement activities (see e.g. Guérard 2000 p. 12), but not on whether it made factories more compliant with child labour rules, or reduced the rates of injuries and fatalities. These were in any case still very high at the beginning of the 20th century – 130 for 100,000 in construction, over 100 in metal industry (1905 data, quoted in *ibid.* p. 3), whereas similar rates at the end of the century in major industrial economies would be around 10-15 times lower for construction, even lower for industrial activities (see Feyer *et al.* 2001 and section 4.2.a.i. below).

Many other aspects and issues of early labour inspections in France were to have long-lasting effects. We will only briefly discuss one of the most important: enforcement tools and the requirement to use "improvement notices" (or their French equivalent).

On the first issue, the 1893 law on labour safety, further detailed by a 1894 decree, required inspectors, when they enforced regulations taken by the government on safety issues, to first issue a "*mise en demeure*" (improvement notice), and give a delay for putting the establishment in compliance (Guérard 2000 pp. 1 and 7 – Bouquet 1895 p. 14). This was opposed to cases where inspectors enforced direct provisions of the law, in which they could directly issue a "*procès verbal*" and bring the offender to court for swift sanctioning. The delay foreseen for the improvement notice was a minimum of one month, and could be much longer in some cases.

Such a provision is quite unusual in French law – leaving officials some discretion as to whether they should enforce a rule or not is done in some (though not all) laws, but requiring them to first give a warning and improvement period is quite a unique case. The suggested explanation is that there was a legal problem in foreseeing sanctions for violations which were still for the most part vaguely defined (or not defined at all yet). While violations of the rules on employment of minors and women (1892 law) were clear, the safety requirements (1893 law) had mostly not been laid out yet. As Guérard puts it (*ibid.,* p. 1): "so that an employer could be penalized, in accordance with the legal principles formulated by the French Revolution, all the elements of the violation have to be defined in the law or in legislation that stems from it. But in matters of safety, the law can obviously not foresee everything. It is thus necessary to rely on implementation decrees already (…) that are insufficient, in the initial state of prevention concepts and methods, to define in detail the measures to be implemented. Whence comes the use of improvement notices by labour inspectors, procedure imposed by the (…) 1893 law for all regulations issued to implement it".

The extended delays for improvement foreseen by the 1894 decree, the lack of flexibility and exceptions in the procedure (e.g. for construction sites which, unlike many other establishments, are temporary and change rapidly, improvement notices with long delays were simply inadequate – see *ibid.* p. 7), as well as the cumbersome way in which notification had to be done (see *ibid.* p. 8 and Bouquet 1895 p. 14). As a result, inspectors are constantly complaining about this requirement, and a new law in 1912 includes a number of specific safety requirements so that they can be directly enforced (Guérard 2000 p. 10). Later on, a 1931 law

will reform the system so that improvement notices become the exception rather than the norm. By contrast, in Britain, improvement notices are a major part of the HSE's activities, and inspectors are clearly satisfied with the system's effectiveness (see Tilyndite 2012 pp. 137-138 and 249-253). While the difference may reflect a number of institutional and cultural issues, the exceedingly unpractical notification procedure and long delays adopted in France in 1893-1894 probably played a role in making the system function poorly, thus lastingly "disqualifying" this instrument – and contributing to a modern system which is seen by employers as often excessively harsh. It is also interesting to see that the practice of prior notices was in a way only seen as a "stop gap" measure until more precise requirements could be developed, and not as a useful tool by itself. Finally, this initial difficulty also reflects the problems created by constant technical developments, which meant that regulations were always outdated compared to the latest innovations (Guérard 2000 p. 5) – a problem that was only gradually solved over the following decades, with the growing reliance on performance or target standards, rather than specification standards (see Ogus 1994 pp. 151-152 and Baldwin 1995 pp. 175-185)[62]. Even in the way such performance-based rules are used, however, French labour inspectors exhibit to date a considerable reluctance to give specific guidance[63], in strong contrast to the HSE's practice[64].

A couple more remarks on the long-lasting effects of initial choices. First, the initial choice to have "departmental" inspectors, and to keep one inspector per *département* even once they became state inspectors, has been preserved in a structure where the fundamental organizational unit is local (in spite of inspectors being state civil servants), and staffing levels are only poorly proportional to the level of activity (the "one inspector per department" was evidently inbalanced froms this perspective). Second, merging the different inspectorates respectively in charge of "general" labour inspections, labour inspections in agriculture, and labour inspections in transports, had to wait until 2009[65]. Finally, France's decision to build a medical insurance system based on a "Bismarckian approach" in 1945 (i.e. based on a network of industry-specific statutory health insurance funds) rather than a "Beveridgian approach" (a national, tax-funded health service) resulted in a duality of inspections, whereby the health insurance funds conduct occupational health visits with no connection to the labour inspection[66], a problem that is not without connection with what can be observed with the occupational accidents statutory insurance funds in Germany (see Tilyndite 2012 pp. 162-164).

A very brief look at a few other countries[67] confirms both some level of similarity in timelines, and some important differences that relate to different "country trajectories" in terms of overall political and institutional context, social issues etc.

### Netherlands

In the Netherlands, labour legislation was introduced relatively late compared to Britain and (to some extent) to France. In 1874, child labour was banned in factories (van Houten legislation), then in 1919 the Labour Law comprehensively prohibited child labour and mandated rest periods and maximum working hours. It was only in 1934 that the Safety Act introduced mandatory norms on labour safety. The Labour Inspection was created

[62] For more explanation and discussion of the different types of standards, see below pp. 107-112

[63] Author's interviews with French government officials and businesses.

[64] See illustrations of it at: http://www.hse.gov.uk/guidance/

[65] See France's report to the ILO for 2009, available at: http://travail-emploi.gouv.fr/IMG/pdf/Rapport_au_BIT_intranetW_28022011.pdf. Note that labour inspections in mining, electricity and gaz industries remain separate.

[66] Author's interviews with French government officials and businesses.

[67] The following cases were selected for their relevance (major economies, among the early industrial powers, particularly for the US, Germany and France) and because they exemplify very different approaches (Germany and France for instance), and diverging timelines (earlier actions in Germany and France, later in the Netherlands and the US). As such, they allow to present an overview of the diverse paths taken in setting up OSH inspections, their similarities and differences, and the significance of historical path-dependency for today's inspections practices.

in 1890, which is also considerably later than in Britain (and a bit later than in France). It would be interesting to look more closely in future research as to why there was this delay (given comparable stages of industrial development), and whether this resulted in any difference in how injuries and fatalities rates evolved (declined) over time (i.e. whether this decline was slower in the Netherlands, which could be because of later introduction of regulation and inspections, or whether there is no observable difference, and the main drivers appear to be technology, culture, economic structure etc.).

An interesting feature of the Dutch system was the creation, in 2012, of the Inspection for Social Affairs and Employment ("Inspectorate SZW" in English or "*Inspectie SZW*" in Dutch, with SZW standing for "*Sociale Zaken en Werkgelegenheid*"). This institution regroups "the organisations and activities of the former Labour Inspectorate, the Work and Income Inspectorate and the Social and Intelligence Investigation Service of the Ministry of Social Affairs and Employment[68]". It thus gathers a number of functions, *some* of which are frequently found combined elsewhere, but rarely all. It supervises compliance with "regulations in the area of working conditions and the prevention of major hazards" (like the HSE – but unlike the French Labour Inspectorate, which does not oversee major hazards[69]), regulations concerning illegal employment and minimum wages (*to some extent* like the French Labour Inspectorate[70] but unlike the HSE, which deals only with health and safety[71]), and it is also involved in "detection of fraud, exploitation and organised crime within the chain of work and income (…) under the direction of the Public Prosecution Service (some of which, but only a small part, falls within the purview of the French Labour Inspectorate[72] – and none of which is done by the HSE) as well as "studying the implementation of social security acts by the Employee Insurance Agency (UWV), the Social Insurance Bank (SVB) and municipalities[73]" (a function that is typically done, if at all, by completely distinct bodies from OSH/labour inspectorates).

There is no easily accessible, open information on the reasons why the Dutch government decided to go for this precise merger, rather than envisioning potentially different mergers, with different synergies, e.g. merging all functions related to social security fraud with the Tax Service[74] – it is not even clear that other merger options (or full transfer of some functions to other institutions) were considered at all. The only official information we were able to access (internal documentation of the Ministry of Social Affairs and Employment from 2012, gathering working documents from 2009) treats the merger as a *fait accomplis* and does not discuss the reasons this precise merger was decided – it only advocates its benefits, and lays out how to make it happen. What we can piece together[75] is that, at some stage probably in the first half of the 2000s, the Netherlands government decided to consolidate national inspectorates (excluding the Tax Service) and to more than halve their number (from 25 to 10), as a way of reducing staffing levels (down close to 30% over 15 years) – consolidation being seen primarily as a way to make this staff reduction possible while keeping roughly similar levels of effectiveness.

It is too early to discuss the results of this merger, and it may turn out to be a very good decision in terms of overall effectiveness, but what is interesting from our perspective is that (at least based on the information

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[68] Official English-language brochure "What does the Inspectorate SZW do?" – available at: http://www.inspectieszw.nl/Images/What-does-the-Inspectorate-SZW-do_tcm335-330702.pdf

[69] In France, this is done by the *Inspection des Installations Classées* see: http://www.installationsclassees.developpement-durable.gouv.fr/

[70] Which does not look at social contributions, handled by the bodies in charge of the social security system.

[71] In the UK, illegal employment of foreigners is tackled by the UK Border Agency and the Gangmasters Licensing Authority (see: http://www.gla.gov.uk/ ) which "regulates businesses who provide workers to the fresh produce supply chain and horticulture industry, to make sure they meet the employment standards required by law". Compliance with wage and working hours regulations is not enforced by public inspection institutions, but by litigation, wherein workers are supported by Trade Unions. Payment of social contributions is handled as part of the tax inspections by HM Revenue and Customs.

[72] Social security fraud is handled by social security institutions themselves. Organized crime is tackled by special units in the police.

[73] And some additional analytical functions, risk assessment in the field of social affairs etc.

[74] Whereas collection of social contributions has been done for a long time already by the Tax Service – see Bakirtzi 2011 pp. 67-71

[75] Author's discussions with current and former Netherlands government officials involved in inspections issues.

we could obtain) there does not seem to have been a real conceptual review of what inspectorates were doing, what (if anything) from this set of duties could possibly abandoned, what could be done better through mergers or transfers of functions (and which ones). Rather, it was decided to conduct mergers to save costs, and these were done by grouping together the functions that looked most similar or, simply, were under the same ministry (in this case SZW). This illustrates once again how rarely "evidence-based" decisions are taken regarding inspection structures, staffing levels etc.

### Germany

The occupational safety and health regulatory and enforcement system in Germany, as in the other countries we have reviewed, has features reflecting its history – but maybe even more so than others.

The German OSH system is characterized by a system that is both "federal and dual" (Tilyndite 2012 p. 161[76]) – there is a federal labour law but inspections are done by the *Länder* (federated states), and in parallel there is a set of "non-governmental" (but government-backed) regulations and inspections handled by the "statutory insurance bodies" (*"Berufsgenossenschaften"*). We will try and briefly cover the origins of such a rather unusual structure (and we will discuss in a later section how the system appears to perform compared to the British one).

The early origins of the OSH system are not very different from what they were in Britain and France, and contemporary as well – but, due to the political fragmentation of Germany at the time, they took place in one state at a time. The most significant developments were in Prussia, which was to become the "unifying" state over the 1860s (and with full unification of Germany achieved in 1871). Like in other countries, the first concern was about children working in factories, and the emergence of the concern took place in the 1830s. A particular twist of the German situation was that the driving worry that led to call attention to the plight of children in modern industry was military – that, because of stunted development, the army was unable to find sufficient numbers of able recruits[77] (report of Lieutenant-General von Horn to King Friedrich Wilhelm III). This, and other similar reports, led to the adoption in 1839 of the "Prussian Regulation" (*"Preussisches Regulativ"*) that, similarly to the 1833 UK Act and the 1841 French Law, limited employment of children (in terms of minimum age, maximum duration, schooling requirements). Like in France, and unlike in Britain, no specific inspectors were appointed – enforcement was left to local police, school authorities and (from 1847) voluntary local commissions. Due to their limited effectiveness, in 1853 state inspectors were appointed (and, at the same time, rest on Sunday and public holidays made mandatory). In 1869, a regulation (first applicable to the Northern German Confederation, then from 1871 to the whole German Empire) gave a stronger basis to the activities of labour inspectors, and further reinforced existing requirements on working conditions, age, hours etc.

The developments from the 1870s again to some extent paralleled those observed in France and Britain, with a legal amendment adopted in 1878 that allowed inspectors to conduct at any time a "revision" of the workplace, and order safety improvements, but implementation was still problematic. From 1874, the

[76] This short account of the German system and its origins is based on Tilyndite 2012 for the present, and on publicly available information, in particular websites such as the *Helmut Schmidt Universität*'s http://www.hsu-hh.de/arbeitsschutz as well as the *Arbeitsschutzverwaltung im Freistaat Sachsen*'s http://www.arbeitsschutz.sachsen.de/ as well as a section on "40 years of labour law" on the *TÜV Rheinland* website http://www.tuv.com/de/deutschland/aktuelles/40_jahre_arbeitsschutzgesetz/40_jahre_asig.html. Given the fact that we just aimed to present some of the key characteristics of the system, and how it differs from France and Britain, such publicly available facts were sufficient and we did not do a further literature review.

[77] Note that this concern, though not necessarily articulated in the same way, was clearly present elsewhere, at least in France – see Sarrut 1894 and his concerns about consequences for "the race", which mirror von Horn's. This again shows that what was perceived as "risk" was not necessarily what we would imagine from our modern standpoint (harm to people), but more a "social harm" or "social risk".

increasingly significant scores obtained in elections by "workers'" and "socialist" parties[78] were creating a growing incentive for the Government to try and "undercut" these parties by making significant reforms that would secure the support of industrial workers for the regime. Accident and health insurances for workers were announced in an Imperial statement in 1881, and turned into law in 1883 (health insurance) and 1884 (accident insurance) (cf. Tilyndite 2012 p. 167). The latter, crucially, replaced the 1871 regime of compensation for work accidents (where workers had to prove the responsibility of the employer, which seldom was possible) by a "no-fault" compensation regime. Finally, in 1891, the "Law on Worker Protection" (*"Arbeiterschutzgesetz"*) was adopted. This gave a stronger foundation to state labour inspections, and extended them to all industrial activities regardless of size and sector. As a result of these reforms in the 1880s and early 1890s emerged a dual system of state supervision and supervision through the mandatory insurance bodies institutions (since the "no fault" system meant there was otherwise a risk of "free riding", where employers with poor safety practices would just be subsidized through other employers' contributions, the *Berufsgenossenschaften* had from the start a supervisory role). The new system saw a strong decrease in work-related injuries and fatalities until the First World War – though, as we will see in other sections too, how much of this can be attributed to the specifics of the inspection system is debatable.

The "state supervision" side was from the start exercised by the federated states – and this was further reinforced by the 1949 Constitution, which reserved a number of powers to the *Länder.* Further developments of labour law included the 1973 Labour Safety Law ("*Arbeitssicherheitsgesetz"*), which required for each business to have an assigned medical doctor for occupational health, and one (or several) staff members assigned for safety (mirroring developments in Britain and France, and institutionalizing gradual developments in Germany since the 1920s). In 1996, a new Labour Protection Law (*"Arbeitsschutzgesetz"*) incorporated the EU OSH directives and principles, in particular risk assessment.

What is particularly noteworthy is how specific early decisions, and features of the legal and institutional structure, have had a defining effect on the OSH inspection system. First, *Länder* inspectorates, even though they implement the same law, are organized in very different ways (see Tilyndite 2012 pp. 166-167), and with varying staffing levels (*ibid.*, p. 176). In addition, in some of the federated states, "state inspectors perform not only OSH tasks but have functions in the areas of, for example, consumer or environmental protection" (*ibid*., p. 175). While a similar variety can to some extent be seen between different Local Authorities in Britain, the HSE provides unity in methods, and of course directly supervises "higher risk" sectors. Second, a complete parallel system of inspections by the mandatory insurers exists, with its own legal foundation (*"Sozialgesetzbuch VII"* – Seventh Volume of the Social Code, adopted in 1996, is the current framework), and a considerably higher number of inspectors than state inspectorates (see Tilyndite 2012 p. 175). Indeed, even though their purposes are defined differently (with a strong emphasis on prevention for the insurers) and stem from different laws[79], both state and mandatory insurers inspectors "have similar enforcement mandates but different tasks, organizational structures and enforcement approaches[80]" (*ibid.* p. 195). We will see in a later section that this appears to result in far higher frequencies of inspection visits, and difficulties in coordination.

### United States

[78] Until 1887, these got up to around 10% of the votes in each *Reichstag* election. From 1890, the SAPD and then SPD got 20% and more. See: http://de.wikipedia.org/wiki/Reichstagswahl_1884

[79] In addition, the mandatory insurers enforce their own statutory requirements (binding accident prevention regulations), resulting in a certain level of complexity and even confusion (cf. Tilyndite 2012 p. 170).

[80] When the system was created, in the late 19th century, state inspectors were more clearly focused on rules concerning employment of children and women, and working hours and rest days, whereas mandatory insurers looked more at the technical safety issues – but this allocation of responsibilities, if it ever was clear, has long ceased to be straightforward, as state labour law has increasingly regulated technical safety issues.

By contrast with the different European cases seen above, which share a number of common characteristics at least in terms of initial timeline, the development of OSH regulations and inspections in the United States has a number of specific features – the late emergence of state intervention in the OSH sphere, the prominent role of industry actors for several decades, the choice of a radical reform path in 1970, and of a legal framework that very starkly constrains inspector discretion.

As Aldrich (2001) puts it "Before the late nineteenth century we know little about the safety of American workplaces because contemporaries cared little about it. As a result, only fragmentary information exists prior to the 1880s" – which means that the recognition of the relevance of labour conditions came significantly later than in Western Europe. For a variety of reasons, including "legal and regulatory climate that diminished employer's interest in safety" (*ibid.*) as well as economic and natural conditions, and the practice of piece rates payment, which incentivized workers to producer more, even at the expense of safety[81]. As a result, injuries and fatalities appear to have been substantially higher than in Britain, for instance (Aldrich 1997 calculates that in coal mining, fatality rates were approximately 2.5 times higher than in Britain between 1890 and 1904. Similarly, fatality rates in railroad work were approximately twice higher).

In many matters, the United States are often said to have a more "litigation-based" than "regulation-based" approach – while the general validity of such a claim can be disputed, it certainly seems to have been the case for OSH in the 19th century. Unfortunately, as Aldrich (2001) puts it: "workers injured on the job or their heirs might sue employers for damages, [but] winning proved difficult. Where employers could show that the worker had assumed the risk, or had been injured by the actions of a fellow employee[82], or had himself been partly at fault, courts would usually deny liability. A number of surveys taken about 1900 showed that only about half of all workers fatally injured recovered anything". This meant that the economic incentive was too limited for most firms to do real efforts (and investments) in worker safety.

The first responses came in form of insurance coverage against accidents, which developed in the late 19th century, some purchased individually, some provided by unions, and some by the (larger) employers themselves. The first state-led efforts were some commissions to improve the situation in railways and mines, which developed from the 1840s and 1860s respectively, but with little powers and even less results. The first noticeable improvements "began on the railroads in the 1880s as (…) railroad regulators, workers, and managers began to campaign for the development of better brakes and couplers for freight cars" (*ibid.*). The technological solutions turned out to mean "not only better safety, but also higher productivity and after 1888 [railway companies] began to deploy it". State intervention then further accelerated the process. First, through information "in 1889-1890 (…) the newly-formed Interstate Commerce Commission (ICC) published its first accident statistics. They demonstrated conclusively the extraordinary risks to trainmen from coupling and riding freight (…). In 1893 Congress responded, passing the Safety Appliance Act, which mandated use of such equipment" (*ibid.*). This led to the rapid diffusion of the new equipment, and major improvement in injuries and fatality rates for trainmen.

The next steps of state intervention in OSH took place in the "Progressive Era" between 1900 and 1914, which also saw the adoption of the Pure Food and Drug Act (1906) and of the Federal Reserve Act (1913). In 1910, the Bureau of Mines was established, but it "was to be a scientific, not a regulatory body and it was intended

[81] E.g. the differences in types of deposits and methods of exploitation between British and US coal mining – "In Britain, coal seams were deep and coal expensive. As a result, British mines used mining methods that recovered nearly all of the coal because they used waste rock to hold up the roof. British methods also concentrated the working, making supervision easy, and required little blasting. American coal deposits by contrast, were both vast and near the surface; they could be tapped cheaply using (…) coal pillars and timber to hold up the roof, because timber and coal were cheap. (…) labor supervision was difficult and much blasting was required to bring down the coal. Miners themselves were by no means blameless; most were paid by the ton, and when safety interfered with production, safety often took a back seat. For such reasons, American methods yielded more coal per worker (…) but were far more dangerous" (Aldrich 2001).

[82] See also Stein (2003) on the difficulties of the "emerging tort of negligence", employers' and co-workers' responsibilities.

to discover and disseminate new knowledge on ways to improve mine safety" (*ibid.*). The most important step for OSH was the passing in 1908 of a "federal employers' liability law that applied to railroad workers in interstate commerce and sharply limited defences an employer could claim", and sharply increased compensation. Following up, "in 1910, New York became the first state to pass a workmen's compensation law", modelled on "no fault" compensation already in place in much of Western Europe. It "appealed to businesses because it made costs more predictable and reduced labor strife [and] to reformers and unions it promised greater and more certain benefits. (…) Between 1911 and 1921 forty-four states passed compensation laws" (*ibid.*).

As per Aldrich (2001), "the sharp rise in accident costs that resulted from compensation laws and tighter employers' liability initiated the modern concern with work safety and (…) the long-term decline in work accidents and injuries. Large firms (…) suddenly became interested in safety. (…) Managers began to look for hidden dangers at work, and to require that workers wear hard hats and safety glasses. They also set up safety departments run by engineers and safety committees that included both workers and managers. In 1913 companies founded the National Safety Council to pool information" (*ibid.*), Government agencies and universities participated in the effort. As a result, after 1910, fatality rates in railroads, steel making, and a number of other major industries (e.g. chemical) declined. There were also social and technological changes, such as a "decline in labor turnover [that] meant fewer new employees who were relatively likely to get hurt, while the spread of factory electrification not only improved lighting but reduced the dangers from power transmission". Overall, "manufacturing injury rates [went down] about 38 percent between 1926 and 1939" (*ibid.*). Improvements, however, remained uneven, particularly in smaller firms – and, in spite of progress, hazards in mining remained significant, which led to the 1941 Federal Mine Inspection Act. Other inspections, where they existed, were organized by the states. While not insignificant in many instances, they had a "relatively conciliary stance" and "saw themselves less as adversaries of industry than as technical advisers to it" (Vogel 1986 p. 232, quoted in Clark 1999 p. 97).

Against this background and early history, the adoption of the 1970 Occupational Safety and Health Act comes as a major turning point, a radical change of course. The view of backers of this new legislation was that it had been made strictly necessary by the situation with workers' health and safety, which they saw as having gotten worse. A few years after the Act's entry into force, for instance, Stender (1974) wrote: "The increasing growth and complexity of modern industry, with its sophisticated work processes and cascade of new materials, were resulting in the deaths of more than 14,000 workers and disabling injuries to more than two million others in the years immediately preceding passage of the Act. (…) In addition to the needless human suffering involved, this workplace toll constituted a significant drain on the resources of the country. Lost wages exceeded $1.5 billion a year and the total workmen's compensation cost to employers was $4.82 billion in 1970 alone. By the middle of the last decade it was apparent that the efforts of those concerned with this problem-state legislatures, industry and its safety specialists, and labor unions-had not decreased the workplace toll" (p. 641). Now, we have seen that this particular claim (that the "workplace toll" had not decreased) is false when seen in longer perspective. It is unfortunately difficult to access statistics from the decades immediately preceding 1970, so we have not been able to verify how true it was *from a shorter historical perspective*, i.e. for the decades immediately after WWII. Aldrich (2001) puts it thus: "in the 1960s however economic expansion again led to rising injury rates[83] and the resulting political pressures led Congress to establish the Occupational Safety and Health Administration (OSHA) and the Mine Safety and Health Administration in

[83] As evidenced by Smith (1972), injuries usually rise when unemployment falls because work intensity increases and many inexperienced workers are hired.

1970". It seems that there may indeed have been a plateau in the decline in injury and fatality rates in the 1950s and 1960s, at least in some sectors[84].

There was also an emergence of the "health" concerns in OSH – while injuries and fatal accidents were readily observable, the long-term health effects of many substances were poorly understood, or had been hidden on purpose, for a long period, leading to serious health effects on workers. Stender (1974) thus mentions several chemicals-related concerns: "occupational health was often misunderstood or ignored completely. Even where effective state regulation was attempted, it was necessarily limited by state boundaries. When Pennsylvania banned the manufacture, use, and storage of the chemical betanaphthylamine, an extremely hazardous substance linked with cancer of the bladder, the manufacturer moved its plant to Georgia, which did not then regulate the chemical. Industry's response was similarly ineffectual. Many large manufacturers had developed programs designed to create employee awareness of safe work habits (…) [but] few of these programs even considered the deleterious effects of toxic substances, partly because of the long studies necessary to prove a correlation between a substance and its effect on those exposed to it" (p. 642). Stender goes on to show that this concern with long-term health effects of chemicals was one of the points highlighted by the bill's sponsors, e.g. Senator Williams: "the competitive disadvantage of the more conscientious employer is especially evident where there is a long period between exposure to a hazard and manifestation of an illness. In such instances, a particular employer has no economic incentive to invest in current precautions, not even in the reductions of workmen's compensation costs, because he will seldom have to pay for the consequences of his own neglect" (quoted in *ibid.*). The reform's advocates were thus well aware of how the previous setup had achieved considerable improvements by relying on workers' compensation and economic incentives, but they considered that the system was not anymore adequate to current conditions, in particular because (i) those that invested the most in safety ended up at a competitive disadvantage (since insurance covered all workplaces and rates were set regardless of their record) and (ii) the health effects of many technologies and products were too long-term to be properly addressed through this system anyway, as the effects could happen far beyond the time horizon businesses were planning for.

This leads us to several extremely important points. First, we can see that in this case there seems to have been a combination of actual risks possibly increasing (and/or at least stopping a secular decrease), and new risks that scored strongly on the "dread" and also on the "unknown" dimensions (see Slovic and Weber 2002, p. 11) – and were also for many of them *objectively* under-addressed by current regulations and practices[85]. Second, when the United States had established worker compensation insurance as the cornerstone of its OSH efforts in the early 20th century, it had only partially copied the German system – in that it took "no fault" compensation, but not the inspection and enforcement powers of the "statutory insurers". Thus, there was a real problem of "free riding" by the least conscientious businesses, since there also was generally little (if any) link between insurance premiums and the track record of a business in terms of safety[86]. This illustrates well that, for any system intending to promote compliance and safety practices, it is essential to understand how all pieces of the system fit together. Third, context played again an important role – as these trends did not take place in a vacuum but on the contrary concerns with health and safety, and in particular with toxic chemicals, were growing outside of the workplace as well, and environmental and consumer activism were on the rise. As Clark (1999) puts it, the 1960s and 1970s "marked a major transformation of US politics, with the

[84] See CDC (1999), p. 466, for a graph of mining fatality rates, which shows precisely such a plateau between 1950 and 1970, but the time periods are too broad to identify precisely the turning points.

[85] On the policy mistakes in the field of chemical safety caused by over-optimism about long-term effects, see e.g. Blanc, Macrae and Ottimofiore 2015, pp. 61-62.

[86] This contrasts e.g. with the French system for mandatory insurance of construction contractors – where premiums are based on the risk of the project *and* on the risk profile of the company being insured (research by F. Blanc and G. Ottimofiore for a forthcoming World Bank Group publication).

emergence of new social movements pressing for change in fundamental social values in the areas of civil, welfare and consumer rights (…) and environmentalism" (p. 98).

These elements led to a reform coalition where "US advocates for occupational health and safety reform had ties to the contemporaneous environmental and consumer movements" but where, on the contrary, labour unions had limited influence – which helps explain "why a statutory approach to the occupational health and safety 'problem' was pursued" despite US unions' "wariness" towards "legislative solution for 'industrial' issues" (*ibid.,* p. 99). The reform design adopted was aimed at preventing by all means "regulatory capture" and reformists, considering that "political influence of industry" had made previous efforts ineffective, were "resistant to any regulatory solutions that institutionalised collaboration between regulatory officials and industry representatives" (p. 99). In this new system, "conflict was deliberately designed [in] (…) and discretion (…) was deliberately designed out" (Vogel 1986 p. 255 quoted in Clark 1999 p. 98). A small example can illustrate this approach – on advance notification. While the 1947 ILO convention (of which the United States are *not* a signatory, but which we use here simply as reference point) requires that signatories give the *right* to inspectors to enter premises at any time, unannounced, the 1970 OSH Act goes a step further. Indeed, not only did the Act authorize "OSHA compliance officers (inspectors) to make unannounced inspections of virtually any establishment" but "anyone giving advance notice of an inspection without authority from OSHA will, if convicted, be fined up to $1,000, imprisoned for up to six months, or both" (Stender 1974 p. 645). The rationale for this, of course, is that "if employers received advance notice of an inspection, they would tend to make cosmetic corrections of hazardous conditions, which result in no more than momentary protection for employees" (*ibid.*). Now, in reality, OSHA standards usually require considerable investments for compliance, and short-term "cosmetic corrections" would be very unlikely to bring an establishment from massive violations to complete compliance, but this illustrates well the spirit of the Act. It is also worth noting that, precisely because "discretion was designed out", OSHA inspectors are far more restricted to looking at "objective" and "material" aspects than inspectors in, say, the HSE, who can look more at practices, how workers and supervisors understand their roles, how risk-assessment is conducted etc. – and thus could on this basis see beyond any "cosmetic" improvements anyway[87].

#### Short conclusion

Overall, all the OSH cases reviewed above show how much the scope and type of regulatory intervention, structure, powers, methods and resources of inspection agencies all depend on a number of factors – perception of risks as mediated by the culture of the times, institutional and political context etc. As the effects of initial decisions can still be seen many decades later, many aspects of the structures and practices of inspection institutions end up having far more to do with contingent historical trajectories than with a science-based risk assessment.

### b. The emergence and development of modern inspectorates - Food Safety

As we have seen above, some of the earliest regulations and reported cases of "inspections" applied to food – aiming at preventing fraud, adulteration, ensuring that consumers are not abused, but also not poisoned. Thus, controls of food safety and food labelling have deep roots in the past. In spite of that, and in sharp contrast with the OSH field, there are few research works looking at the origins and developments of food regulations and food control functions. Most of the research work is not "about" food safety but "in" food safety – microbiological, chemical, epidemiological work, looking at pathogens, contaminants, prevention

[87] Authors' interviews with officials in HSE and UK Better Regulation Delivery Office. See also HSE Enforcement Management Model (discussed in later section), available at: http://www.hse.gov.uk/enforce/emm.pdf.

measures etc. The issue appears to be simultaneously far less contentious than OSH (where debates between advocate of more or less regulation have fuelled a considerable amount of writing), and more technical (at least in comparison with the "safety" part of OSH, not with the "health" side), thus possibly "scaring away" lawyers, social scientists and economists. It may also be that the topic is simply too little known to attract much interest – whereas "hotter" food safety issues, particularly when it comes to whether certain practices, additives etc. are "safe" or present "unacceptable risk", have ignited major disputes (and significant research efforts). What historical research on food regulation and its enforcement is mostly focused on the United States Food and Drugs Administration, its origins and development – which makes our aim to compare different cases difficult to reach.

Because of this scarcity of sources, we will limit ourselves to a relatively cursory overview of some of the most relevant aspects of the historical development of food inspectorates, in particular inasmuch as they help to understand lasting differences in practices, and challenges in the implementation of the most modern approaches – with more details on the United States case, by virtue of the larger volume of accessible research (and of its strong relevance to our central questions). This overview will rely to the extent possible on some of the most significant publications, e.g. Wagstaff 1986, Young 1989 and 1992, Coppin and High 1999, Koolmees 2000, Theves 2000 and 2002, Ferrières 2002, Shears 2008, Lásztity *et al.* 2009, Hardy 2010, Manion 2012 *et al.* – but these cover more heavily the United States than other countries, and rarely cover the control and inspection questions in depth. Thus, we have supplemented them with a combination of public information (websites of the relevant agencies and institutions), and on authors' repeated interviews and discussions with regulatory officials involved in food safety in all the countries covered here.

We will first briefly present the timelines and most salient features of several food safety inspection systems (the United States and Britain in greater details, France with less details on the timeline, the Netherlands more cursorily – and we will also add a short discussion of post-Soviet systems), as well as the influence of international organizations (the *Office International des Epizooties,* OIE – as well as UN FAO and UN WHO) and of the European Union (which, in this area, has had a major impact), then briefly consider the factors involved in the emergence and development of different structures and approaches (and the way these factors, including "crises", present similarities between past centuries and the most recent period). From this, we will consider three transversal themes: the interaction between food regulatory inspections and science (in particular the limitations of science at the time of regulation, and the difficulty to fit new science into old structures), the difficulty to settle disputes as to the effectiveness and relevance (or lack thereof) of these inspections, and the question of how risk is and has been understood, assessed and prioritized.

### *i. Emergence and development of food safety inspections – introduction*

At different points in the 19th and early 20th century, most of what then counted as the world's "developed" economies established systems of food control that featured a stronger emphasis on safety as had been the case until then, a new vocabulary, and new methods. The extent to which these new controls were in fact really "scientific" increased gradually – the first decades had maybe a scientific *ambition* but not really a scientific content (or the science was simply too weakly developed to be of use), this changed from the 1900s at the latest, but considerable gaps in understanding remained. Successive decades, in particular post-WWII, brought major improvements in our understanding of food-borne diseases[88]. These led to significant changes in the regulatory and institutional frameworks – but also revealed weaknesses and tensions in the structures

[88] Which, we would argue, should make us *modest* about our assessment of our current level of understanding – it is likely that much will be discovered in future, leading to re-assessments of risks.

inherited from earlier steps, not all of which have been solved to date (far from it), showing once again the significance of path dependence.

### *ii. Food Safety in Britain*

#### Early developments – Britain as a "precursor"

As in the field of OSH, Britain was in some ways a precursor in food control regulation and inspections (but, as we shall see, this "early mover" status also included significant shortcomings). In response to growing reports and concerns about food "adulteration", and complaints and worries about "nuisances" (e.g. from slaughter), a series of Acts of Parliament were adopted, some of them accompanied by the creation of new types of inspectors. "Nuisances" came first, driven by the growth of "hygienist" conceptions: "Edwin Chadwick, a Poor Law Commissioner, conducted an inquiry into the causes of poverty which concluded that people often became poor because of ill health due to a bad environment. He believed that improving sanitation was the key to breaking this vicious circle. Chadwick led a vigorous campaign for change (…) resulting in the Public Health Act 1848. The Act provided for the appointment of Inspectors of Nuisances (…) in areas of need[89]". However, the scientific basis for "nuisance inspections" was tenuous, hiring of inspectors at the discretion of local authorities, and their effectiveness mixed at best[90]. More clearly focused on food (but also on drugs) was the "first Food Adulteration Act (…) passed" – but several key points were missing, "most importantly perhaps the compulsory appointment of food inspectors" (Shears 2008 p. 126). The real creation of food safety[91] inspections in Britain came in 1872 with the "Adulteration of Food and Drugs Act strengthening enforcement powers by requiring the appointment of a public analyst and empowering local enforcement officers to take samples and bring prosecutions" (*ibid.*). This was followed by the 1875 Sale of Food and Drugs Act which "created two basic adulteration offences: the mixing of injurious ingredients; and selling to the prejudice of the purchaser a food not of the nature, substance or quality demanded. (…) The Public Health Act 1875 gave local enforcement officers powers to inspect and seize." (*ibid.*) The entire food safety inspection system in Britain was to remain based on local authorities' inspectors, first called "Public Sanitary Inspectors" and later "Environmental Health Officers", organized in an Association in 1883 (since 1984 the Chartered Institute of Environmental Health), and with gradually increasing qualification requirements (a certificate was required for London in 1891, then this became the norm gradually throughout the country, and the level of qualifications increased throughout the 20th century)[92].

While, as elsewhere, the initial remit of these inspections included food fraud even when no adverse effect on safety was expected, their focus was clearly on health, and issues of consumer fraud not involving safety were to become over time the purview of Trading Standards Officers (also working for Local Authorities). One of the most marked specificities of the model was that, in England and Wales at least (though not so in Scotland), veterinarians were mostly excluded from the build-up of the inspection services and practices. Indeed, "Britain's public health administration" as first between 1850 and 1875 "was dominated by medical men and medical models of human disease (…) [that] medicine viewed the opinions of veterinarians with suspicion" (Hardy 2010 p. 371). This early feature was driven both by the relative weakness of the veterinary profession in comparison with other countries in Western Europe (e.g. the stronger prominence of veterinary medicine in France where the first royal veterinary schools had been founded in the 1760s), and by what was to be a lasting feature: "the popular perception that animal disease constituted a very small risk to human health in

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[89] Chartered Institute of Environmental Health (CIEH) website – "history" section, accessed at: http://www.cieh.org/about_us/history.html

[90] See above on their lack of effectiveness in the context of the 1866 Cholera epidemic in London.

[91] In terms of their purpose, and regardless of their scientific basis and effectiveness, or lack thereof, at the time.

[92] See CIEH website at http://www.cieh.org/about_us/history.html

Britain" (*ibid.*). This situation also contrasts with the US's where, as we will see in the next section, veterinary inspections were set up at the federal level even before the Food and Drug Administration's creation[93].

### Attempting to understand the weak role of veterinary control in Britain

This difference is important in understanding the contrasts between the UK and "continental Europe" systems, in both its relative strengths and weaknesses – and thus, understanding its roots is relevant to our research. The origins of this dominance of "medical men" and of the veterinarians' weakness appear to lay in a combination of specific aspects of the British market, both cultural and economic, combined with path dependence.

First, the British market, until World War II, was wealthier than the rest of Europe, with higher meat consumption, and more of it coming from imports. At the same time, eating habits contributed to relatively safer conditions: "the country felt wealthy enough to dispense with [meat hygiene controls], priding itself on the production and import of quality meat, and (…) was comparatively free from meat-derived human disease owing to the British preference for well cooked meat, and to livestock more or less free from such conditions as trichinosis and beef measles (…). In other words, tuberculosis apart, animal infections had not constituted any serious threat to human public health in Britain in the period before World War II" (Hardy 2010, p. 374). In addition, the country's relative wealth meant that there was a far greater importance of imports, and as a result more emphasis on import than on domestic controls: "meat consumption in Britain was[94] amongst the highest in Europe (…) The market share of imported meat rose from less than 30% in 1880 to a peak of around 50% by 1923 (…). Precisely during this period, major meat exporting countries around the globe, as well as most European states, were implementing meat inspection systems under veterinary supervision (…). By 1930, Britain's imports came from countries whose exports were certified by qualified veterinary inspectors, and verified by meat inspectors at the port of entry. (…) Meat coming into Britain was examined and passed as fit for human consumption according to the rules of 'meat hygiene', a more rigorous system than that imposed on home-killed meat[95]" (*ibid.,* p. 377).

A second aspect that seems to have driven this weak role of veterinary control is trust. Whereas there is a general assumption that confidence in the effectiveness of control is an important factor in securing trust in the market, it can be observed (e.g. in the US's case, see next section) that the "demand" for inspections only arises when pre-existing trust is on the decline because of changes in the structure of the market. In Britain's case, it seems that trust in the market remained relatively strong as far as meat is concerned, for a variety of cultural factors, and thus the push for more regulation remained rather weak for a long time. This is at least what research on consumer trust in Britain can suggest: underlying trust in the mechanisms of food control may provide the key to this apparent British indifference to germs in meat and milk. One recent study, which argues that trust in food is dependent on the way in which a given country or government deals with food issues, found high levels of trust in food among modern Britons, despite the food crises of the years 1985-2000 (Kjaernes, Harvey and Warde, 2007, 1, 60-1). The British consumer, this study noted, trusted her local butcher, and advice given on food labels (…) In the nineteenth century, Keir Waddington has argued, food consumption was shaped by material concerns, standards of living and domestic technology rather than by medical or press reports and the fears they engendered around food and disease (Waddington, 2010, pp. 51-

[93] Even though Hardy (2010) lists also the US as having a weaker veterinary involvement than most European countries in food safety, this involvement has clearly been far earlier, and stronger, than in the UK.

[94] Again, before World War II.

[95] Exactly how and at which stage these controls happened changed over time, of course: "Domestic supplies were augmented initially with live animal imports, and veterinary surgeons became involved with state efforts to limit the associated import of animal diseases following the major outbreak of cattle plague in 1865 (…). By the end of the century, animals were being slaughtered on arrival at the ports; and, by this time, developments in transport had led to a significant shift to the import of chilled and frozen meat" (Hardy 2010, p. 376)

71). This seems to have been especially the case in respect of culturally prized staples like meat, where actual food poisoning was only rarely associated with the meat itself rather than with manipulated foods (pies, sausages), and where episodes of more or less minor gastric disturbance were a commonplace experience" (*ibid.,* p. 375). None of this appears entirely conclusive, but we can assume that cultural and social factors played a role in making meat safety concerns relatively less prominent in Britain.

Finally, once the original set up of the system started being in place, path dependence ensured it remained mostly in place going forward, i.e. that veterinary control remained secondary for in-country meat trade: "medical men were the managers of Britain's public health administration, and their loyalties lay with their staffs of trained sanitary and meat inspectors, who vigorously resisted the claims of the veterinarians" (*ibid.,* p. 372).

### Limitations in effectiveness – pressure for change

Overall, not only were veterinarians "marginalized"[96], but the overall level of supervision of the meat supply was, for a long time, markedly more relaxed than elsewhere in Europe – where national veterinary supervision and systematic inspection in slaughterhouses were introduced in many countries from the late 19th century. Whereas "Belgium and Norway passed meat inspection acts in 1891, and their example was followed by Luxembourg (1892), Germany (1903), France[97] and Spain (1905), Austria-Hungary (1908), Switzerland (1909) and Denmark (1911)", England focused on regulating imported meat "with Merchandise Marks Acts between 1887 and 1953, and for the inspection of imported meat with the Public Health (Foreign Meat) Regulations of 1908, but placed that responsibility in the hands of customs official and medical men" (Hardy 2010 p. 377). It was assumed that domestic supply was safe – which was, in fact, a somewhat heroic assumption.

Indeed, "in general, slaughtering in England and Wales was conducted in small, local slaughterhouses, of which there were said to be some 15,000 on the eve of World War II. (Bywater, 1948, p. 219). Many of these were in rural areas which were very difficult to regulate systematically. At any point when slaughtering became concentrated in a particular locality, either on grounds of economy of effort during the Great War, or through the very gradual movement towards the establishment of municipal abattoirs, startling increases in the number of carcases being condemned were noted" (*ibid.,* p. 378), which strongly suggests that problems existed, but control was too infrequent and unequal to consistently detect them[98]. This also raised, as Eleni Michalopoulou has noted, serious questions of market distortion between producers and traders in more strictly controlled areas, and others operating in loosely supervised ones. This was only addressed at the end of the 20th century with the development of a national meat hygiene service, and then the creation of the Food Standards Agency.

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[96] "In Scotland, the veterinary supervision of meat supplies was introduced in 1897, and local authorities in England and Wales, slowly and in piecemeal fashion, began to do likewise; by 1937, local authorities were employing some 220 full-time and 700 part time veterinary inspectors" (a trend that was to be reversed after the establishment of a national veterinary service in 1938, which led to a decrease in the number of local authorities' veterinarians) – but "medical men were the managers of Britain's public health administration, and their loyalties lay with their staffs of trained sanitary and meat inspectors" (Hardy 2010, p. 372).

[97] Cf. also Koolmees 2000 – passing laws did not always mean creating serious inspection services – while Belgium did create a real veterinary inspection, in France it was only present in major cities – see below.

[98] Indeed, "when, during the war, the Home Counties kill was concentrated in the London borough of Islington, and the private slaughter houses closed, the amount of meat condemned rose from some 2-300 tons per annum to the 'appalling figures' of between 1,600 and 2,000 tons (…). A similar situation arose when the city of Sheffield opened a new public abattoir in the late 1920s: the amount of diseased meat detected shot up by 80%. As the abattoir's designer noted, the only possible inference was that this was the amount previously eaten, mostly by the poorest classes" (Hardy 2010, p. 378). Similarly, worrying issues are noted in an unpublished presentation by Eleni Michalopoulou, University of Liverpool, School of Veterinary Science, e.g. the very poor conditions even in centralized slaughterhouses (e.g. Manchester in early 20th century), and unequal levels of inspection, unequal stringency in seizures etc. See: http://www.northwest-zoonoses.info/writedir/963aRegulation%20of%20food%20controls_Eleni%20Michalopoulou.ppt

Increasing international "benchmarking" and harmonization were the forces that started to generate changes, as they showed not only the specificity, but the overall laxity of the system: "by the mid-1950s, when a survey of meat hygiene practices in Europe was conducted under the auspices of the World Health Organisation, Britain was the only country (…) which did not normally carry out ante-mortem inspection by qualified veterinary surgeons, and (…) [Scotland excepted] where the post-mortem examination of animals slaughtered for commercial purposes was not obligatory by law" (*ibid.*). Only during WWII was 100% inspection achieved in slaughterhouses, and this was quickly reversed by the reopening of a vast number of private premises once rationing ended.

Growing evidence of contaminations and outbreaks (in particular caused by *salmonella*) in the 1950s led to the Slaughterhouses Act 1958 and several sets of successive regulations and legal amendments (including to empower local authorities to "close private slaughterhouses under certain conditions"). In particular, "the establishment of the Public Health Laboratory Service (PHLS), initially as an emergency war-time measure, now led to more systematic and rigorous scientific investigation of many of these outbreaks" (*ibid.,* p. 381) – which, in turn, built up knowledge and evidence, and led to increased action. This shows an important link between better detection ability and increased demand for control, that we will also observe in other cases (e.g. the US food safety case in the next section). The new evidence meant that a "chain of infection" had been "demonstrated from the farm to the consumer, and abattoirs (…) shown to act as a focal point for the transmission of infection among animals awaiting slaughter" (*ibid.,* p. 383), which led to increased attention paid to the problem. In addition, effectiveness was hampered by the lack of continuity in food chain supervision: "it was pointed out that veterinary surgeons were greatly handicapped in their work with animal disease by the unavailability of slaughterhouse evidence that could be correlated with live animal statistics" (*ibid.*)[99].

While the number of slaughterhouses was reduced, and the physical premises much improved, practices remained problematic, and the lack of a link between veterinary surveillance and pre-slaughter inspections also created a gap in surveillance[100]. Additional regulations in the 1960s only brought about limited change (*ibid.* pp. 384-385). Even Britain's joining the EEC did not bring major changes initially, as European regulations in the 1970s only covered exports. This changed radically with the European Single Market, and the unfolding of the Bovine Spongiform Encephalopathy (BSE) crisis[101]: the Fresh Meat (Hygiene and Inspection) Regulations 1992 (adopted in view of the Single Market start date in 1993) led to 300 local authorities establishing full meat hygiene services (*ibid.* p. 387). The worsening of the BSE and nvCJD scare then led to "the establishment of the Meat Hygiene Service in April 1995, in which veterinary surgeons played a central role, local authority veterinarians being transferred into the new service" (*ibid.*).

### The BSE crisis, the creation of the Food Standards Agency, and the modern food safety system in Britain

The considerable loss of credibility caused to the system by the BSE crisis (and other scandals) then led to another radical reform: the creation of the Food Standards Agency (FSA) in 2001. The Government vision was of "an Agency with a clear focus on protecting the public and a powerful statutory remit across the whole food chain, at arm's length from Government and independent of sectoral interests, governed by a Chairperson

[99] An early example of the importance of "Farm to Fork" control, that we will discuss in the EU section later on.

[100] Hardy 2010 p. 383: "it was pointed out that veterinary surgeons were greatly handicapped in their work with animal disease by the unavailability of slaughterhouse evidence that could be correlated with live animal statistics" – as we will discuss further, all models of effective food safety inspections emphasize the importance of achieving unified surveillance over the food chain.

[101] The BSE scare *alone*, as previous food scandals too, had not been enough to profoundly change the system – it led to limited changes only: "Authorised Officers (Meat Inspection) Regulations 1987 included veterinary surgeons among the personnel permitted to undertake such duties, along with Environmental Health Officers and qualified meat inspectors. Responsibility for meat inspection remained in the hands of the local authorities" (Hardy 2010 p. 387).

and Commission appointed openly on the basis of their personal standing and expertise, operating under guiding principles which put the interest of the public unequivocally as the first priority, able to make public its views on any issues related to food and public health, taking a strategic view of food safety and standards issues across the whole food chain, with wide-ranging powers to commission research and surveillance, propose legislation, monitor food law enforcement and take action to remedy problems, with a clear responsibility to provide the public with information and advice[102]". The FSA took over the Meat Hygiene Service as one of its divisions, and assumed a role of guidance and supervision on the inspection and enforcement work of local authorities (which supervise the food chain "downstream" from primary production), of coordination and sharing of information, as well as of scientific risk assessment.

This historical process has resulted in a structure where nowadays control responsibilities are divided between local authorities on the one hand ("lower tier" authorities, e.g. district councils, are responsible for food safety and hygiene - there are 406 of these - and "upper tier" authorities, e.g. county councils oversee food labelling), and central structures on the other[103]. Local authorities in fact handle most of what would have been the province of the "hygienists" or "sanitarians" in earlier times[104] - and are responsible for the food chain "downstream" from primary production (processing, transport, handling and storage, sale, catering etc.). Primary production is controlled by the Meat Hygiene Service (part of the FSA), animal health and welfare are supervised by several agencies under the Department for Environment, Food and Rural Affairs (DEFRA), and other parts of DEFRA supervise plant protection and phytosanitary issues generally, but specifically safety of phytosanitary chemicals is overseen by the Health and Safety Executive (HSE)[105]. In spite of the creation of the FSA, and of some consolidation efforts within DEFRA, the set-up has remained to a large extent as "inherited" from earlier times. Thus, efforts to make regulatory supervision and enforcement better coordinated, more consistent, built on a stronger risk analysis have proceeded without affecting the structure, using different mechanisms (guidance, evaluation, Primary Authority scheme etc.) that we shall describe further in this research.

The creation of the FSA appears to have been, overall, successful. Anecdotal evidence can be taken from the fact that the reaction to successive food-related "scandals" or "scares" (e.g. the 2013 horsemeat scandal) have not given rise to the same loss of confidence as in the 1990s – but also from the fact that these scares were simply far less significant in terms of danger to human health. The FSA also was found to enjoy strong public support, and rumors that it may be abolished in 2010[106] did not come true (though the Government did take away some of its responsibilities relating to nutrition – which in turn led Scotland to create its own "Food

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[102] *The Food Standards Agency, A Force for Change*. Command Paper presented to Parliament by the Minister of Agriculture, Fisheries and Food, January 1998 – available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/265718/fsa.pdf

[103] For details on the basic FSA/Local Authorities split see the FSA website: https://www.food.gov.uk/enforcement

[104] As we have noted above, this is a feature of the British system that is relatively unusual in the EU, and among developed countries – but a number of other countries around the world have food inspection systems with a strong prominence of sanitary inspectors with a medical background – e.g. most of the former Soviet Union (where, by contrast with Britain, inspectors are typically MDs, and not environmental health officers).

[105] We have to clarify that this presentation is an over-simplification, based on public information and on many clarifications given directly by staff of the UK Better Regulation Delivery Office. Exposing full details would take much space and time, and add little to the essence. One point of importance, however, is that the exact set up differs in each constituent part of the United Kingdom, and is evolving. The latest change is that Scotland now has its own Food Safety Scotland agency, instead of the FSA, with the same remit as the *original* FSA remit (the UK Government having in 2010 taken the decision to transfer responsibility for nutrition and food labelling and standards in England from the FSA to the Department of Health and the Department for Environment, Food and Rural Affairs – a decision that was widely seen as following industry complains about the FSA being "too aggressive" – led to the Scottish Government deciding to create a new agency for Scotland, with the full original mandate) – see https://www.food.gov.uk/about-us/new-scotland and also http://www.foodstandards.gov.scot/about-us.

[106] The discussion was well covered by the media at the time – see e.g. in the *Guardian*: https://www.theguardian.com/politics/2010/jul/11/food-standards-agency-abolished-health-secretary and *Reuters*: http://uk.reuters.com/article/uk-britain-food-idUKTRE66A1AI20100711. The Chair of the FSA reacted through an open letter to the Health Secretary: http://www.food.gov.uk/sites/default/files/multimedia/pdfs/board/letter140710.pdf

Safety Scotland" agency, with nutrition included in its mandate[107]). Rumors of the FSA being abolished after the Conservative Party's 2015 electoral victory also met with negative reactions[108], and were not followed up in fact. Existing evaluations also conclude broadly to the FSA's success in improving food safety governance, enforcement effectiveness and consistency (see Flynn *et al.* 2004), and to its ability to do so with innovative approaches, and a more "growth-friendly" approach (see BRE, BERR and NOA 2008). We can thus conclude that the FSA's set up and activities appear to have been successful, as have been reform efforts in the local authorities' practice in the last decade, and there is reason to consider the "new" British system as a very interesting example of risk-based and risk-proportionate inspections and enforcement, and of "responsive regulation"[109]. It remains, however, that the system has many features that result clearly from historical accident and not from rational design, and have long hindered its effectiveness and development, and that only strong external pressure and major crises were able to bring about deep changes. On the positive side, however, one can argue that the reliance on local authorities "environmental health officers" (as they have been known for the last few decades) has considerable advantages: more flexibility and ability to experiment and innovate in methods (compared to a centralized system), more information and resource sharing between different, related inspection fields (food safety and OSH, which environmental health officers both supervise, but also trading standards, which are controlled by other specialists, but as part of the same enforcement services of local authorities). Thus, one should not look at idiosyncrasies in structures only as a negative – but clearly as evidence that the shapes and functions of inspection bodies how much to history, culture, institutions, and little to rational planning.

#### *iii. Food Safety in the United States*

While discussions of adulteration and the risks it created to health were intense, and roughly contemporary with the same concerns in the UK, the development of regulation and inspections took a very different route – and, overall, was significantly slower and difficult. The specific features taken by the regulatory framework and the inspections system in the US can, it seems, be traced back to a significant extent to their historical development – starting from a background of purely municipal/local regulations (as in much of Europe at the time), but with a somewhat slower and more conflicted development of "national-level" intervention (with the tension of whether this should mean "state" or "federal"), and successive major turning points in the 20th century.

##### Early History: controlling export quality to build trust

The first rules and controls applying to food appear to have been aimed at ensuring exports were of adequate quality, and thus the exporting city or region (colony, state) did not lose export markets. The risk that was being addressed was that of losing market share, and thus precious income. As Young (1989) puts it, in the 17th century, "officials were far more concerned with the city's commercial reputation than with what the citizens ingested" – for instance, Massachusetts "began to inspect exports of fish, beef and pork routinely (…) in 1641" (p. 35). Even though Young also writes that "legislatures in British American colonies imitated statues earlier enacted in the mother country seeking to protect the purses and safeguard the health of their citizens"

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[107] See an archived FSA web page on this creation: http://webarchive.nationalarchives.gov.uk/20150624093026/http://www.food.gov.uk/about-us/new-scotland

[108] See article in *Environmental Health News*, the magazine of the Chartered Institute for Environmental Health: http://www.ehn-online.com/news/article.aspx?id=14246

[109] One point to note is that the FSA's creation and demonstrated independence, and the overall perceived success of the reforms, have managed to re-establish public trust in food safety regulation, which had been dented by the BSE and other crises. The high level of trust is noted in Kjaernes, Harvey and Warde 2007. The interpretation of this being because of the FSA's role and overall changes in the system is not necessarily proven, but is one widely shared by current and former Government officials we interviewed.

(p. 3), the main focus in terms of controls appears to have been on exports. This shows the intimate relationship between the establishment of inspections and the need for establishing trust. Local commerce and food supply clearly were perceived as inherently more "trustworthy", better known, less risky. Imports from distant locations were where trust could break down – and where inspections could help safeguard or restore it.

### Drug regulation as a precursor of food regulation – the "adulteration" issue

The first half of the 19th century seems to have seen rather a loosening up of regulations than their strengthening, with a combination of democratic and *laissez faire* trends resulting in the United States being most probably one of the most lightly regulated countries in the North Atlantic space. An example of this is the trend in health care and drugs regulation (which, in the United States, has its history tightly linked to food regulation). Whereas, in the early years after the Revolution, the "patrician elite" of doctors educated in the first medical school "used their prestige and power to strengthen (…) a licensing system to control admission to their profession", these restrictions came under strong criticism. As a result "opponents of orthodoxy swept licensing laws from the statute books" (*ibid.,* p. 22).

What brought back regulations and control efforts was the fear of *adulteration* (very much like what was observed in the United Kingdom). Scientific and technical progress was one of the driving forces for this - "American scientists adopted the ever-improving European techniques of analytical chemistry (…) which advanced the art of detecting adulterants beyond the centuries-old organoleptic tests" (*ibid.,* p. 8). Tools were now available, which enabled scientists to ascertain (to some extent) whether a product was indeed what it was advertised to be. The first efforts to fight adulteration focused on drugs – and relied on a treatise published in 1846 by Dr Lewis Beck that purported to show the extent of adulteration (particularly of imports), as well as the means to detect it (*ibid.,* pp. 9-12). There does not appear to have been actual reports of *adverse effects* of this adulteration, at least nothing that could pass as even rudimentary statistics showing effects on life and health. Indeed, while science had made progress in chemistry, it had made significantly less in medicine, and the adulterated medicines were judged a danger from the perspective of medical theories which were mostly to be proven wrong later on. Dr Oliver Wendell Holmes Sr. (the father of the later Supreme Court Justice) famously wrote: "I firmly believe that if the whole *materia medica*, as now used, could be sunk to the bottom of the sea, it would be all the better for mankind – and all the worse for the fishes[110]" (quoted in *ibid.,* p. 19). It is likely that much adulteration was indeed dangerous (*ibid.,* p. 12) – but it is noteworthy that the fight for regulation was based more on the availability of detection tools, than on an observed public health crisis.

The first attempt at regulating drug imports was a 1848 law establishing border controls, but its enforcement was difficult and haphazard, and unscrupulous traders could always go to another port "at which the examiner was more lenient" (*ibid.,* p. 15). Then, "when poor enforcement kept that [1848] law from being effective, organized pharmacy launched a new attack on drug adulteration by reviving state laws (…) Enforcement, however, was feeble" (*ibid.,* p. 31). Then, during the Civil War (in a time when the effectiveness and safety of drugs was of course a major concern), Congress enacted "a law aimed at banning adulterated drugs offered for import" (*ibid.,* p. 3). All these laws were limited in their effectiveness by the weakness of enforcement means – one also is brought to wonder to what extent these issues appeared to be a serious concern to the public at large, as opposed to the medical professionals that were pushing for their adoption – indeed, regulating the trade and sale of drugs was linked to a large extent to chemists, doctors and pharmacists trying to strengthen their social and economic status (Swanson 2011, p. 339).

[110] He made exception for opium (clearly and effective medication, but which we owed to nature), and for wine ("which is a food", he added, and for which doctors could thus claim no credit). He led an ongoing fight against "massive bleeding and purging" (*ibid.*, p.21), but was very much in the minority at the time.

## Key drivers of early efforts at food regulation

While the first efforts at strengthened regulation focused on drugs, foods were not very long to follow – indeed "throughout much of the nineteenth century, the boundary between food and drugs was porous" (*ibid.,* p. 341)[111]. Again, the successive efforts at promoting stricter regulation, and the regulations effectively adopted, were largely linked to the development of control methods, to commercial interests, and to conceptions of disease and health that were later often disproved. Infectious diseases were of course widespread (and among them a large amount of food-borne diseases), but there is little evidence of a link between outbreaks and regulation. We will look briefly at each of these drivers of regulation.

The emergence of modern methods for chemical analysis clearly was a critical factor in the push for more food regulation: "microscopes and lactometers offered enhancements to traditional ways of seeing based on the intuitive knowledge of the dairyman or housewife. But chemistry, that is, laboratory analysis of compounds, offered an entirely new understanding of both food and drugs. In the laboratory, any food or drug could be analysed for its constituents" (*ibid.,* p. 345). Indeed, not only did the new chemistry offer tools to identify adulteration, it also "created a new ontology of food and drugs" by allowing to define them based on a "cellular and molecular understanding" (*ibid.*). Selling consumers anything else could be presented as abuse – not necessarily endangering their health (though this was often argued), but definitely defrauding them financially.

Commercial interests did contribute powerfully to the development of food regulation and control –not necessarily always the consumers' best interests, but rather that of groups of producers and traders. In practice, "although most of the rhetoric of regulation addressed itself to issues of nutrition and health, most of the actual regulation addressed itself to competition" (Coppin and High 1999, p. 18). One of the earliest focal issues for food regulation was the "dreaded" oleomargarine (a French invention, followed by successive similar products developed by American industrialists) – dreaded not because of its health effects, but for its effect on sales of butter. Thus, the margarine regulation fight pitted dairy producers (supported by a number of scientists and officials, whose views and/or interests coincided with theirs) against oil-seeds farmers and margarine processors. Arguments were that margarine was not natural – but "Wiley [who was to be the lead inspirator of the 1906 Pure Food and Drugs Act] used the term natural not as a scientific term, but as an emotional term that commended products of which he approved" (*ibid.,* p. 32). The words of a deputy food commissioner for Connecticut, working on the enforcement of a new law regulating margarine, are telling: "we are trying to make everybody believe we are doing them a favor by enforcing the oleomargarine law" (*ibid.,* p. 26). Low-income consumers clearly were ready to buy the cheaper product (margarine)[112], and dairy production was losing considerable market share. In the end, the fight between two lobbies resulted in a 1886 Act of Congress "placing a tax of two cents per pound on margarine and requiring license fees (…) Although burdensome, the legislation did give margarine official recognition as a food product" (*ibid.,* p. 32). Overall, the "consumer information" or "consumer protection" driver of regulation was (and has remained) ambiguous from the onset. On the one hand, "consumer advocates would increasingly identify knowing foods as a problem, eventually calling for federal regulations setting standards for a multitude of foods, particularly those sold in packaged and/or processed forms. A pickle, it turned out, could be defined and known scientifically[113]"

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[111] This connection between food and drugs has a long history – cf. Ferrières 2002 pp. 38-42, 105-113, 364-369 etc.

[112] Indeed, the very persistence of massive adulteration on the market strongly hints to demand for these products: "given the large percentage of income that they spent on food, workers often chose the cheaper cut of meat (…) even goods that were classified as adulterated found a market if the price was low enough" (Coppin and High 1999, p. 26). Note that once again "adulterated" was far from meaning *ipso facto* more hazardous than other foods (which were themselves often unsafe given problems with hygiene, preservation etc.). On demand for cheaper (even adulterated) foods see also Alsberg 1921 p. 213.

[113] Margarine was one of the first foods thus regulated. The FDA was to adopt many standards defining what given food names were to cover starting from the 1930s (see Swanson 2011 p. 365). Many other countries, and the EU, were to follow the same approach.

(Swanson 2011, p. 346). On the other hand, in these early times of food regulation development, "although most of the rhetoric of regulation addressed itself to issues of nutrition and health, most of the actual regulation addressed itself to competition" (Coppin and High, p. 18) – and the strongest forces seem to have been those of commercial self-interest.

Another important area of early food regulation, milk, would appear at first glance to have been more driven by safety concerns (and thus more in line with our modern understanding of food safety regulation, and with the official pronouncements of proponents of regulation) – but a closer look makes this seem less of a clear case. Milk has long held a particular place in North-Western European and North American food culture[114] - and in the 19th century fresh milk was the only substitute to breastfeeding for infants. Because of its inherently high epidemiological risk (a warm, nutrient-rich liquid is just about the most conducive medium for bacteria growth), milk was certainly a major factor in food-borne disease outbreaks (and consecutive deaths) in the 19th century – in fact, even before the science to explain it (Pasteur's and Koch's discoveries in particular) emerged, observation of epidemics origins and spread led to the conclusion that milk was involved in a number of them – "the first typhoid fever outbreak traced to milk was in the year 1857, in Penrith, England" (North 1921, p. 247). In this context, it is not surprising that some early efforts to impose new rules and controls focused on milk. In New York City in the 1830s, a "crusader against impure milk", Robert M. Hartley, launched a campaign against "swill milk" – milk produced by cows held in stables adjacent to alcohol distilleries in the city, and few "swill", the remnants of fermented grain and malt used for distillation. He saw "distillery milk as the primary cause of death among slum children" (Young 1989, p. 36) his arguments combined religious piety, "common sense public health" and compassion. A 1848 report by "a committee of the New York Academy of Medicine (…) blamed swill milk for the high infant death rate in the city" (*ibid.*). Then in 1858, Frank Leslie's Illustrated Newspaper launched a "major continuing campaign" against swill milk – with pictures that attempted to "depict the filth of the stables" (*ibid.,* p. 37). While conditions depicted by Leslie's reporters were indeed quite gruesome, they went further and "quoted physicians reiterating the earlier charge that distillery milk was the leading cause of infant death" (*ibid.,* p. 38). The City Aldermen, however, essentially did nothing – some very friendly investigation, leading to them declaring distillery milk fully fine. Young sees this as a clear proof of corruption resulting in Aldermen protecting the industry – which, knowing the 19th century "Tammany Hall politics" is indeed quite likely. What is interesting, however, is that modern science does *not* support Leslie's (and others') insistence that "swill milk" was particularly bad. In fact, distillery residues are highly nutritious feed, and are among the animal feed types routinely used in modern farming[115]. That "swill milk" was held to be uniquely evil was most probably due to the religious and moral vision of its opponents, and the link with anti-alcoholism views. Probably, distillery stables had indeed very poor hygiene and practices, and their milk was unsafe – but so was the milk from pretty much every stable at the time, regardless of how "natural" and "rural" it was. Eventually, "swill milk crusaders" were successful - in 1862 the State adopted a law making it "a misdemeanor to sell of exchange 'impure, adulterated, or unwholesome milk" (…) [and] keeping cows in "crowded or unhealthy conditions' and feeding them food that made their milk impure" (*ibid.,* p. 39) and an amendment two years later clarified that distillery milk was "automatically impure". But this is vanishingly unlikely to have had any significant effect on public health, in particular on infectious diseases. What was to change matters on that front was the understanding of microbial contamination, and how to prevent it.

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What has increasingly emerged as modern "good practice" food regulation, however, is that such "labeling" rules are mandatory only to the extent that one wants to use a certain name that is protected by legislation – but producers are free to put other goods on the market, as long as they are safe. In many countries, however, food standards are fully mandatory, i.e. it is forbidden to produce and sell goods that are not included in the list of food standards, and/or not made in accordance with them (this is the case in many post-Soviet countries).

[114] See Ferrières 2002 pp. 99-104 and 387-389 or, for a more recent example (and from the United States), North 1921.

[115] See e.g. the absolutely neutral, dispassionate and factual account in the Feedipedia portal (a joint project of INRA, CIRAD, AFZ and FAO): http://www.feedipedia.org/node/4266.

## The run-up to the 1906 Pure Food and Drugs Act – progress without regulation, and a jarring scandal

In 1906, after several decades of discussions about the topic, Congress adopted the first real federal regulation of food and drugs – the Pure Food and Drugs Act. The "classical narrative" is one of a breakthrough against industry abuse, and of the forces of progress finally overcoming corrupt opposition. The impetus for the Act's adoption was given by Upton Sinclair's *The Jungle* – a book whereby he in fact purported to advocate for socialism against the havoc wrecked by capitalism upon the poor's lives, but whose descriptions of astonishing malpractice in Chicago's "meat packing" industry led to a public outcry against slaughterhouses and factories seen as poisonous and deceitful. The direct cause-and-effect relationship is taken as granted by most authors: "public outcry over unsanitary meat products in the early 20th century resulted in the passage of the Pure Food and Drug Act of 1906" (Manion 2012, p. 539).

Several elements are in fact somewhat puzzling for a modern analyst of food safety regulations and inspections. First, food safety is commonly seen as being one of the areas where incentives for producers/sellers are to a large extent aligned with regulatory objectives: indeed, poisoning one's customers is rarely good business, and unlikely to lead in increased or sustained market share – thus, deliberate flouting of hygiene and other food safety rules (as opposed to involuntary mistakes) is expected to be rarely seen outside of "fly-by-night", deliberately criminal operators, who aim at a quick profit before disappearing. How to understand, then, that the Chicago "meat packers" exhibited such massive, total, lasting disregard for all the most basic, "common sense" precautions? Second, a substantial part of the food industry was in fact actively working on improving safety – for well-understood commercial reasons (and, possibly, for philanthropic reasons too in some cases). The first federal meat inspections themselves were "made available at the request of meat packers whose products needed Government endorsement before they would be accepted for import into certain foreign countries" (Wagstaff 1986, p. 630)[116]. It had long been understood that higher, more reliable safety could be a commercial argument – in the mid-19th century, the inventor of condensed milk, Borden, "had to overcome any suspicion that his milk was contaminated. He developed a strict set of sanitary rules for the farmers (…) and even sent inspectors around" (Coppin and High 1999, p. 20)[117]. In fact, some of the most significant changes in production and processing practices in terms of reducing morbidity and mortality were introduced voluntarily by the industry, using processes recently developed by scientists and inventors, with very little or no regulatory pressure, at least at first – this is particularly the case for milk. As North (1921) retraces, medical and scientific developments in the years 1880-1890 led to better understand the "necessity for heating milk for the artificial feeding of infants" (p. 238, see also pp. 265 and 269-277). Improvements in sanitation of dairy in the early 1900s were an important step (*ibid.*, pp. 265-266), but what brought a "decided drop in the number of epidemics (…) and also a great reduction in the infant mortality" (*ibid.*, p. 242) was the spread of milk pasteurization in 1907-1910. This, however, had nothing to do with the Pure Food and Drugs Act (or the Meat Inspections Act) of 1906, neither of which mandated pasteurization. Rather, it was primarily driven by the industry itself (eager to secure market share with a demonstrably safer product), gradually supported by a number of municipal regulations (*ibid.*, pp. 275-277).

Considering this, while it would not be surprising at all (in the context of a still very partial understanding of microbiology and other food safety issues) that the *Jungle*'s "meat packers" would have *some* important lapses in hygiene or cross-contamination control, Upton Sinclair's description of pure horror remains puzzling. It

[116] But early meat inspections had limitations: "A meat inspection law was passed in 1891, but this law was not very effective and meat inspection did not become so until 1906, when the present meat inspection law was passed and machinery in the Bureau of Animal Industry provided for its enforcement" (Alsberg 1921, p. 216)

[117] This helped him gain a very strong standing in the regional market around New York – the Civil War then proceeded to make his product a major success nationally, as a fundamental army supply.

would be tempting to partly dismiss it as literary hyperbole, but all accounts report that President Theodore Roosevelt's envoys on site generally confirmed all or most of the book's descriptions (see e.g. Young 1985). Now, it may of course be that these envoys were also complicit in a conspiracy aimed at tarnishing the meat industry and helping the adoption of new legislation, but this kind of conspiracy theory makes for bad history. Far more likely is that conditions in Chicago's slaughterhouses and the attached processing plants were indeed really dismal – but the modern reader then is bound to think "how was there no outbreak of fatalities prompting action, why was a novelist's work necessary?". Several hypotheses come to mind. First, there might indeed have been an increase in morbidity and mortality, but little noticed among a generally high prevalence of infectious diseases and overall far higher mortality compared to today's rates. Second, meat was at that time generally thoroughly cooked – this would have strongly limited the potential for infections – remained possible chemical contaminations, but even all the dirt described by Sinclair as making its way into sausages would not generally have killed people in any sudden way. Any spikes in morbidity would likely have taken years to be visible, and only if there had been serious statistical research (which was not yet the case). It thus seems that, in an age of higher mortality, weaker statistics and safer cooking habits, the "meat packers" could maybe genuinely think they could get away with such practices without losing their customers. Once exposed, however, the damage was severe, particularly for exports - "in response to these types of writings, American meat purchases, both domestic and foreign, fell by one-half. As a result, Congress passed the Pure Food and Drug Act and the Meat Inspection Act in 1906" (Manion 2012, p. 539).

Still, from the above it is obvious that what could be called the "*Jungle* meat packing scandal" was only one part of the story – the last drop, rather than the main driving force. As we have outlined above, there was a coalition of interests and beliefs at play, as well as scientific theories – which all seem to have pre-existed any actual scandal or outbreak. Coppin and High (1999) see the 1906 Acts[118] as linked to a combination of "conflict between local and national food companies" (with "federal regulation [conferring] competitive advantage on national firms") (p. 6) and "bureaucratic entrepreneurship" on the side of the Bureau of Chemistry and Wiley, his head (p. 5). In support of this perspective, it is noted that the new regulations and control power did relatively little (at least in the short term) to effectively promote safety (in spite of their claims to this effect) – in fact, "the 1906 [Act] was built on the idea that false claims must be prosecuted, rather than addressing the real issues of whether food put on the market [was] safe" (Manion 2012, p. 542). The Act did deem food to be adulterated "if it contain[ed] any added poisonous or other added deleterious ingredient which may render such article injurious to health" (*ibid.*, p. 539) but it made no difference between this and other (relatively harmless) forms of adulteration, and had no provisions for preventive control at the production or processing stage.

Most research seems to concur on the question of *trust* having been the most fundamental and powerful driver for the new regulation – both in terms of long-term, deep trends, and in the way the "meat packing" scandal unfolded and was addressed. At its core, the increasing demand for food regulation came from "the transformation of the United States from an agrarian to an industrial society changed the way in which people ate. Food became something to be purchased rather than something to be home-grown" (Coppin and High 1999, p. 18). "Through urbanization, consumers and producers became strangers to each other, separated by distance, and through industrialization, dairy products also became strange to consumers, created by mechanisms of production that were no longer part of the general knowledge of an agrarian population" (Swanson 2011, p. 339). With food obtained more by trade than self-production, and trade increasingly

[118] Note that the Pure Food and Drugs Act is mentioned far more often than the Meat Inspection Act, even though one could argue that the latter was far more important to advance actual food safety at least for the first decades (until the Food and Drugs Administration – FDA – was created and its powers increased) – just as nowadays the FDA is far better known than the US Department of Agriculture's Food Safety and Inspection Service (FSIS), even though the latter plays a major role in ensuring safe food (in charge of all the meat supply chain). Whether this is due to the more striking name (including "food" prominently), the different institutional status, or other causes, it somewhat distorts the public perception of the US food safety system.

involving large distances and very unequal actors (individual consumers vs. large corporations[119]), trust increasingly became problematic. Regulation and regulatory control (inspections) came to be increasingly seen as a response to this breakdown of trust – as an instrument that would make it possible to move from "trust from familiarity" (which was not possible anyway) to "trust in rules and control" (which was to be established).

Very interestingly (and this is one of the reasons why we thought it worthwhile to present this historical account in some details), the situation has many similarities with what is observed in contemporary regulatory issues, and with a phenomenon that has been coined the "Risk Regulation Reflex"[120]. In both cases, a real issue of lack of trust on the side of customers and citizens is used by active interest groups to promote specific regulations that correspond to their (financial, professional or ideological) interests – the resulting regulation may have some benefits for safety, but its costs may be higher than its benefits, and/or its impact on safety may be far smaller than its effects on competition, markets etc. Coppin and High (1999) thus write that "on the consumer side, the change from growing food on the farm to buying it in the market created doubts about purity and healthfulness. These doubts were the origin of demand for food experts" (p. 33). They also insist on the importance of "bureaucratic entrepreneurs" in promoting new regulation, on the need for such "entrepreneurs" to "influence voters or elected officials" (p. 13) – reminding that "voter preferences (…) can be manipulated and created through the information and misinformation provided" (p. 14). Such an account is very close to what Helsloot and Schmidt (2012) write about the role of "experts" in pushing for new regulation in a "Risk Regulation Reflex" situation: "The single minded risk professional is (…) only interested in the best possible defence against his own pet risk, his advice is difficult to ignore for administrators when they have no other means of mobilising expertise to balance that advice" (p. 312). They also expose the way in which "risk experts" effectively work to *shape* public opinion in favour of regulation "no matter the costs", whereas an informed and nuanced public debate could end up with public opinion striking a very different balance (pp. 308-310).

### The early days of food regulation in the 20th century

The twin Acts of 1906 (Pure Food and Drugs and Meat Inspection) foresaw significantly different provisions and mechanisms, and led to different evolutions. The Food and Drugs Act[121], as we briefly indicated, mostly went after "adulteration" and "deception" – it was more about ensuring that label were not deceiving consumers than controlling production, and constitutional limitations also meant that it had to be combined with state legislation in any case (which was also true of the Meat Inspection Act): "because of the limitations of Commerce Clause jurisprudence, it outlawed [only] the interstate shipment of "adulterated" or "misbranded" food or drugs and their manufacture [solely] within the District of Columbia and the territories" (Swanson 2011, p. 363).

The focus for meat inspections was relatively clear from the onset – led by the Bureau of Animal Industry, they took place at slaughter/processing stage, they concentrated largely on "controlling Trichina and other types of parasitic infestations of meat" (Wagstaff 1986, p. 628). Over time, these infestations (and their health

[119] Quoting Coppin and High: "mass distribution in the form of chain stores" as well as "large firms that integrated mass production with distribution had begun to appear in the 1880s and 1890s" (p. 18).

[120] See on the "Risk Regulation Reflex" (RRR) e.g.: Tol 2012, Tol 2014, Helsloot & Schmidt 2012 (a), and Blanc, Macrae and Ottimofiore 2015.

[121] It is worth pointing out that the way the Act was drafted was not a foregone conclusion – it ended up conforming mostly to Wiley's vision, but many others had pushed for alternative approaches: ""Wiley's version of a pure food law was vigorously opposed by many respectable persons who simply wanted a different law". Many (but not all) state food officials "favored national legislation, but could not agree on the administrative mechanisms of a national law (…) Some advocated (…) a new agency headed by a national food commissioner (…) Others saw little need for a regulatory agency at the national level; they believed that a law allowing states to regulate all foods entering a particular state would be sufficient" (Coppin and High 1999, pp. 5-6). On this last point, modern experience and science strongly suggest this belief was mistaken – and indeed "with even fresh milk crossing state lines from producer to consumer, the best efforts at the state level were unsatisfactory" (Swanson 2011, p. 349).

effects) indeed went down "there were 13 deaths reported for Trichina in 1913 compared with none in 1978" (*ibid.*). By contrast, the Bureau of Chemistry that was tasked with implementing the Food and Drugs Act controlled mostly at the market stage, with a far broader scope, and with less clear-cut rules. The Act prohibited "adulterated", "misbranded", "poisonous" etc. foods, but with no clear guidelines on how to assess this – and "judicial decisions narrowed the capacity of the Bureau of Chemistry to enforce the statute by requiring high standards for proof of fraudulent intent" (Manion 2012, p. 541). In addition, enforcement powers were burdensome to use: "it required that the government take each offender to court and prove that each particular food was adulterated or mislabelled, and by what standard it was making that judgment." (*ibid.,* p. 542). This means that, even though inspectors apparently very easily found a number of violations (Young 1992, p. 120), it is unclear how much of an impact they could have on the *overall level of safety* of the food supply.

In terms of approach and methods, the Bureau under Wiley was very prone on controversy, with the support of "some branches of business" hoping to use this "as a weapon against competitors" (*ibid.,* p119). The "impetuousness" of Wiley led his superiors to start to "distrust his science" (*ibid.*) and he was eventually replaced by Alsberg (*ibid.*). In these early days, methods were still to be developed, and planning was essentially non-existent: "the inspectors, hired to collect samples of foods and drugs entering interstate commerce, were given minimal training and no structured plan of action was initially devised" (*ibid.,* p. 120). Interestingly, after the initial "conflict-oriented" phase, a far more "cooperative" approach emerged: inspectors found that "shortcomings seldom resulted from "wilful intent" but rather from "law or faulty control" systems" – and this cooperative approach allowed the Bureau to overcome (to some extent) the Act's limitations: "the law did not give the Bureau direct authority over sanitation in processing plants, but inspectors (…) realized how poor sanitation could lead to illegal products" and passed on this lesson to manufacturers" (*ibid.*, p.120). Manufacturers, in turn, often agreed to follow these recommendations to keep good relations with Bureau officials.

Gradually, "the Bureau's somewhat haphazard method of sample collection [was replaced] with a project system (…) [which] set priorities of effort for each year" (*ibid.,* p. 121). Investigation of outbreaks (as the botulism poisoning case with olives in 1920) led to new knowledge and new processing standards. The "*entente cordiale"* between "regulators and major segments of the regulated industries" allowed officials to proclaim victory over "adulteration and misbranding". It is interesting to note the sharp contrast with OSH: whereby OSH inspections in the United States are (as we have seen above) characterized by a high emphasis on deterrence, and very limited discretion, food safety inspections from early on were far more "cooperation-based", and far less rigid. It is likely, in fact, that this experience, and the claims (justified or not) of "regulatory capture" that it led to, was an important factor in the way the OSH Act was drafted.

### Weaknesses and reform – from the 1938 Food, Drug and Cosmetic Act to the 2011 Food Safety Modernization Act

In 1927 already the Bureau of Chemistry had become the Food, Drug and Insecticide Administration – but changes in name were not sufficient. The crisis that triggered legal reform was drugs-related, but affected food regulation and inspections too. The "Elixir Sulfanilamide" scandal resulted in 107 deaths in 1937 (Manion 2012, p. 542) – and it showed that the focus on "adulteration" was clearly insufficient. In fact, the "Elixir" was mostly compliant with existing rules, and the FDA could have done little against it *before* people died – the ingredients used were legal, and the label compliant with rules. However, one of the ingredients had not been tested for safety, and proved mortal. The new Act brought completely new powers to the FDA: it "authorized administrative establishment" of definitions of "standards of food identity" (*ibid.*) and also established "remedy of court injunctions" and "authorized factory inspections". On its basis, the FDA "established food standards and lists of [authorized] ingredients" (*ibid.,* p. 542-543).

*Problems in the US food safety regulatory system – reality or perception?*

While US food safety regulations and controls continued to develop in the subsequent decades, many criticisms have been made of insufficient modernization, inadequate methods, lacking resources, weak enforcement - "at the turn of the twenty-first century, Americans are inundated with news stories suggesting that their food and drugs are not safe. (…) Often, critics suggest that the FDA is inadequately funded to perform this inspection role well (…). Other critics identify overregulation by the same agency" (Swanson 2011, p. 332). International comparisons have their pitfalls, but in the past couple of decades at least EU food regulations have increasingly appeared stricter, and better enforced, than US ones, at least to a number of observers[122] – even though this is a highly debated issue, with data pointing in opposite directions[123] (and presenting many reliability issues anyway), and there are many more differences that may influence the results (for instance the significantly higher income level of the US, with the EU incorporating countries with very different GDP/capita levels, histories, regulatory systems etc. – all of which means that *even* if its regulatory enforcement system were indeed more effective[124], the EU could well have overall worse outcomes on food poisoning than the US). At this stage, it is enough to note that there was growing agreement that the US system *needed improvement* – in methods, powers, and practice[125].

From an anecdotal perspective, a number of high-profile cases in recent years have pointed to apparent weaknesses in the US's food safety inspection and enforcement system. In 2015, an outbreak of Listeria

[122] For arguments and data suggesting higher effectiveness of the EU food safety regulatory system over the US one, see e.g. the following articles in ThinkProgress (website of the Centre for American Progress): http://thinkprogress.org/health/2014/09/30/3573680/trade-deal-europe-food-safety/ and http://thinkprogress.org/health/2013/02/20/1601231/meat-industry-horsemeat/ (but both compare two sets of data that are not directly comparable, resulting in incredibly low disease prevalence in the EU – the source for their EU data is here: http://www.foodsafetynews.com/2010/01/food-ills-sicken-45000-kill-32-in-eu/#.VX2d49LS383). For a contrary view that the US system performs better, see e.g.: http://achesongroup.com/2014/03/foodborne-illness-us-eu-compare/. In fact, none of the data sets are fully reliable (too much depends on self-reporting, detection rates etc.).

[123] Many arguments centre on the relatively low life expectancy in the US given its high income level, and the fact that it used to have higher life expectancy than all EU members – and now lags many of them – see e.g. for a ranking of countries https://en.wikipedia.org/wiki/List_of_countries_by_life_expectancy. Any internet search of "life expectancy US Europe" will return a number of articles drawing conflicting conclusions. While causality is clearly complex, broadly-defined "lifestyle" and "environmental health" are likely to play a role (along with health care) – and food safety could be a part of the explanation (but most likely very minor). Other food issues (nutrition) are likely to be far more important, and are also handled differently by regulators on both sides of the Atlantic.

[124] In spite of *perceptions* on both sides that one or other system may be "stricter" or "more risk-averse", research suggests caution in conclusions. Wiener *et.al.* 2011 showed that the level of precaution is higher in the EU for some areas, higher in the US for some others. For a specific application to food safety, see a summary presentation of findings by Wiener at: https://ssri.duke.edu/sites/ssri.duke.edu/files/Wiener_Duke_Food_Working_Group.pdf - which again suggests the importance of different risk perceptions leading to different intensity of responses to different risks, with variations between the EU and US – rather than a uniform trend of one or the other being more "risk averse". A 2005 presentation by G. Kushner on the US Farm Foundation website provides a convenient comparison of some aspects of the two systems: http://www.farmfoundation.org/news/articlefiles/971-gkushner.pdf - but, as several other documents written in the US, it focuses in our view too much on the European Food Safety Agency (EFSA), which is not at all analogous to the US FDA, but rather is only in charge of scientific risk assessment. The operational coordination is ensured by the EC Food and Veterinary Office (see below), a very important entity (and often insufficiently perceived as such).

[125] For more detaild insights see e.g. Fagotto 2015

monocytogenes in *Blue Bell Creameries* products comes at the latest[126], and shows that "upmarket", highly regarded brands are not immune to problems[127].

This comes on top of several significant scandals in the past. In 2009, a major *Salmonella* outbreak[128] was traced to *Peanut Corporation of America* products – and investigations revealed that violations at this firm's plants had been particularly blatant, and repeated over the years[129]. Eventually, this became one of the rare cases in the US where a guilty verdict was delivered on criminal felony charges – highlighting the particularly reckless behaviour of the management, and the way in which the contamination resulted from intentional and major safety violations aimed at increasing (or maintaining) profits[130]. Major outbreaks have repeatedly been linked to the fast food chain *Taco Bell*: a 2006 *E.coli* outbreak that sickened dozens and killed at least 3[131], and *Salmonella* outbreaks in 2010 and 2011[132]. One of the early cases that led to developments in food safety practices and in regulatory discussions was the 1992-1993 *Jack in the Box* fast-food chain *Salmonella* outbreak[133].

Of course, an anecdotal collection of outbreaks does not substitute statistically significant data, and there are conflicting arguments as to whether the recent *Listeria* ice cream contamination cases reflect systemic issues with the US food safety system, or just the difficulty to control this bacterium (suggesting that the EU should not feel that is immune to such problems)[134] . Different outbreaks point to different issues. While the 1993 outbreak arguably opened a "new era" of heightened attention to microbiological contamination[135], and while the company (*Jack in the Box*), after dramatically botching its initial response, changed tack and ultimately became by some accounts a "leader" in food safety practices[136], the successive outbreaks and controversies at and around *Taco Bell* show how some other firms are far slower at improving – and seem to tend to fight

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[126] As of late Spring 2015, the outbreak caused 3 fatalities. Details are avaialable on the CDC website: http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm438104.htm and the final CDC update on this outbreak here: http://www.cdc.gov/listeria/outbreaks/ice-cream-03-15/ as well as additional information on the Wikipedia page for *Blue Bell*: https://en.wikipedia.org/wiki/Blue_Bell_Creameries#2015_recalls.

[127] *Jeni's Ice Creams*, another (smaller) upmarket brand, has also had to conduct a *Listeria*-caused recall at the same time, though so far no human cases have been reported because of it – see: http://www.foodsafetynews.com/2015/05/a-tale-of-two-recalls-blue-bell-and-jenis-ice-cream/#.VYPKcNLS381. This article also points out the difficulty and complexity of *Listeria* management.

[128] See detailed description of the outbreak on the CDC website: http://www.cdc.gov/salmonella/typhimurium/update.html.

[129] See Wikipedia page for *Peanut Corp. of America*: https://en.wikipedia.org/wiki/Peanut_Corporation_of_America#Inspection_findings.

[130] See a CNN news report on the case and verdict: http://edition.cnn.com/2014/09/19/us/peanut-butter-salmonella-trial/.

[131] Details on the outbreak from the CDC: http://www.cdc.gov/ecoli/2006/taco-bell-12-2006.html and overview from Wikipedia here: https://en.wikipedia.org/wiki/2006_North_American_E._coli_O157:H7_outbreaks.

[132] The CDC description of the 2010 oubreak is here: http://www.cdc.gov/salmonella/baildon-hartford/index.html and that for the 2011 outbreak is here: http://www.cdc.gov/salmonella/restaurant-enteriditis/011912/ but in both cases the CDC refused to specifically name *Taco Bell* – see on this point several articles (quoting several state food safety authorities among other sources): on the 2010 outbreak http://www.foodsafetynews.com/2010/08/taco-bell-sued-over-salmonella/#.VYVyrtLS380 - and on the 2011 onea number of articles: http://www.foodsafetynews.com/2012/02/analysis-restaurant-a-revealed-to-be-taco-bell/#.VYVyndLS380, http://www.theatlantic.com/health/archive/2012/02/restaurant-a-how-bill-marler-tied-taco-bell-to-salmonella-outbreaks/252778/ and http://www.cbsnews.com/news/taco-bell-tied-to-2011-salmonella-outbreak-that-sickened-68-report/.

[133] See CDC summary here: http://www.cdc.gov/mmwr/preview/mmwrhtml/00020219.htm and the Wikpiedia page on the outbreak, which outlines the follow up and consequences: https://en.wikipedia.org/wiki/1993_Jack_in_the_Box_E._coli_outbreak.

[134] Arguing that the outbreaks reflect systemic US issues is e.g. this article (but it is by an author writing mostly about environmental issues):
http://www.salon.com/2015/04/24/americas_frightening_food_safety_gaps_how_our_massive_complex_system_undermines_public_health/ - on the other side, this article in a professional food industry website suggests the problem could just as well affect Europe: http://www.foodmanufacture.co.uk/Food-Safety/Listeria-in-ice-cream-could-also-be-a-UK-problem. The EC regulations on *Listeria* emphasize HACCP-based control (which is only now becoming mandatory in the US, see below) – but they also allow for residual levels of the bacterium that are higher than the levels found in some US outbreaks – see EC guidance here: http://ec.europa.eu/food/food/biosafety/salmonella/docs/guidoc_listeria_monocytogenes_en.pdf and UK FSA guidance here: http://www.foodlaw.rdg.ac.uk/pdf/uk-06001-micro-criteria.pdf.

[135] See on how it opened a "new era" in food safety practices and regulations here: http://www.foodsafetynews.com/2013/01/food-safety-since-jack-in-the-box-progress-made-and-progress-still-needed/#.VYWJ0dLS380.

[136] See for instance: http://www.ou.edu/deptcomm/dodjcc/groups/02C2/Jack%20in%20the%20Box.htm.

back against criticism more than they actually solve problems. The recent *listeria* outbreaks may point to specific weaknesses in the US regulatory requirements and controls[137] – but they may also indicate how difficult the bacterium is to control, something that may come to create challenges for other food safety regulatory systems.

A note of context is required to assess better the degree to which these large food outbreaks reflect (or not) on the underlying robustness of the food safety regulatory regime, and of regulatory enforcement and inspections in particular. The United States has a very different enterprise structure from the EU: large enterprises (more than 500 employees) make up a substantially larger share of total number of firms and (even more strongly so) of total employment – and this holds true in manufacturing and services (in particular food service)[138]. This means that, considering a unified supply chain for many large food firms, outbreaks may mechanically end up being larger and more "visible", even assuming identical prevalence rates for a given disease. There may also be a specific vulnerability linked to size and methods of animal feeding commonly used in the US: concentrated animal feeding operations (CAFOs) a.k.a. "feed lots" present strong potential for spreading of bacteria strains to a vast number of animals[139]. A tendency to have generally much smaller food service operations in the EU may have led so far to more fragmentation and more isolated, undetected cases. Supply chain integration, conversely, brings the potential for larger, observable outbreaks, such as the infamous 2011 *E.coli* outbreak originating in Germany and caused by fenugreek seeds used for sprouts[140].

Overall, in spite of claims made on both sides, and of the obvious elements of imitation of some aspects of EU regulations in the 2011 FDA Food Safety Modernization Act (see next section), it is not possible on the basis of available data and research on whether the US food safety regulatory system performs worse, better, or on the same level as the EU one. Some US-specific features, such as the greater reliance on litigation as a compliance driver, may relate to characteristics of the entire regulatory enforcement regime, and not only to food safety. Indeed, in the US, class action suits are an important force driving regulatory compliance[141] - and this is true across all regulatory fields. By contrast, in spite of developments in the past few years, class action possibilities and practice in EU countries are still narrow and limited in scope, as well as in the amount of damages (and thus deterrence strength)[142]. In this perspective, one could argue that the salience of civil lawsuits in food safety scandals in the US is as much a reflection of a strength (the power of this avenue of

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[137] In particular the lack of systematic testing for *listeria* (which was not legally mandated), and the delays between the first test results showing *listeria* and the broader recalls – see this set of articles on these inter-related issues: http://dfw.cbslocal.com/2015/05/22/fda-documents-show-early-problems-at-blue-bell-plants/ - http://www.dallasnews.com/business/headlines/20150605-blue-bell-ice-cream-made-in-alabama-was-tainted-with-listeria-private-lab-says.ece - http://bizbeatblog.dallasnews.com/2015/05/blue-bell-explains-why-it-didnt-test-its-ice-cream-after-first-discovering-listeria.html/.

[138] See OECD 2005 (b) pp. 18-20 and OECD 2014 (b) pp. 26-33.

[139] For the argument that the apparently somewhat larger number of major outbreaks in the US reflects the size of operations, and thus makes it possible to observe outbreaks (as opposed to a number of isolated, apparently unrelated, and often unresearched cases), see this article by Bill Marler (one of the leading attorneys involved in the 1993 *Jack in the Box* litigation, on the victims' side): http://www.foodsafetynews.com/2013/03/publishers-platform-mcdonalds-and-e-coli-30-years-later/#.VYWJ3NLS380.

[140] This case clearly showed the vulnerability of at least some EU Member States' systems (in particular Germany) – see e.g. Wikipedia's article on the outbreak: https://en.wikipedia.org/wiki/2011_Germany_E._coli_O104:H4_outbreak and see how it compares to other food outbreaks here: https://en.wikipedia.org/wiki/List_of_foodborne_illness_outbreaks_by_death_toll (which again anecdotically suggests a higher number of *large* outbreaks "making the news" in the US compared to the EU).

[141] Even though there is an old usage of "private prosecutions" in the Common Law tradition, most class actions are strictly *civil* cases, not penal, and thus usually do not involve the award of criminal (or other) sanctions that would stem from the regulations directly – in this narrow sense, they are thus not an "enforcement" action. However, because the damages awarded are potentially extremely high, US class action lawsuits often have a stronger "enforcement" effect (in the broader sense), and definitely a very strong power of deterrence.

[142] For comparisons of US and EU practices in class actions, see: short overview but with a number of useful links and references http://www.cpradr.org/About/NewsandArticles/tabid/265/ID/593/International-Practice-OverviewComparison-of-US-EU-Judicial-Class-Action-Structures-Web.aspx - a far more detailed summary of practices in different EU Member States can be found here: http://www.libralex.com/fr/publications/class-actions-in-europe-and-the-us - an EU FAQ on "collective redress", including comments on the European Commission's concerns about the US system leading to "excessive litigation" can be found here: http://europa.eu/rapid/press-release_MEMO-13-530_fr.htm.

redress as a driver for regulatory compliance and safety improvements[143]) as of potential weakness (of the federal and state regulatory enforcement system). The few cases of major food scandals briefly outlined above, however, do suggest that some of the concerns with the US food safety enforcement system may indeed be founded: one company (*Taco Bell*) not only was repeatedly involved in several outbreaks (suggesting limited, if any, improvements in handling practices and internal control systems), but was shielded from negative publicity by the CDC and FDA (and thus one of the most important compliance drivers was left unused). In the *Blue Bell* outbreak, delays in identifying the problem point to weaknesses in internal control (HACCP-type) implementation, lateness in recalls indicate insufficiently strict legal requirements in terms of food business operator responsibilities, and so does the fact that *listeria* problems appear to have been "endemic" at *Blue Bell* facilities for a while. All this anecdotal evidence does not allow to adjudicate conflicting claims of effectiveness between the EU or US (nor is this necessary for this study), but do suggest that there are some aspects of concern in the US system – and we will see in the next section what efforts are currently made to address them.

### *Addressing the problems? The Food Safety Modernization Act, and implementation difficulties*

The 2011 FDA Food Safety Modernization Act came as the result of several years of pressure for reforms (with a first Food Safety Enhancement Bill having passed the House in 2009 already), and negotiations in Congress. It focuses on the FDA, and to a large extent bridges an important gap in powers and approaches between the FDA and the USDA FSIS, in charge of meat inspections. In the approaches it mandates, the requirements it puts on food business operators, and the new powers it gives to the FDA[144], the Act is clearly strongly inspired by current EU food safety legislation (namely the 2004 "Hygiene Package" and in particular EC Regulation 882/2004 on Official Food and Feed Controls[145]).

The Act grants "greater systematic oversight of all food production facilities" (Manion 2012, p. 537). It specifically gives increased inspection powers – including "comprehensive preventive controls for most facilities" (*ibid.,* p. 546), rights of access to records, as well as a mandated (minimum) inspection frequency for high risk establishments[146] (*ibid.,* p. 548). Specifically, "the frequency of food facility inspections will be based on the level of risk associated with the facility, and an increased risk level will result in immediate increase in inspection frequency. All high-risk domestic facilities must be inspected within five years of the date of enactment and no less than every three years after that." (*ibid.,* p. 549)

It also introduces new requirements for food business operators, e.g. mandatory testing in accredited laboratories for specific food products and contaminants (p. 548). The Act emphasizes the "scientific" basis of new regulation: it "mandates that the FDA 'establish science-based minimum standards' to conduct hazard analysis and employ preventative controls" (*ibid.*, p. 538). In the Act, "science based" specifically means approaches similar to Hazard Analysis and Critical Control Point (HACCP) methodology, data collection and

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[143] See OECD (2014) principle 2 suggesting the usefulness and relevance of class-action as a regulatory compliance driver. See also Bentata and Faure (2015) for an example of how collective litigation can powerfully drive changes in regulatory compliance and regulations.

[144] See explanation, contents, guidance on the FDA website at: http://www.fda.gov/Food/GuidanceRegulation/FSMA/.

[145] See summary and full text of the 882/2004 regulation on the EC website at: http://europa.eu/legislation_summaries/food_safety/veterinary_checks_and_food_hygiene/f84005_en.htm.

[146] The fact that the Act sets a *minimum* frequency, that is mandatory for the FDA to achieve, speaks to the *ex ante* situation as being one of (at least perceived) under-inspection. In a number of countries, as we will see in subsequent chapters, risk-based planning serves to *reduce* the frequency of inspections – in the US food safety context, it is being used as basis for an increase. Indeed, as we will discuss in the last chapter and conclusion, there probably is a lower threshold under which risk-based inspections are not effective anymore because overall inspections are too rare – in this perspective, this provision of the FSM Act can indeed make sense.

management to monitor and assess epidemiological risks, and is also to be understood in line with the World Trade Organization Sanitary and Phytosanitary Agreement (WTO SPS)[147] (*ibid.,* p. 539).

In a US context where introducing new regulation tends to be very difficult because of concerns about administrative burden, the Act specifically "includes language to alleviate undue burdens on small food producing facilities" (*ibid.,* p. 549) – but its adoption did meet a lot of resistance by wholesalers, farm organizations, small and organic farm advocates[148] etc. (*ibid.,* p. 545).

As we have mentioned, rather than breaking entirely new ground, the Act (to a large extent at least) is rather bridging the gap between meat inspections and other food inspections in the US – and between FSIS and FDA powers and methods. The FSIS work has long been strongly "science based" as the Act now mandates the FDA to be[149] (*ibid.*, p. 557) – and HACCP has been a cornerstone of FSIS work and requirements for some time as well. FSIS can serve as a model of "risk-based" inspectorate for the FDA, as it relies heavily on data collection to detect and respond to food contamination hazards. FSIS methodology involves a data analytics technique called the Public Health Information System, a web-based application establishing an automated data-driven inspection system. This system allows "analysts to identify trends that will automatically adjust domestic and import inspections and sampling" (*ibid.,* p. 558).

Adoption of the FSM Act does not, however, solve all challenges with food safety regulations in the US. First, there are significant implementation problems with the Act itself. Second, even though FSIS has in many aspects stronger methods (and has had stronger enforcement powers for longer), there are resource limitations and areas where its methods are questioned. Third, the duality between federal and state-level enforcement not only creates complexity, but also is likely to lead to important variations in effectiveness. Finally, the question of the overall institutional structure remains to be addressed (but is starting to be asked).

Implementing the FSM Act has proven difficult – both in terms of rule-making and of actual controls. The FDA's implementation timeline for the Act shows many draft regulations having been published, but none yet adopted so far (though first approvals are forecast to happen by end 2015)[150]. Possibly even more significant is a major funding shortfall that means the required retraining of staff, additional resources for intensified in-country and border controls are currently not possible to implement. In order to raise the needed resources, "the F.D.A. proposed user fees that would cover the bulk of the cost of carrying out the food safety law. Last year, for example, it asked for $263 million for the law, with about $229 million coming from fees on food companies. But lawmakers soundly rejected those proposals after lobbying by the food industry[151]". As a result, the FDA has asked for budget funding to compensate for the shortfall, but the requested amount is around 50% lower than the projected user fee would have been – and it is unlikely that Congress will even

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[147] There clearly is an increased attention to the international aspect of food safety in the FSM Act, not only by the adoption of language that is comparable to EU or WTO rules, but also by the emphasis on border controls – it "emphasize prevention, inspection and compliance, response, regulations on foreign imports, and enhanced partnerships with other government agencies" (Manion 2012 p. 547).

[148] Two observations are in order here. First, that there has been insufficient assessment of the business and economic impact of the EU 2004 "Hygiene Package" (see below on this point). Second, that there are real tensions between environmental sustainability goals and food safety regulations (particularly the latest "generation" of ever more demanding ones) – which makes the opposition of organic farm advocates relatively unsurprising. This tension between different regulatory objectives (environmental protection, food safety) is one that can be expected to be felt increasingly sharply in Europe as well, even though it is still not really widely perceived.

[149] "The term "science-based" also surfaces often in reference to the Food Safety and Inspection Service (FSIS). The FSIS is a public health agency of the USDA responsible for overseeing the safe production of meat, poultry, and eggs. (…) FSIS assures processes are scientifically validated. Teams of expert auditors conduct periodic in-depth food safety assessments which can take days or weeks to complete and may involve extensive microbiological sampling of the plant's environment and finished products. Annually, FSIS conducts more than 8,000 microbiological tests to verify the production processes are under control" (Manion 2012 p. 557)

[150] See the FDA website here: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm257986.htm and a recent New York Times article: http://www.nytimes.com/2015/09/11/science/food-industry-gets-new-safety-rules-to-prevent-illness.html?_r=0

[151] See New York Times article here: http://www.nytimes.com/2015/04/08/us/food-safety-laws-funding-is-far-below-estimated-requirement.html?ref=topics

approve it (given the current Republican majority's opposition to both government spending and regulation)[152].

On the FSIS side, there are also significant challenges, once again related to funding. Presumably for relatively similar reasons (industry opposition prevailing), FSIS slaughterhouse inspections are not user-funded[153], contrary to what is the case in the EU[154]. Partly as a result of this, and partly because of active policy choices leading to a reform of poultry inspections in 1997, FSIS does not conduct 100% inspection of every slaughtered animal (unlike what is the rule in the EU). To accommodate higher production speeds, and to cope with lower inspection requirements, FSIS allows treatment of chicken carcasses with chlorine or other antimicrobials[155] – which is frequently and sharply criticized, even within the US but most strongly in the EU[156], which has imposed a ban on some imports, resulting in a WTO dispute[157]. Critics of the new FSIS approach (less-than-100% inspections, but a more systemic, HACCP-based control approach – and authorization of the use of antimicrobial products) say that the antimicrobials are toxic for workers, potentially toxic for consumers (though there is no proof of this at present), and that they provide illusory safety only (surface decontamination changes nothing to potential internal meat contamination). The HACCP-based approach has also been strongly criticized as being too industry-friendly[158] – in fact, looking more closely, it appears there is a case of confused goals and designs, resulting in problematic implementation. The changes, introduced following a series of pilots in the late 1990s and early 2000s, apply to all meat inspections – purporting to increase effectiveness, and to put more responsibility on the industry, but doing so in a way that raises concerns about other pressures (cost cutting, industry demands). In 2001, the General Accounting Office conducted an audit of the pilots and of the proposed reforms, and was highly critical: "notwithstanding the project's design problems[159], which we believe make the results unreliable, we found that, so far, the data themselves do not conclusively demonstrate that modified inspections are at least equal to traditional inspections" (GAO 2001, p. 4). The GAO made a series of recommendations[160], which the USDA and FSIS implemented (or at least reported to have followed).

What is remarkable in the case of FSIS reforms and the negative reactions they provoked, is that many food safety experts would agree that the general idea of the reforms is valid: 100% regulatory inspections of carcasses are inefficient and (because they mostly rely on visual checks) not always effective[161], putting more

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[152] See *ibid.*

[153] See on the USDA FSIS website the Federal Meat Inspection Act: http://www.fsis.usda.gov/wps/portal/fsis/topics/rulemaking/federal-meat-inspection-act as well as summary information on slaughter inspections: http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/production-and-inspection/slaughter-inspection-101/slaughter-inspection-101.

[154] For an overview of EU practices see e.g. the UK FSA website – summary here: https://www.food.gov.uk/enforcement/monitoring/meat and the guide to different applicable charges here: http://www.food.gov.uk/sites/default/files/multimedia/pdfs/chargesguide0311.pdf

[155] See applicable regulation and its annexes here: http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/directives/7000-series/safe-suitable-ingredients-related-document

[156] See e.g. the following article in *Bloomberg Businessweek*: http://www.bloomberg.com/bw/articles/2014-08-08/why-chlorine-chicken-from-america-inspires-dread-in-europe and this article in *Salon* for a critical view from within the US: http://www.salon.com/2014/05/26/chlorine_in_your_chicken_why_poultry_is_more_dangerous_than_ever_partner/

[157] See US background paper on this dispute: https://www.fas.org/sgp/crs/misc/R40199.pdf

[158] See an example of such criticisms – *Washington Post* 2013 article: http://www.washingtonpost.com/politics/usda-pilot-program-fails-to-stop-contaminated-meat/2013/09/08/60f8bb94-0f58-11e3-85b6-d27422650fd5_story.html - there is considerable media coverage on this topic, nearly uniformly negative. Also a related article on reductions in the number of inspections in exporting countries: http://www.foodsafetynews.com/2012/11/usda-quietly-eliminated-60-percent-of-foreign-meat-inspections/#.VYfOxtLS381.

[159] The GAO highlights in particular the lack of a control group, and the non-random selection of the plants for the study.

[160] See summary results of the study, and recommendations, here: http://www.gao.gov/products/GAO-02-59

[161] The GAO reports the FSIS inspectors' views that the new system would be more effective (GAO 2001, p.5). This is also the opinion of a number of UK food safety and regulatory enforcement specialists (author's interviews), suggesting that many practitioners have doubts about the old "100% visual inspection" method and suggest it is costly without being really effective.

emphasis on responsibility (and liability) of operators is considered a foundation of modern food safety regulation[162], and HACCP is likewise seen as an approach that is essential to delivering reliable, consistent safety throughout the food chain[163]. The reform, however, reveals some level of confusion between the introduction of HACCP as a requirement and a change in inspection methods (which should logically be two distinct, though related issues), and tensions which seem related to pressure to reform primarily with a cost-cutting and burden-reducing perspective, with effectiveness being more of a window-dressing claim than a real concern. The enforcement weaknesses seen above when dealing with major outbreaks (even though the examples mostly related to the FDA and not to FSIS) may also explain why many (the GAO, food safety advocates etc.) are concerned that FSIS may not sufficiently follow through on the "deterrence" aspect in order to give credibility to this new, more "focused" scheme. In addition, the GAO highlighted problems in the legal basis for FSIS work in terms of enabling discretion and more "focused" inspection activities: "this report reiterates our previous recommendation for legislative revisions aimed at reducing the potential for further legal challenges by providing USDA with clear authority to modify its inspection system" (*ibid.,* p.5).

Overall, even though there is no certainty (at this stage) in terms of health outcomes, there is some evidence that indeed US food inspections are cost-constrained in comparison with what is the case in the EU at least in some respects[164]. A final challenge faced in improving their effectiveness is due to the fragmented structure of food safety control in the US – the duality between FDA and FSIS at the federal level, and the complex articulation of federal and state regulation (with state controls themselves coexisting with local inspections conducted by counties, cities etc.). The boundaries of different agencies' competence are dictated by the history we have tried to outline, and by US constitutional arrangements – but end up being seriously problematic from a "comprehensive food chain safety" perspective (a.k.a. "from farm to fork" or "from stable to table"). While the FSIS controls animals and meat at the slaughter and processing stage, it is neither responsible for milk and dairy, nor for control of animal health prior to slaughter. Whereas the FDA supervises supermarkets, state (or local) authorities are in charge of restaurants. Dairy production is supervised by state authorities, dairy products can be supervised by the FDA if they are destined to interstate commerce, but only by state authorities if they do not cross state borders. The FDA also does not control conditions in farming – the use of pesticides is regulated by the US Environmental Protection Agency (EPA), and state authorities supervise compliance with state laws.

While such complexity and involvement of different agencies and levels is not unusual in practice, it is not easily reconciled with aims of achieving optimal effectiveness and efficiency. International organizations tend to recommend "unified agencies" dealing with most food safety matters, or at least a very clear split of

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[162] See for instance: (a) World Bank Group (2014) – module 2, page 8 (pillar 3) "In a food safety system, primary responsibility (and liability) for the safety of food rests on food business operators" – (b) in the EU context see EU Standing Committee on the Food Chain and Animal Health (2010) p. 14 as well as the text of Regulation 178/2002. In addition, "Directive 85/374 lays down the principle of strict liability of the producer, which means that a producer may be held responsible for a damage caused by a defective product s/he has put on the market even in the absence of fault" (van der Meulen 2013, p. 88).

[163] See the *Codex Alimentarius Recommended International Code of Practice General Principles of Food Hygiene* (links: http://www.fao.org/docrep/005/y1579e/y1579e02.htm and http://www.codexalimentarius.org/download/standards/23/CXP_001e.pdf) – as well as World Bank Group (2014) – module 6, pp. 6-7 (which also mentions the high costs that an excessively "rule bound" application of HACCP in small businesses can entail).

[164] Though the difference exists, it is not as "massive" as critics of recent trends would have it – a comparison of the USDA FSIS audits of foreign countries for meat exports (see here: http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports) and of the EU FVO work programme for third countries (see here: http://ec.europa.eu/food/food_veterinary_office/audit_programmes/docs/fvo_inspect_prog_audit_en_2015.pdf) shows indeed overall more EU FVO audits (and with a somewhat more systemic approach to food safety), but the difference in numbers is not very large (10 for FSIS in 2014, 16 for FVO planned in 2015 counting only FSIS-supervised issues, but with different approaches and FSIS has a somewhat narrower remit, making it difficult to fully compare numbers – this does show, in any case, that FSIS has not become "inactive").

responsibilities with effective data-sharing mechanisms, and coordination of work[165]. Though a memorandum of understanding between FDA and FSIS on data sharing is in place (since 2012 only)[166], it is a long way from automated sharing or integrated information management. While the FDA has undertaken efforts to make state regulations and enforcement more homogeneous[167], this is far from being fully accomplished, and concerns exist about the effectiveness of its audit programme to ensure state inspections are all roughly equivalent[168]. In a number of states, the FDA contracts to a large extent its own oversight to state inspection agencies[169]. The overall result is a system where uniformity of means and methods is far from guaranteed, and where swift communication of information[170], while desired, is not always ensured. In response to this situation, and in addition to the efforts to improve coordination and consistency through the (difficult) implementation of the FSM Act[171], there have been growing calls for the creation of a unified food safety agency. In Congress, a proposal has been made to create a new, centralized "Food Safety Administration", and President Obama has expressed support for the initiative and included a variation of it (consolidating all existing agencies under the Department of Health and Human Services) in his 2016 Budget proposal[172]. While the current political situation (in particular the Republican majority in Congress) mean this is unlikely to happen any time soon, the proposals show that policymakers' views on the topic are evolving towards more "radical" solutions.

*Conclusion – path dependence and the challenges of introducing "risk-based inspections" in a difficult context*

The notion of *path dependence* originates in economics, where it is used to explain primarily the entrenchment of particular standards, but also the lasting attractiveness of large metropolitan areas due to network effects[173] and – particularly relevant for us – the development of specific institutions. In the perspective of historical institutionalism[174], which is the one most relevant for our research, the notion means that the development

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[165] See e.g. World Bank Group (2014) module 4 pp. 7-9, OECD (2014) principle 6 ('coordination and consolidation'), FAO guidance on food safety systems here: http://www.fao.org/docrep/006/y8705e/y8705e05.htm. The EU has also been pushing all candidate countries to consolidate their food safety systems as much as possible, something which was done e.g. in Croatia, Estonia, Latvia, Lithuania etc. Fragmentation, on the other hand, has been seen by some as a factor in the seriousness of some food contamination outbreaks, e.g. the *E.coli* 2011 crisis in Germany (see: http://www.bloomberg.com/news/articles/2011-06-09/scattered-health-model-draws-fire-for-germany-s-response-to-e-coli-threat) or the 2008 *Listeria* outbreak in Canada, which led to some institutional changes (see: http://www.phac-aspc.gc.ca/about_apropos/evaluation/reports-rapports/2011-2012/feipdra-pdimeoa/app-ann-b-eng.php).

[166] See : http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm294512.htm

[167] See e.g. guidance on milk processing http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074974.htm - even though FDA does not have jurisdiction (except when products are shipped in interstate commerce), it attempts to promote some uniformity of approach.

[168] See Gibbs Brown 2000 (Inspector General of the Department of Health and Human Services' report). Unfortunately the report is not recent, but it points out shortcomings in terms of audit frequency and overall resources available to ensure consistency (pp. 2-5).

[169] See http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm315486.htm#coordination_local_state and Gibbs Brown 2000

[170] Which also involves the Centers for Disease Control for outbreaks detection, monitoring, investigation.

[171] See FDA summary on these efforts here: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm436155.htm

[172] See a summary of the proposals in *RegBlog*: http://www.regblog.org/2015/02/17/knofczynski_food_safety_admin/ - and some media reports about it: *New York Times* http://www.nytimes.com/2015/02/21/us/obama-proposes-single-overseer-for-food-safety.html?_r=0 – *USA Today* http://www.usatoday.com/story/news/2015/02/02/obama-proposes-consolidating-food-safety-oversight/22764529/. Unsurprisingly, officials in existing structures are unenthusiastic about a merger: http://www.foodsafetynews.com/2015/05/top-food-safety-officials-value-collaboration-between-agencies-over-combination-into-one/ (but their concerns and remarks also point out to the real challenges involved in making a merger successful, and achieving better collaboration is often a more realistic goal indeed).

[173] For a good definition, examples and bibliography, see: Puffert, D. (2008) "Path Dependence". EH.Net Encyclopedia, edited by Robert Whaples. February 10, 2008. URL http://eh.net/encyclopedia/path-dependence/

[174] See Thelen (1999) and Steinmo (2008). A quote from Steinmo about Theda Skocpol's work perfectly illustrates the gist of historical institutionalism: "Most famously, Theda Skocpol wanted to explain the sources and patterns of the great revolutions (Skocpol 1979). But rather than assume that class structure or elite power would explain different patterns, she did the hard work of examining actual revolutions and placing them in their comparative and historical contexts. Eventually, Skocpol realized that the structure of state

of specific systems and practices is neither only determined by the different forces at play (economic, social, political) and the interests of different parties, nor by rational calculations and/or ideological models, but also (and in a very important way) by the specific choices made at an early stage (possibly under completely different conditions, with different forces at play, different ideological models etc.). In a *path dependence* perspective, the fact that specific institutions have been created, laws adopted, officials hired, practices put in place, means that it will be far likely that future developments will take place *on this basis* rather than *ex nihilo*. As Steinmo (2008) puts it: "political choices made at time A have important consequences for time B", and the different variables and factors in historical evolution are not independent. This means in our case that the current differences in institutions, legal systems and practices that are found, for the same field of inspections, between countries such as Britain, the US or Germany cannot be solely (or even primarily) explained by reference to today's situations (differences in political and social contexts, for instance), but to a significant extent arose because of the accumulated differences resulting from initial diverging choices made when designing the first regulatory responses to specific issues.

This overview of the history of food safety regulatory inspections and enforcement in the US has taken us far and wide, and abundant sources have allowed us to understand better the roots and successive transformations than was possible in other countries and regulatory spheres. If we decided to use this opportunity and make this a considerably longer chapter than others in this section is that it allowed us to investigate some key issues of relevance for the entire research, and for inspections issues everywhere.

First, the importance of *trust* (or its breakdown) and of demands for reassurance in driving inspections development. Rather than addressing statistically-assessed risks, regulations and institutions often seem to have been created and grown in response to shortfalls in consumer or citizen trust.

Second, the difficulty of objectively and reliably estimating regulatory inspections' contribution (or lack thereof) to safety improvements, when other forces (e.g. scientific and technological change) are at play in the same period, and when data (in particular epidemiological) are subject to caution (at least in terms of doing reliable international comparisons). We know that food safety improved over the past century, and we know that it is now at a high level (notwithstanding some issues, outbreaks etc.) in both the EU and US – but we cannot tell how much of it was caused or even made faster by regulatory interventions, and we cannot really tell whether the EU or US perform better (at least not with currently readily available data – in principle, an epidemiological survey, or maybe an in-depth review of existing sources, may yield robust results).

Third, introducing new, more "risk-based" and "risk-focused" approaches is particularly difficult when the context features acute political disputes about regulation where its very necessity and legitimacy are disputed[175], and success is made less likely when reforms that ostensibly aim at improving effectiveness and efficiency are made in a context of (and/or as cover for) budget restrictions. There is a serious possibility, in such context and circumstances, that public trust will further decrease, and that this will undermine the whole regulatory system, and the reform effort.

#### *iv. Snapshots of developments in food safety inspections*

Going into the same depth for a number of cases would go far beyond the scope of this research, but considering briefly a few country cases, as well as the influence of international organizations and the EU, will help us build a sketch of how (and to some extent why) food safety inspections have developed. We will first look at a couple of country snapshots, in particular at the Netherlands, but also at some of the "new" EU

institutions in the pre-revolutionary period had enormous consequences for revolutionary outcomes". What we are attempting here is, in a very modest way, somewhat similar in looking at the development of inspection institutions and practices.

[175] Which, on the other hand, is one of the reasons why the US case has far more abundant literature available. Conversely, situations (e.g. in France) where regulation is seen in a large part of the population as an absolute good that cannot be discussed or relaxed, however slightly, also create a very difficult context for any reform effort.

Member States. Then, we will briefly consider, some broad international trends, the role of international organizations such as FAO and WHO, the effect of the WTO on food safety regulations, and the transformations brought about by the EU. We will then try and summarize a few short and tentative conclusions.

## A few country snapshots

What we have seen above for the UK and the US can, to a large extent, be seen in other countries too: first, "food safety" as such was for a long time not perceived as a unified field, but rather different aspects of it were addressed separately, often combined with other policy issues, creating a fragmented regulatory field. Second, institutional building was gradual, often slow, and generally came significantly later than the adoption of regulations.

### France

In France, for instance, municipal veterinary inspections existed since 1898, but really effective only in Paris and, to a lesser extent, other major cities. Regulations ensuring somewhat uniform control were not adopted before 1933, and a national food hygiene service (with a veterinary focus) only created in 1965 (Theves 2002, p. 56). As for the 1905 *Loi sur la répression des fraudes* (Law on fraud and adulteration) its focus was initially, much like what we have seen in the US, more on protecting commercial interests than on protecting consumers from hazards (Canu and Cochoy 2004, p. 6). A service is set up in April 1907[176] to implement it, but though it looks after consumer interests, it is (at least in the first decades) mostly in terms of prices, labelling and adulteration – controlling safety only comes incidentally (*ibid.,* pp. 12-16). The parallel development of veterinary legislation and inspections, and of consumer protection legislation and services, has led to a dual structure which persists to this day, with two national *Directions Générales* (General Directorates): one in charge of *Alimentation* (Food), the other of *Consommation, Concurrence et Répression des Fraudes* (Consumer Affairs, Competition and Fraud Suppression). The term of "food safety" as such is absent, and the mandates of both directorates are broader, with safety only one of several issues. The Food DG looks at production and supply as well as safety, at all that is "upstream" (primary production, processing, storage and handling etc.) but also au trade and catering). The Consumer DG looks at consumer complaints, competition, intellectual property, labelling, and safety only at the consumer stage (catering, retail). The division of responsibilities is not "obvious" in that both DGAL and DGCCRF look at the consumer stage - the former from a sanitary safety perspective, the latter from a consumer protection and fraud prevention one. In practice, however, though inspectors report to the national DGs in terms of professional competence, career, guidelines, their operational management is at the local (*département*) level. Thus, actual inspections and control measures are conducted by inspectors that report to local directorates at the administrative level of the *département* and thus report to a local director and to the *Préfet,* who heads all state services in each *département.*

Since January 2010, as a result of the *Révision Générale des Politiques Publiques (RGPP* – General Review of Public Policies[177]), both groups of inspectors have been part of the same joint local directorates, called *Directions Départementales de la Protection des Populations*[178]*.* They continue, however, to have different

[176] Initially under the Ministry of Agriculture, the *Répression des Fraudes* was later merged with services in charge of price controls (later price monitoring), competition, consumer protection. After having been part of the Ministry of Consumer Affairs, the service has been assigned to the Ministry of Finance since 1983. See: *Historique des Directions et des Services du Ministère de l'Économie, des Finances et de l'Industrie - CAEF - Août 2004* available at: http://cadastre.pagesperso-orange.fr/Fichiers/historique_direction.pdf

[177] See 2012 report on the RGPP (assessing results, outcomes, lessons) by the General Inspectorate of Public Administration – available at: http://www.ladocumentationfrancaise.fr/rapports-publics/124000520/index.shtml

[178] In some (less populated) *départements*, these have been merged with social assistance services too and are called *Directions départementales de la Cohésion Sociale et de la Protection des Populations.* See: http://www.economie.gouv.fr/dgccrf/coordonnees-des-DDPP-et-DDCSPP and https://fr.wikipedia.org/wiki/Direction_d%C3%A9partementale_de_la_protection_des_populations

cultures, qualifications, guidance from the centre, keeping a "technical" reporting line to their respective DG and using different information systems depending on which DG their work relates to. The unusual experiment to conduct mergers at the local level while leaving central structures separate[179] needs to be evaluated further, but actually overcoming the cultural differences between different *corps* is likely to take a long time and be rather difficult, and it is less than clear that this challenge is really being addressed. A vision of food safety controls, and a corresponding effort on developing guidelines and training, are both lacking[180].

### Former Soviet Union

Such a division between several services, each looking at food safety from a different perspective (and, often, along with other issues), is quite frequent – as the idea of "food safety" as a unified problem appeared relatively late, and with institutional structures already well established. In the Former Soviet Union (FSU)[181], for instance, supervision of food safety issues has for decades been divided between the Sanitary and Epidemiological Service (SES), the Veterinary Service, and inspectors controlling conformity with Standards (some elements of which relate to food safety). The SES embodied a "holistic" conception of health, not unlike the UK's "Environmental Health" approach (but even broader in some ways) – the SES institution, and its inspectors (normally all medical doctors, most often epidemiologists), would be responsible for environmental issues, epidemiological control, and food safety. While in principle the Veterinary Service should be responsible for all food of animal origin, there is, in such a system, a vast area of overlap between Veterinary and SES – as soon as meat, dairy or eggs leave the farm and enter the processing and trade chain, SES claims responsibility, but Veterinarians do not relinquish it. On top of this, Standards inspectors control nearly every food product for conformity with their mandatory standards. In addition to problems of overlap and conflicting responsibilities, such systems also feature strong "cultural" rivalries between veterinarians and medical doctors (not unlike, again, what has been seen in the early development of food safety control in the UK, but with veterinarians having achieved a somewhat stronger position in the Soviet/post-Soviet systems).

While this dual system of SES and Veterinary control (or in fact triple control, including Standards) has to a large extent remained the norm in most Former Soviet republics (e.g. Russia[182], Kazakhstan, Kyrgyzstan[183], Uzbekistan, Tajikistan, Azerbaijan, Belarus), some have initiated reforms that are at varying stages of

[179] See short overview in Blanc (2012) pp. 29 et 66

[180] Interviews with senior officials in the President's Office and both DGs, 2012-2013.

[181] All this section is based on the author's direct experience working on this topic in these countries since 2004, and numerous interviews with senior officials in all relevant institutiona (SES, Veterinary, Standards, line ministries, ministries in charge of economic development and administrative reforms). In addition, the reader can refer to the following published sources: Gotsadze et al. (2010) provides a comprehensive overview of reforms in the FSU and Central and Eastern Europe (CEE), but with a health (not a food safety) focus – IFC (2009 b) describes in some detail the Ukrainian system, and how it contrasts with accepted practice in the EU (see e.g. pp. 23-25 and 44-47) – World Bank Group (2014), module 8, has four relevant case studies: Armenia (pp. 5-6), Lithuania (pp. 17-18), Moldova (pp. 19-22) and Ukraine (pp. 27-29) - Josephson, Dronin and Cherp (2013) provides information on the early history of the SES that is relevant for food safety, even though the book focuses on environmental issues.

[182] Some consolidation has taken place in Russia, but a fundamental duality remains: *Rosselkhnadzor* on the one hand (Russian Federal Service for Agricultural Surveillance, in charge of veterinary and phytosanitary safety) and *Rospotrebnadzor* (Russian Federal Service for Consumer Rights and Human Wellbeing Surveillance, which merged the SES functions with consumer protection and standards supervision). See the respective websites for overview of functions: http://www.fsvps.ru/fsvps/main.html?_language=en (*Rosselkhnadzor)* and http://www.rospotrebnadzor.ru/en/deyatelnost/san_epid.php (*Rospotrebnadzor*)

[183] Consolidation of the SES and Veterinary Service was attempted in 2012 by the Government (see IFC 2012, pp. 32-33), but rolled back after a few months and fierce lobbying of the former SES (author's interviews with officials, 2012-2015)

implementation (e.g. Ukraine[184], Armenia[185]), and some have completed complete transformations including the creation of unified food safety agencies, as part of their entry into the EU (Estonia, Latvia, Lithuania).

In September 1922, in order to fight what they considered a dramatic epidemiological situation[186], Soviet authorities created the first sanitary and epidemiological centre – and in 1931-32, the Government set up what became a nationwide network of SES[187]. The system was successful in eradicating epidemic typhus and cholera[188]. While in 1933 the inspection function was separated from the Sanitary and Epidemiological Centres, they were merged again at the beginning of the 1950s, and the structure remained essentially unchanged until the end of the Soviet Union and, to a large extent and for the majority of post-Soviet states, until today. Interestingly, the Soviet SES developed a kind of early and rough "risk-based classification" of establishments[189], with some being designated as "of acute epidemiological risk". However, this classification remained set in the conditions which presided to the SES's creation – thus, alongside hospitals, hairdressers and beauty parlours are considered "high risk" all over the Former Soviet Union[190].

This early approach to risk-based prioritization, however, has not resulted in a real "risk based approach". Rather, contemporary SES (or successor institutions) and (to a lesser extent due to generally lower staffing levels) Veterinary Services are characterized in most FSU countries by complete "risk aversion", and efforts to achieve "total control" of every establishment and product on the market. We will come back to what this means in terms of inspections' depth, and effectiveness. It is worth noting that it reflects both an ideological vision (that each and every risk should be prevented by the state), and vested interests (considering the extent of corruption in inspections)[191]. This has led, in several countries, to deep and comprehensive reforms. While the Baltic States have all set up unified Food Safety inspections (following very strict EU guidance during the accession process), Georgia in 2003-2004 took a different, radical approach.

Reforms in both the Baltic States and Georgia were a response to somewhat similar problems (though they were certainly even more acute in Georgia): ineffective controls, high administrative burden, significant levels of corruption[192]. In Estonia, Latvia and Lithuania, new institutions were set up, with mandates covering all food safety inspections – and sometimes an even broader food safety responsibility[193]. Old institutions were shut down, merged or split, staff was profoundly retrained (and partly renewed), and methods entirely transformed. This resulted in a new institutional framework that proved considerably more effective, and far less corrupt (it is always difficult to assert that corruption does not exist at all, hence our cautious wording).

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[184] As in Russia, the Veterinary and Phytosanitary Services were merged in an Agriculture Inspection. In Summer 2014, the new Government of Arseniy Yatsenyuk took a decision of principle to create a wholly new, consolidated inspectorate, that would include all of food safety, as well as non-food products market surveillance, but this institution is not yet operational (author's own interviews with officials, 2015).

[185] In Armenia, a unified Food Safety Service exists, but there remain some "grey areas" of overlap on hygiene issues with the Public Health Inspections, and methods and approaches have not really been reformed.

[186] Typhus, spread by body lice, was a particularly deadly disease towards the end of WWI and in the Revolutionary War period. Lenin is quoted as saying "either the lice conquers socialism, or socialism conquers the lice" (quoted by Josephson *et al.* 2013, p. 90) – see also this page at the University of Kansas Medical Center: http://www.kumc.edu/wwi/index-of-essays/typhus-on-the-eastern-front.html

[187] See Josephson *et al.* 2013, p. 90 and http://www.rospotrebnadzor.ru/en/region/history.php

[188] *Ibid.*

[189] Which was not necessarily unusual for the Soviet Union – the Fire Safety Service had a similar classification, which emphasized a combination of inherent fire risk, potential for life loss and potential for economic loss (in which it differed strongly from contemporary "western" approaches, which emphasize only life loss potential – but the Soviet State was an economic operator as much as a State) (author's interviews working with Fire Safety Services in Former Soviet Republics since 2004).

[190] Though typhus is spread by body lice and not hair lice, all hygiene-related establishments were critical to epidemiological progress in the 1930s. The situation, however, has changed considerably over 80 years – but not the classification and targeting.

[191] On all this see Blanc 2011 b and 2012 b.

[192] On Georgia, see World Bank Group (2012).

[193] E.g. in Lithuania where the State Food and Veterinary Service covers all food safety inspections, as well as the network of food laboratories, a rule-making function for veterinary issues, and the scientific risk assessment function (author's interviews and discussions from 2011 to 2015 – see also SFVS website at: http://vmvt.lt/en/about.sfvs/)

The new setup played a strong role in transforming the food processing sector, with a number of establishments closing as the costs of putting their operations in conformity was prohibitive[194]. The new system was found to satisfy EU requirements and thus fulfil one of the conditions for EU accession. In fact, the Baltic states provide examples of full implementation of the EU Food and Veterinary Office (FVO) recommendation for unified food safety inspectorates, something which in practice has remained the exception (due to the historical path dependence we have been researching here, in no small part). In Georgia, by contrast, the reform essentially shut down the previous inspecting bodies, drastically reduced their staff and activities, and in effect was a major deregulation effort. Only from 2006, with the process of negotiation (and, after signature, the implementation) of a Deep and Comprehensive Free Trade Agreement (and thus with both EU pressure and EU assistance) was a new National Food Agency (NFA) set up. This Agency barely conducted any inspections, however, for the first years of its operations. The NFA only started ramping up its staffing and inspections significantly after 2012, with a new government in charge[195]. We will come back to this example and its impact in further sections, for it provides a very interesting experiment of essentially shutting down food safety inspections for several years – and, this much we can say already here, it did not result in the disaster that critics predicted.

### Netherlands

In the late 19th and early 20th centuries, the Netherlands was relatively slow to introduce food safety legislation, and controls, compared to a number of other countries in Western Europe. According to Koolmes (2000) this is because of the prevalence of "liberal doctrines of free trade and the restriction of state interference" (p. 58)[196]. As he shows, there was very little control in practice, including regarding meat slaughter, processing and sale, which exposed the population to contamination hazards (*ibid.,* pp. 55-56). While legislation was adopted in 1908 to control meat exports, it was not before 1919 that it was extended to cover the internal meat market (Theves 2002, p. 56).

The development of regulations and inspections in food led, however, to a similarly fragmented structure, as we have seen in other countries. First, because of a duality between consumer products inspections, and veterinary inspections. Second, because of a Dutch specificity, the delegation of regulatory conformity inspections in some areas of food safety to institutions of a private nature (COKZ, NCAE[197]). Simplification and closure of several private sector "product boards" (*product- en bedrijfschappen*) which were in charge of supervision in different agricultural areas has been going on in recent years, but this delegation of powers remains a specificity of the Dutch system[198]. In addition, some inspections (of hygiene in catering, in particular) are done by the local authorities, independently of national food safety bodies. While there are efforts to introduce coordination and information sharing, and these have been going on for several years, the duplication remains[199].

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[194] We will come back to this question of costs in the last part of this research.

[195] Interviews with government officials conducted in 2014.

[196] As we have seen above, there was a similar delay in adopting OSH regulations and controls, possibly due to similar reasons.

[197] COKZ (*Centraal Orgaan voor Kwaliteitsaangelegenheden in de Zuivel,* Central Body for Quality Issues in Dairy) is tasked with conducting regulatory food safety inspections (based on national and EU legislation) in dairy production/processing. NCAE (*Nederlandse Controle Autoriteit Eieren*, Netherlands Eggs Control Authority) is tasked with the same for egg production/processing. NCAE is a subsidiary of COKZ, and took over egg inspections from CPE (*Controlebureau voor Pluimvee, Eieren en Eiproducten*, Bureau of Control of Poultry, Eggs and Egg Products) in 2012. They work on the basis of an official delegation of powers and competences (and funding allocation) by the state. For details, see websites: http://www.cokz.nl/SitePages/over-COKZ.aspx http://www.ncae.nl/pages/over-ncae.aspx.

[198] The model appears to enjoy strong legitimacy since, when CPE functions were taken back, they were not given to the state inspectorate, but to another private sector entity (NCAE).

[199] See e.g. *Werkprogramma samenwerkende rijksinspecties 2014* (Work Programme for State Inspections Cooperation 2014), avaialble at: http://www.inspectieloket.nl/organisatie/publicaties/Werkprogramma_samenwerkende_rijksinspecties_2014.aspx.

National (state) food safety inspections in the Netherlands have been considerably consolidated in the past 10-15 years (starting ca. 2000[200]), resulting in a novel institutional structure. The *Nederlandse Voedsel- en Warenautoriteit* (NVWA - Netherlands' Food and Consumer Product Safety Authority), under the Ministry of Economy (and an additional reporting line to the Ministry of Health), was established in two steps in 2002 and 2006. In 2002, services controlling meat and livestock (*Rijksdienst voor de keuring van Vee en Vlees*, RVV - State Service for Supervision of Livestock and Meat) and those supervising consumer products (*Keuringsdienst van Waren*, Consumer Products Supervision Service) were both put under the VWA as "umbrella organisation". Then, in 2006, they were fully merged, and what was now the NVWA underwent an internal reorganisation so that its internal structure matches better the modern approach to food and consumer safety.

This followed previous efforts at consolidation and mergers, over more than two decades. In 1980, the RVV was formed merging local meat inspection services and the veterinary services from the Ministry of Agriculture. In 1988, provincial and municipal products inspection services were merged into a State Inspection, that itself was consolidated in 1995 with other services in charge of food, alcohol legislation supervision etc. In the late 1990s and early 2000s, the "consumer products" and "veterinary and meat" sides were themselves gradually merged. At the same time, there remain specific inspection functions that are *outside* of the NVWA's mandate - eggs, milk and milk products, the control of which is delegated to institutions of a private nature (COKZ, NCAE). Simplification and closure of several private sector "boards" (*schappen*) which were in charge of supervision in different agricultural areas has been going on in recent years, but this delegation of powers remains a specificity of the Dutch system.

Thus, not unlike in the UK, the original situation involved control mostly implemented by local authorities, a gradual emergence of the food products control function, and a separation between control of products and of production (in particular animal health). Consolidation was a process that was slow and complex. A feature of particular interest (and again underlining how much variation there can be, and how little of these structures is "obvious") is that in the Netherlands the NVWA groups inspection and control of both food *and non-food* products, which is quite unusual (though not unheard of[201]) internationally.

### The role of international institutions and international integration

In sharp contrast with OSH, food safety is an area where international institutions and structures (of a variety of nature and scope) have a very important influence – not only on the formulation of norms but, at least in some cases, on the ways in which inspections are organized, and the manner in which they are conducted. This, of course, is linked to inherent characteristics of food safety issues. First, food is a tradable good – and not only tradable, but in practice largely traded across borders. Second, some food-related pests, parasites and diseases can spread rapidly – regardless of whether they affect humans, plants or animals. Third, the development of food safety regulations and regulatory practices has been strongly underpinned by the development of science regarding food-borne human pathogens, as well as plant and animal diseases, providing a common basis for rules and enforcement across the globe. As a result, while there remains considerable differences in both contents of rules and practices, there has been several growing and concurring trends: harmonization of regulatory requirements, adoption of generally applicable principles,

[200] While the author has had the opportunity to see internal Government documents laying out the consolidation process starting in 2000, it is not entirely clear when the initial decisions were taken, and the documents are not published.

[201] A couple countries, such as Bosnia and Herzegovina (2004) and Mongolia (2003) created "unified inspectorates" covering most inspection functions (Croatia was one of the first, but with a narrower scope). Ukraine (2014) decided to create a body similar to NVWA. But these remain exceptions. (Sources: World Bank Group (2010), author's interviews and experience in Mongolia 2008-2015, Bosnia 2010). In France, there is a partial combination in the functions of the DGCCRF, but it has only narrow food safety competence, and mostly looks at consumer products. In the UK, non-food products safety is controlled by the Trading Standards inspectors (which are part of local authorities' services) – they also control labeling, including for food, but no substantial food safety issues..

endorsement of "best practices" – and, at least in the EU context, increasing harmonization of practices. There are a number of institutions involved in this process – in particular a group of UN agencies (Food and Agriculture Organization – FAO – and World Health Organization – WHO), the World Trade Organization (WTO), two structures with a specific status but related to the UN and WTO (the World Animal Health Organisation, OIE, which is recognized as competent organization by the WTO – and the International Plant Protection Convention, a convention ratified under the auspices of FAO) – and the European Union (EU). We will limit ourselves to considering WHO and FAO, WTO and EU – as regulations and inspections relating to animal health (epizootic diseases) and plant health (phytosanitary issues) are, though important, further from our core focus in this research (and would entail detailed considerations of border control and quarantine regimes).

### FAO, WHO and the Codex Alimentarius

While FAO is primarily concerned with food security[202], in the sense of ensuring a continuous and sufficient supply of food to populations around the globe[203], it has some activities related to food safety, i.e. ensuring that food for human consumption is safe to eat. Limited funding resources means that operational projects implemented by FAO to support the development of food safety in developing countries are relatively rare and small in size. Likewise, while FAO has developed a number of important guidance documents on food-related legislation and inspections[204], these do not have as much influence as, for instance, the EU's (even when considering non-EU members). As for WHO, it is "the directing and coordinating authority on international health within the United Nations' system[205]" and, as such, responsible for a very wide range of issues – in particular, coordinating responses to major epidemics and pandemics, e.g. the recent Ebola outbreak. Considering limited means and the vast number of issues WHO is responsible for, its activities in food safety are limited, even though it runs a few projects on this topic in some developing countries[206]. In fact, the main way in which FAO and WHO are active, and significant, in food safety regulation is through the *Codex Alimentarius.*[207]

The *Codex Alimentarius*[208] (or, shortly, *Codex*) is primarily "a collection of standards, codes of practice, guidelines and other recommendations. (…) Some deal with detailed requirements related to a food or group of foods; others deal with the operation and management of production processes or the operation of government regulatory systems" (FAO – WHO 2006, p. 10). The *Codex* is developed by the *Codex Alimentarius Commission*, which was created in 1961 by the 11th FAO Conference, and met for the first time in 1963[209]. The main aims of the *Codex* are to be a reference guide to define (a) what particular food names actually mean (contents, definition of foods), (b) what are acceptable (safe for human health) residue levels of specific contaminants, (c) how to conduct sampling and testing procedures, (d) what are safe methods for the

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[202] It defines its mandate thus: "Our three main goals are: the eradication of hunger, food insecurity and malnutrition; the elimination of poverty and the driving forward of economic and social progress for all; and, the sustainable management and utilization of natural resources" - http://www.fao.org/about/en/

[203] But FAO is not responsible for emergency food relief, which is the mandate of the UN World Food Programme (WFP).

[204] See in particular for legislation http://www.fao.org/food/food-safety-quality/capacity-development/food-regulations/en/ and for inspections http://www.fao.org/food/food-safety-quality/capacity-development/inspection/en/. Main publications include the *New Model Food Law* (FAO 2005 – see: http://www.fao.org/3/a-a0274e.pdf) and the *Risk Based Food Inspection Manual* (FAO 2008 – see: http://www.fao.org/3/a-i0096e.pdf).

[205] See: http://www.who.int/about/what-we-do/en/

[206] Direct author experience and observations in several dozen countries since 2001.

[207] For details on the *Codex Alimentarius* work and its effects e.g. in EU law, see for instance Everson and Vos 2008, Matthee 2009.

[208] Interestingly, the name was taken from a much earlier codification exercise regarding food, the Codex Alimentarius Austriacus (see: https://en.wikipedia.org/wiki/Codex_Alimentarius_Austriacus), which was developed in the last decades of the Austro-Hungarian Empire. Much like the modern *Codex* standards, its norms were not directly enforceable, but could be referenced in case of litigation.

[209] See: http://www.codexalimentarius.org/about-codex/codex-timeline/en/

preparation and handling of specific foods and (e) how to organize and conduct controls of food safety (both internal controls and regulatory inspections)[210].

While *Codex* "standards[211]" are not mandatory for the countries that participate in the Commission (186 in total, plus the European Union as such), they provide an importance reference point, in several ways. First, they provide a basis for standards, regulations and practices that can be adopted by member countries – and, in fact, they frequently form the basis of modern food safety regulations. Second, they are recognized by the WTO (in the SPS agreement, see below), and thus they are used to adjudicate trade disputes. In particular, having stricter requirements than those foreseen in *Codex* would have to be justified in case of a dispute.

Nonetheless, while generally OECD and EU members have regulations that are mostly aligned with *Codex,* this is far from the case everywhere – be it because *Codex* standards would be too complex, too costly to comply with, set the bar too high – or because there are vested interests which benefit from using older standards (e.g. Soviet or post-Soviet ones), or simple path dependence and refusal to change[212]. The development and increasing influence of *Codex* standards is important for our topic because it has driven, or at least supported, a growing approximation not only of *rules* being enforced, but also of *methods*, in particular of what gets checked during inspections, and how. In particular, the *Codex General Principles of Food Hygiene* (introducing the HACCP approach) and the standards for inspection and certification practices are significant in this respect. While *Codex* standards are not necessarily driving the development of new practices (but rather codifying them), they constitute an important factor of diffusion of risk-based inspection approaches, at least in terms of targeting of controls, and of focus of attention during controls (but not as strongly when it comes to risk-proportionality in determining regulatory instruments, and enforcement actions).

### The WTO Sanitary and Phytosanitary (SPS) Agreement

In 1995, the General Agreement on Tariffs and Trade (GATT), which had been in effect since 1948, gave birth to (and was replaced by) the World Trade Organization (WTO). Thus, from a multilateral agreement, world trade regulation moved to an international organization, i.e. a stronger structure, with more robust regulation and litigation mechanisms[213]. During the Uruguay Round of the GATT, along with the main treaty creating the WTO, were negotiated two key agreements on product market regulations and their effects on trade: the Agreement on Technical Barriers to Trade (TBT), and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)[214], both of which entered into force in January 1995. These two agreements marked a major turning point[215] in the way states regulate their product markets (both food and non-food) because, for the first time, international agreements applicable to the vast majority of the world's nations (161 countries as of April 2015) lay out what are the acceptable practices in terms of restricting free market access, what level of protection and methods are acceptable – and do so in a way that is backed by the possibility of litigation. While the conflicts that reach the main headlines (such as the UE-US conflict on poultry that we briefly discussed above) are mostly between the most developed economies, and point to areas of acute

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[210] For more details on what *Codex* covers see FAO – WHO (2006) pp. 11-12.

[211] We put the word in quotation marks because, even though they are officially called thus, they differ strongly from the definition of "standard" used e.g. by the International Standardization Organization and the WTO Technical Barriers to Trade (TBT) agreement.

[212] Broadly speaking, there are two cases of non-adoption of *Codex* standards: low-income, low-capacity countries, which lack resources to translate and, even more, implement them (and, in some cases, non-adoption is wise, as the standards may just be impossible to implement in practice) – and countries, where existing rules are in fact costly and complex, and less adequate than *Codex* ones (either because they are less effective, or because they harm trade), but where regulators and/or incumbent businesses benefit from them (a case that is observed in many post-Soviet countries – see e.g. IFC 2009 b).

[213] See WTO website: https://www.wto.org/english/thewto_e/thewto_e.htm.

[214] For more in depth considerations of the balance between risk prevention and trade in the SPS agreement, see Prevost 2009.

[215] GATT rules with a similar purpose existed earlier, but weaker and less specific. In addition, the WTO has considerably expanded compared to the GATT membership. See WTO (2010) p. 14.

disagreement but rarely to deep and far-reaching differences in how regulatory systems are organized, the more substantial effects of the TBT and SPS agreements are often felt in developing countries and transition economies, during or just after the accession process, where they can result in very important transformations of the regulatory framework.

From our perspective attempting a review of food safety inspections experience, the SPS Agreement is the relevant one[216]. The WTO defines the problem to which the Agreement intends to respond thus: "How do you ensure that your country's consumers are supplied with food that is safe to eat — "safe" at the level you consider appropriate? And at the same time, how can you ensure that unnecessary health and safety regulations are not used as an excuse to protect domestic producers from foreign competition?" (WTO 2010, p. 9). This means that, from the onset, the WTO SPS perspective is one of *balancing* the expected benefits of regulation (safe food, in this case) against its costs (in this case, barriers to trade protecting domestic companies from competition[217]). What is important and interesting from our perspective is *how* the SPS Agreement seeks to regulate this: by emphasizing the notion of *risk,* and using it as the foundation to determine the legitimacy of SPS "measures"[218].

In the SPS Agreement, international standards form a "baseline", which allows to avoid a complex cost-benefit assessment model: implementing the international standards (as adopted by *Codex,* OIE and IPPC) is accepted as the baseline option, doing *less* (i.e. being having a higher tolerance of risk) is accepted in the sense that it restricts trade less (and thus does not harm the WTO's purpose), however doing *more* needs to be justified – using "risk" as the fundamental criterion. As the WTO puts it, "WTO member countries are encouraged to use the standards developed by the relevant international bodies whenever they exist. However, members may use measures which result in higher levels of health protection, so long as their measures are based on an appropriate assessment of risks and the approach is consistent, not arbitrary" (WTO 2010, p. 9). The Agreement clearly articulates that risk assessment must be the foundation for adoption of "measures", that science must be the basis for risk assessment, and that in any case the "measures" must be non-discriminatory (treat domestic and foreign producers equally) and their necessity must be demonstrated: "regulations must be based on scientific findings and should be applied only to the extent that they are necessary to protect human, animal or plant life or health; they should not unjustifiably discriminate between countries where similar conditions exist" (*ibid.*). The Agreement goes further than just a general requirement to base "measures" on risk, however, it also "clarifies which factors should be taken into account when risks are assessed" (*ibid.,* p. 10). First, "measures" should be based on an assessment of "the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations". Then, "Members shall take into account available scientific evidence" as well as "relevant economic factors" such as "the potential damage" and "the relative cost-effectiveness of alternative approaches to limiting risks" (SPS Agreement Article 5, quoted in WTO 2010, p. 30).

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[216] The TBT Agreement is very important for other types of inspections, those concerned with non-food products safety, as well as with labeling (all together commonly called "Market Surveillance"). The labeling component has some implications for food, of course, but from a food safety perspective the fundamental agreement is the SPS one. What we write here of the SPS Agreement's effects is largely, *mutatis mutandis*, applicable to the TBT Agreement and non-food products regulations and inspections, with ISO and other international standards playing a somewhat comparable role to the *Codex,* OIE and IPPC standards under SPS, and the same overall approach of minimal level of trade restriction and risk-based approach to regulatory intervention (there are also important differences, e.g. the TBT's reliance on the notion of "technical regulation", which is not applicable to the SPS field). See WTO (2010) pp. 16-17 for the scope of the two agreements.

[217] Many have argued against considering free trade as an unalloyed benefit, and thus necessarily seeing barriers to trade as costs (see e.g. Chang 2007), but *from the WTO perspective*, in any case, limiting competition is a negative (and a majority of economists would generally support this view).

[218] The Agreement does not refer to "regulations" in order to avoid any peculiarities in various legal systems, but the neutral "measures", which covers any form of SPS-related restrictions to trade.

Interestingly, what the SPS Agreement emphasizes is the risk-based *approach*, but not the specific level of risk that should be acceptable. This, as befits an international agreement, is left to the states that are party to it to decide upon: "the SPS Agreement allows countries to give food safety, animal and plant health priority over trade, provided they can demonstrate that their food safety and health requirements are based on science. Each country has the right to assess the risks and determine what it considers to be an appropriate level of food safety and animal and plant health". Once this level is set, "there are often a number of alternative measures which may be used to achieve this protection (such as treatment, quarantine or increased inspection)" (WTO 2010, p. 20). The SPS Agreement thus aims at ensuring that WTO member states select the least burdensome, most efficient, most trade-friendly way to achieve the goals they have set themselves, i.e. the level of risk-mitigation they deem appropriate.

Risk assessment must also be demonstrated and justified in case of challenge or litigation: "Countries' SPS measures must be based on an appropriate assessment of the actual risks involved. If asked, they must make known what factors they took into consideration, the assessment procedures they used and the level of risk they determined to be acceptable" (*ibid.,* p. 11). The Agreement emphasizes that countries do not have to accept international standards "as a floor or ceiling" (*ibid.,* p. 19) – but they have to justify variations (particularly if their requirements are more stringent, more restrictive).

The SPS Agreement has relatively little details on the question of *inspections* specifically – in any case it covers only the measures imposed to imports (i.e. primarily border controls). It states in its Annex C that "any requirements for control, inspection and approval of individual specimens of a product are limited to what is reasonable and necessary" and that "any fees imposed for the procedures on imported products" have to be "equitable in relation to any fees charged on like domestic products or products originating in any other Member and should be no higher than the actual cost of the service" (*ibid.,* pp. 43-44). Thus, it prescribes general principles of "reasonableness" (proportionality), and non-discrimination. Nonetheless, the Agreement is fundamental in that it sets binding limits on the way in which SPS regulations can be imposed, and mandates that they be based on a risk-based approach. Such a requirement means that aspiring members often need to revise their applicable regulations and, in so doing, end up changing the basis on which inspections are conducted, and pushing their inspection bodies towards a new way of doing things.

Of course, compliance with the SPS Agreement is far from universal. Disputes are relatively numerous (43 disputes stating the SPS Agreement as basis, as of July 1, 2015[219]), but mostly involve major countries (the US, China, India, Canada, South Korean) and the European Union. The way in which the SPS Agreement influences changes in regulations and practices, however, is often less visible, and has to do with the WTO accession process. When applying, and until accession is ratified, countries (particularly those with a relatively weak bargaining position) often have to make considerable changes – or, if these changes have not been made, they sometimes happen post-accession, reacting to the *threat* of litigation[220]. In this way, gradually, the SPS Agreement pushes a growing number of countries to adopt food safety regulations that are based on risk assessment and risk proportionality[221].

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[219] See: https://www.wto.org/english/tratop_e/dispu_e/dispu_agreements_index_e.htm?id=A19.

[220] No detailed account exists of the process, but this is what happened in relation with mandatory state certification of food products in Ukraine (which was not in conformity with the SPS Agreement requirements). Though it remained in place in spite of ratification of the WTO accession treaty (which foresaw its cancellation), in 2008, the threat of litigation was used as one of the drivers to push for the elimination of this mandatory certification, which eventually happened in 2009 (on paper – and in practice in 2011-2012) (see World Bank Group 2014 a, module 8, pp. 27-29 – also based on author's direct experience of involvement in the negotiations regarding elimination of this requirement).

[221] A last point worth noting is that the SPS Agreement, by using internationally accepted standards as "baseline", avoids the need for complex cost-benefity analysis, which is often a major hurdle in implementing "better regulation" or "smart regultion" programmes. With these standards as baseline, any additional cost or hurdle has to be justified, based on a clear benefit in terms of risk mitigation.

## The EU: towards the Single Market, the "Hygiene Package" and the role of the EC's Food and Veterinary Office (FVO)

Of all the international institutions we have reviewed, the European Union (and its predecessor, the European Economic Community) have (and have had) the strongest impact on how food safety inspections are structured and conducted (as well as what they aim at). Arguably, the EU may in fact currently be *the* most important institution worldwide when it comes to food safety regulation[222] – more important than its member states, and possibly (through the influence of its model) more influential than any other state as well. The primary reason for this influence is the sheer size of the EU market: over 500 million of "high income[223]" consumers, and the largest exporter and importer of food (raw and processed) worldwide[224]. Being the largest food market (by value), the EU's regulation mechanically carry the most weight. Their influence is further increased by two factors: the large number of countries having entered (or aiming at entering) agreements with the EU and/or joining it[225], and the level of development of the EU's food safety policy (including its inspections and enforcement component), which has led it to be in some ways considered as the "model" to follow by others – a fact that comes from its having had to solve a number of issues in order to build a "single market", as we will see below.

To understand better how this came about, and what the EU "model" exactly consists of, we will consider successively its early history, the turning points that allowed to move from limited mutual recognition and narrow areas of Community action to full harmonization, and the main elements of today's EU food safety regulations and inspections.

### *The early history: the EEC's gradual intervention in food safety issues*

When the 1957 Rome Treaty created the European Economic Community (EEC), with six members at the time, its primary objective was the establishment of a customs union between its members, but its overall goals and scope went beyond. In its Article 3, it foresaw as activities of the Community "the elimination(…) of customs duties and of quantitative restrictions on the import and export of goods, *and of all other measures having equivalent effect*" (emphasis ours), as well as "the abolition (…) of obstacles to freedom of movement for persons, services and capital" and "the approximation of the laws of Member States to the extent required

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While this does not quantify (or attempt to quantify) costs and benefits, it forces to consider them, and prevents the imposition of additional burden with no clear benefit.

[222] Emphasizing the *arguably* – in the author's experience, this is probably the case, and a vast number of countries are taking the EU's food safety system at least as reference point (though not always as model) – we would certainly not endeavour to *prove* that it is indeed the most influential. It is in any case *one of the most* influential.

[223] In the sense of international income classifications used e.g. by the World Bank, OECD etc. It does not of course mean that *everyone* has a high income inside the EU.

[224] EU 2007, p. 28.

[225] As of July 2015, 5 official candidate countries (which have to approximate entirely the EU *acquis*, including all the food safety legislation and enforcement systems), 2 potential candidate (which are trying to approximate as much as possible to be able to apply officially in the future), 3 European Free Trade Area members (Iceland and Norway, members of the European Economic Area, and Switzerland, which has bilateral agreements – all three of which have approximated their regulations to a very large extent), and a large number of Association Agreements and Free Trade Agreements in force (which include various levels of approximation – 17 countries, counting only those with an Association Agreement or "extended/deep" Free Trade Agreement – plus Georgia, where the Deep and Comprehensive Free Trade Agreement has provisionally entered into force), and ma number of countries targeted by the EU Neighbourhood Policy, which includes a large approximation component. See http://ec.europa.eu/enlargement/countries/check-current-status/index_en.htm - http://ec.europa.eu/trade/policy/countries-and-regions/agreements/ - http://eeas.europa.eu/enp/about-us/index_en.htm.

for the proper functioning of the common market[226]". The Treaty had other elements, e.g. foreseeing a Common Agricultural Policy (CAP), a common transport policy, competition regulations, coordination of economic policies etc. – but its core was what became known simply as "the Common Market", which was for decades the EEC's nickname.

If the EEC had been only a customs union (and not an endeavour towards "ever closer union", as per the Rome Treaty's Preamble), there would have been no need or impetus for harmonization of technical rules – a customs union is not a single market, it just means there are no duties to be imposed, and no quantitative restrictions. What made the EEC different was that it also targeted "other measures having equivalent effect" to quantitative restrictions, in order to ensure the common market was not distorted by what would now be called "technical barriers to trade" in the WTO's vocabulary[227]. Going further, the Treaty established four fundamental freedoms of movement – of goods, people, services and capital – which were to be the foundation for much of the developments to come. – and it created a litigation mechanism, and a European Court of Justice (ECJ) which had the power to make jurisprudence.

In the first decade and more of the EEC's existence, there was relatively little done on food safety regulations. The focus was increasing food *production,* something the CAP (which entered into force in 1962) aimed at doing[228]. Unsurprisingly, given the important and visible cross-border impact of animal health issues, regulations started from animals and meat. The first significant pieces of regulation date from 1964: "Council Directive 64/432 on animal health problems affecting intra-Community trade in bovine animals and swine, and Council Directive 64/433 on health conditions for the production and marketing of fresh meat. The new rules harmonised regulations across Member States, such as laws on testing for tuberculosis. Intra-Community trade" (EU 2007, p. 15). It was not before 1971 that "the EU established harmonised hygiene requirements for the treatment of poultry meat in slaughterhouses, storage and transportation" (*ibid.,* p .20), followed in 1972 by a Fresh Meat Trade Directive[229]. Then, "the EU also laid down health rules for imports of cattle, swine and fresh meat, and made the inspection of meat for *Trichinella spiralis* mandatory" (*ibid.*), but that only came about in 1977. In parallel to these directives in the sphere of competence of the Agriculture Directorate General (DG) of the Commission, environmental regulations led to the adoption in 1976 of the first Maximum Residue Levels (MRLs) for pesticides in food (*ibid.,* p. 22).

Limited awareness and perception of risks explains to some extent (as for national regulations) this relatively slow development. Changes in the food supply and to the perception of risks were one of the drivers in regulatory changes, as we have seen in other contexts: "At domestic level, a rise in home refrigeration and an increase in consumer purchasing power saw a change in shopping and eating habits in the EU. In order to meet the rising demand for easy-to-prepare, processed food, large-scale manufacturing grew and the chain of production expanded. While this enabled the needs of the mass market to be met, it also meant that there were more instances in which food safety problems could arise" (*ibid.,* p. 16). The regulations, however, remained sector-specific, "vertical" in nature, not looking at food safety in a comprehensive way. Consumer issues were handled by a separate DG from agriculture. When regulations were adopted, they tended to be highly prescriptive, mandating the exact characteristics a product had to comply with.

*Turning points: "Cassis de Dijon", the "New Approach", crises and the construction of the "Single Market"*

[226] See full treaty text at: http://ec.europa.eu/archives/emu_history/documents/treaties/rometreaty2.pdf.
[227] And clearly the TBT and SPS Agreements owe much to the development of EEC law and jurisprudence over several decades.
[228] Notwithstanding the many issues raised by the CAP, particularly in the last 30 years, it clearly contributed to the major increase in food production in Europe in the past decades.
[229] See the Food Law webpage of Dr. David Jukes, University of Reading, for a chronology: http://www.foodlaw.rdg.ac.uk/hygiene.htm

Several important regulatory, institutional and judicial decisions in the 1970s started paving the way for deeper and broader changes: in particular the 1974 *Dassonville* ECJ case, the adoption of a directive on food labels in 1979, and the creation of the Rapid Alert System for Food and Feed (RASFF) in the same year. With *Dassonville,* the ECJ drew radical conclusions from the Rome Treaty and, in particular, the clause about "measures with equivalent effect" to quantitative restrictions – and severely curtailed the power of Member States to adopt measures restraining free trade across internal EEC borders, stating that "all trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade are to be considered as measures having an effect equivalent to quantitative restrictions[230]". With the food labels directive, the EEC started using new measures to facilitate cross-border trades: information regulations rather than standardization of contents and processes. By setting up the RASFF[231], the Commission implicitly acknowledged the limit of regulations, and the need to be able to identify and respond to problems rapidly and effectively.

### The *Cassis de Dijon* case

Even though changes were evidently gradual and parts of long-term trends, some important "turning points" can be identified – the first being the ECJ's *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein* (120/78) case[232], better known as "*Cassis de Dijon*", after the product that was at issue in the dispute. With *Cassis de Dijon*, the ECJ significantly changed its own *Dassonville* jurisprudence, in a way that simultaneously enabled regulation, but put requirements on its contents and effects that significantly shaped further European regulatory efforts in food (and in product markets more generally).

Since *Dassonville* meant that "nearly any national measure which qualifies as a "trading rule" could be scrutinized by the ECJ", while it "formed an "effective tool to cull the dead wood of centuries of accumulated legislation" it also threatened rules that "often served a social purpose" and "interfered deeply into the sovereignty of Member States, maybe a little too much for what the Member States could handle", thus threatening a backlash (Purnhagen 2014, p. 7). In *Cassis de Dijon*, while the ECJ found for the plaintiff and struck down the regulation[233] (which prevented fruit liquors of less than 25% alcohol content to be marketed in Germany), it put forth a reasoning that clarified the parameters that would define *legitimate* regulation. It first determined that, if they are "necessary in order to satisfy mandatory requirements", "obstacles to the movement within the community resulting from disparities between the national laws relating to the marketing of the products in question must be accepted." The Court then listed some of these "mandatory requirements": "the effectiveness of fiscal supervision, the protection of public health, the fairness of commercial transactions and the defence of the consumer.". This meant that the Court accepted in particular

[230] From *Procureur du Roi v Benoît and Gustave Dassonville*, ECJ case 8/74.

[231] "The RASFF network has been in place since 1979 and was enhanced by the General Food Law in 2002. Members of the network are the Member States, the European Commission, the European Food Safety Agency, Iceland, Liechtenstein and Norway. RASFF enables the rapid exchange of information between national competent authorities on all foodstuffs and animal feed, specifically when a national authority has identified a risk to human health and taken measures, such as withholding, recalling, seizure or rejection of the products concerned. Thanks to the system, Member States can identify if they are also affected and respond appropriately, ensuring coherent and simultaneous actions across the EU and protecting the safety of consumers. To keep the public fully informed, the EU publishes weekly and annual reports containing information on all notifications on its website." (EC 2007, p. 20)

[232] Which was decided in 1979, making this is a crucial year for European food safety regulations history.

[233] Quoting the decision: "The concept of measures having an effect equivalent to quantitative restrictions on imports (…) is to be understood to mean that the fixing of a minimum alcohol content for alcoholic beverages intended for human consumption by the legislation of a member state also falls within the prohibition laid down in that provision where the importation of alcoholic beverages lawfully produced and marketed in another member state is concerned".

the "defence of the consumer" and the "protection of public health[234]" as justifying restrictions to trade (Purnhagen 2014, p. 9).

The decision sought to avoid both total and careless de-regulation, as well as endless possibilities to regulate and break down the common market (*ibid.,* p.10). It performs a balancing act between "removing obstacles to trade in Member State law in order to ensure the benefits gained from comparative cost advantage" and recognizing and addressing "negative externalities resulting from de-regulation" (*ibid.,* p. 11). To this aim, the decision formulated two key principles that then went on to form the basis for further development of European regulation and of the common market (and then "single market"):

- The "information paradigm", i.e. whenever a market failure has been identified, "preference should be given to an information-related rule wherever that seems sufficient to cure the problem" (*ibid.,* p. 12)
- The "principle of mutual recognition" (or "principle of equivalence) which grants "any producer the right to circulate a product, once lawfully marketed in one Member State, freely in any Member State (…) Disparate regulations may hence generally not hinder the free circulation of such a good, even if they have not yet been harmonized" (*ibid.,* p. 14).

The exception to the second principle is when regulatory measures are needed for one of the "mandatory requirements" (fiscal fairness, public health, fair trading and consumer protection) – but even then, the first principle applies and, whenever possible, an information requirement should be used instead of a stricter standardization, "content related" one – so, in any case, proportionality applies (*ibid.*, p. 14). In addition, underpinning the emphasis on information rather than content regulations, is a view that has been called the "confident consumer", one that refuses to "take the ignorant consumer as a yardstick since such an approach would ultimately require the prescription of uniform products" (*ibid.,* p. 29-30).

*Cassis de Dijon* is a decision that is well known and has been abundantly studied by scholars of EU law. What interests us here is that its principles have far-reaching implications, not only for regulatory issues, but for their enforcement – and that these principles help define some of the most fundamental differences between the EU regulatory approach and others, in a way that makes the EU *less risk averse*, i.e. more "risk proportional". In addition, these principles can be seen at work also in the WTO Agreements we discussed above.

By mandating mutual recognition except when a real risk to some essential issues can be demonstrated, the decision opens the way to a more selective, risk-focused regulatory approach. By emphasizing the use of information provisions whenever possible, rather than prescriptive content-focused regulations, it leads into risk-proportional regulation, where instruments are differentiated based on the level and type of risk at issue. Finally, by relying on a vision of the "confident consumer"[235], it embraces a certain level of "risk acceptance",

[234] Neither were relevant in the case, since mandating a *higher* alcohol content clearly was not beneficial for public health, and since the alcohol content was clearly displayed, nor was consumer protection affected. On this last point, the decision strikes down the over-reliance on mandatory standards when there is no overwhelming public benefit: "standardization of products placed on the market and of their designations (…) in the interests of a greater transparency of commercial transactions and offers for sale to the public (…) cannot be taken so far as to regard the mandatory fixing of minimum alcohol contents as being an essential guarantee of the fairness of commercial transactions, since it is a simple matter to ensure that suitable information is conveyed to the purchaser by requiring the display of an indication of origin and of the alcohol content on the packaging of products."

[235] This is a vision which can be taken both in a normative and positive sense. Purnhagen (2014, p. 26) writes: "the early protagonists of an information paradigm for internal market (…) were certainly not naïve as to the realities of consumers', investors' or other market players' individual capacity to process information and to reach rational decisions on that basis. Steindorff, for instance, made it clear that his concept had to be understood as a normative one when he wrote that the internal market "demanded" a circumspect consumer". At the same time, EC/EU and Member States' institutions have made considerable efforts to significantly increase, over time, the information level (and information processing ability) of consumers – thus taking the "informed consumer" as a positive goal, not just a normative view.

and at the same time *ipso facto* makes consumer education and empowerment important activities, including for regulators[236].

The ECJ decision did not come in isolation, but rather had its effects coalesce with the results of ongoing trends affecting European regulations. In particular, what later came to be called the "Old Approach" to product market regulation, which relied on "vertical", product-specific, detailed and content-oriented rules and standards. As Purnhagen (2014) puts it: "this purely centralized regulator model was subject to heavy criticism on several accounts. For some, this traditional harmonization approach was ill-suited to achieving the objective of market integration, as these Directives regularly covered only one of a wide range of aspects in the respective product sectors. For others, the "Europeanisation"-approach resulted in the use of this command-and-control-regulation to an extent which had never been exercised before even in national law. In their view, "it produced 'Europroducts', which alienated the consumer." Either way, there was widespread agreement that the classical standard setting approach envisaged by Art. 100 EEC (now Art. 114 TFEU) was not suitable for the achievement of the goals set by the respective Directives (p. 8). One can just add that this is a very moderate account of the extent of the backlash that EEC attempts at product standardization started to receive in the late 1970s and in the 1980s, particularly in food. All over Europe, complaints of Brussels bureaucrats wanting to standardize sausages, vegetable and the like abounded[237]. There was a double pressure to change the approach: making it more effective (both in terms of trade, and of safety), and more acceptable (to consumers, producers, opinion-makers etc.).

### The "New Approach"

In 1985 was adopted Council Resolution 85/C 136/01 "on a new approach to technical harmonization and standards". This term of "New Approach" came to designate the way in which the EEC (and later the EU) has developed its product market regulations since then – a term normally used for non-food products regulations, but an approach which also permeates the food safety sphere.

The first change was breadth: developing "general rules which are applicable to sectors or families of products[238] as well as types of hazard[239]". The second was the affirmation that mutual recognition would apply to "the results of tests", and the decision to "establish harmonised rules on the operation of certification bodies" – thus clarifying the practicalities of mutual recognition, and moving towards harmonization of control and certification[240].

The Resolution established a set of fundamental principles, most importantly that "legislative harmonisation is limited to essential safety requirements (or other requirements in the general interest) with which products put on the market must conform". Standards are to be developed by "organisations competent in industrial standardisation". The standards' "technical specifications are not mandatory and maintain their status of voluntary standards" – while the authorities must "recognise that products manufactured in conformity with

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[236] This reliance on the "confident consumer" is a very stark difference between the EU food safety regulatory system, and what can be found in post-Soviet countries (and more broadly former Communist countries), and this difference has made approximation of systems difficult. The (broadly speaking) "post Communist" regulatory approach is one that firmly assumes the consumer to be helpless and constantly under threat, and sees as the only solution a full standardization of products. Even when regulations have been approximated to the EU's, this has continued to create challenges in transforming practices.

[237] In this respect, the "Old Approach" in food was far closer to the post-Soviet model, where standardizing everything, including sausages and yoghurt, is the norm, and consumer choice as well as producer diversity are severely restricted.

[238] Cf. Purnhagen (2014), p. 34: "the 'new approach' was the first systematic regulation to be applied to several product groups".

[239] This quote and subsequent ones are all from Council Resolution 85/C 136/01 accessible at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV:l21001a.

[240] The Resolution also asserted what one could call an early "better regulation" goal: "keep a constant check on the technical regulations which are applied so as to withdraw those which are deemed obsolete or superfluous" (a kind of "sunset clause" aim, which has been inconsistently applied).

harmonised standards are presumed to conform to the essential requirements established by the Directive", a producer can opt to produce goods without adhering to these standards, in which case "he has an obligation to prove that his products conform to the essential requirements". Crucially for implementation, and for our research, the Resolution was also concerned with the means of realization of its aims, and building trust in the system – it stated: "the public authorities must ensure the protection of safety (or other requirements envisaged) on their territory. This is a necessary condition to establish mutual trust between Member States."

Moving from the "Old Approach" to the "New Approach" did not only require a change of concepts and principles – it required a constitutional, legal basis. The combination of market pressure (by consumers and producers alike) and change of legal paradigm after *Cassis de Dijon* enabled this transformation. Whereas early European regulations "stipulated classical command-and-control mechanisms, which regulated the product's lifecycle (…) by the setting of detailed, obligatory substantial and procedural standards", the "change in approach of the ECJ (…) provided the basis for the introduction of more conceptual and systematic EU product safety regulation" (Purnhagen 2014, pp. 33-35). The default assumption was from then on that goods could be freely traded and sold across all the EEC as long as they did not "form a hazard to the health and safety of consumers" (*ibid.,* p. 34) – and, through its preference for information rather than content rules, the ECJ pushed for "lighter" regulation.

As indicated, the "New Approach" is significant also by the emphasis it puts on the effectiveness of post-market control. Growth in market volumes and complexity, even before 1985, led to "an increasing realization that only pre-market measures (…) would not suffice and could not ensure European product safety" (*ibid.,* p. 34). There was a fear that "if it was left to the Member States to establish post-market measures, the result would be a divergence of the marketing of hazardous products. Such divergence would be contrary to the goal of the single-market integration, which enabled the free movement of goods only to the extent that they did not impose a hazard to consumers" (*ibid.*).

To address this problem, the EEC took a dual track, which is highly relevant for the study of inspections and enforcement: while it undertook to make "market surveillance" more uniform (to the extent possible) and effective[241], in line with the "New Approach" Resolution, it also decided to considerably strengthen the liability of economic operators. Thus, it attempted to draw on two compliance and safety drivers at once: more effective direct controls by the state, and stronger economic incentives through liability. As a result, in 1985 was also adopted the "Product Liability Directive" 85/374/EEC – "within this Directive, the Council understood post-market control in a wide sense, covering not only classical post-market administrative supervision, but also, and in line with the 'regulation through litigation' - approach, rules on product liability" (*ibid.,* p. 36).

While the "New Approach" *stricto sensu* applies only to non-food products, the same evolution and thinking also came to be applied to food safety regulations. Several important "horizontal" directives were adopted (under the auspices of the Industry DG) in the 1980s and early 1990s: "Methods of Sampling and Analysis" in 1985, "Official Control" in 1989, "Hygiene of Foodstuffs" in 1993 – while, at the same time, DG Agriculture continued to develop a number of "vertical" directives covering milk, eggs, fishery products, game etc. The logic of the *Cassis* decision applied as much to food as to non-food products. Some additional factors came in to push for a more complete transformation of the food safety sphere, which we will now consider.

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[241] "The General Product Safety Directive also introduced classic regulations on administrative market surveillance. Besides some action towards pre-market regulation, the Directive obliges Member States to supervise the safety of products and empowers them to take specific measures. Inter alia, these measures include the issuance of warnings and the withdrawal of products. It also introduced a notification system to the Commission and a Union-wide system of withdrawal of products in case of urgency, which has been affirmed by the ECJ. The European institutions' political agenda to widen the "new approach" also to enforcement came fully to light when the Commission issued a 1994 Communication to ensure the uniform enforcement of Union legislation across all Member States." (Purnhagen 2014, p. 37)

Food safety crises and the construction of the "Single Market"

Over the 1980s and 1990s, a series of food safety crises and "scares" contributed to a growing awareness of food safety issues and an increase in the demand of regulatory protection by consumers, at the same time as the European construction moved from the "Common Market" to the "Single Market". This, combined with the new foundation for regulation provided by the *Cassis* ruling and the perspectives opened by the "New Approach", led to a completely transformed European food safety framework.

First, food safety crises and public "scares". The beef hormone case unfolded from 1980 until 1985, resulting in a complete ban (EU 2007, p. 26). Outbreaks of botulism, salmonella and *E. coli* were recorded over the decade, and made a significant impression on the public (*ibid.*). Clearly, however, the most significant in terms of its regulatory impact was the Bovine Spongiform Encephalopathy (BSE) crisis, and the cases of variant Creutzfeldt-Jakob Disease (vCDJ) it caused in humans[242]. This crisis cast doubts simultaneously on the science used as basis for regulations and inspections, on the credibility of the authorities and the reassurances they issued, on the regulatory requirements, on the controls conducted to ensure safety – and led to border closings and embargoes, a significant breakdown of the market integration process which ran contrary to the whole European project.

As these successive crises unfolded, the development of the European project entered a new phase with the ratification of the 1986 Single European Act. This first major revision of the Treaty of Rome had as main objective the creation of a "Single Market", to be fully operational by 1 January 1993[243]. The move from the "Common Market" to the "Single Market" was not just semantics, but substantial. In the "Common Market" setting, free trade was the objective, but national markets still functioned separately. Physical border posts (including customs) were still operational. Goods were still exported from one country to another. In the food safety perspective, this had very important consequences. Whereas food markets were to a significant extent segmented until December 1992, they made one from January 1993. This meant that no additional requirement whatsoever could be imposed (except in emergency circumstances, such as came to be the case during the BSE crisis) on food shipments from one European Community Member State to another. Until 1992, for instance, veterinary controls in England were applied specifically to meat destined for exports, while (as we have seen above) controls for the internal market were significantly looser. From 1993, there was no longer an "internal" and an "external" market for England, only a single, unified European market – and thus new procedures (and bodies) had to be introduced for England to guarantee the same level of inspections as other Member States.

Establishing a single market meant that the European Community (and in particular its operational branch, the European Commission) had to guarantee consumers that the same level of safety would be ensured (or even, preferably, a *higher* level of safety, given the weaknesses in existing systems laid bare by the successive crises). This does not mean that an identical level of safety was *objectively* reached – nor that the choices made were, with certainty, the most effective – though both may be the case[244]. It means, however, that citizens, traders

[242] We write here "caused" even though there have been some doubts and questions remaining on the transmission mechanism. We also indicate the crisis as being most significant for its regulatory impact. This is not to say the impact on public health was minor, but it was considerably smaller than feared at some point. Worldwide, the total number of vCJD cases (and fatalities) is 229 as of April 2015 – see the following website for background and data: http://www.cjd.ed.ac.uk. See also Blanc *et al.* (2015) p. 30.

[243] There were other important elements e.g. in relation to political cooperation, but these are not relevant for this research.

[244] In order to assess such claims, one would need to have very detailed and reliable data, allowing to correct for a number of external factors, so as to evaluate the impact of the changes introduced. As we have discussed above (in the section on the United States), the performance of the EU food safety system overall appears high. In addition, it includes (as we will discuss below) a significant component of monitoring aiming at ensuring that the performance of all Member States is adequate and comparable (if not identical, which is a difficult goal to achieve) *in practice*.

and customers had to be *confident* that this level of safety was ensured, in order to provide appropriate *trust* for the market to function.

With hindsight, it is likely that either the full consequences of the changes required by the "Single Market" were not perceived, or that political agreement for the institutional changes required could not be secured at the time. Indeed, while efforts were made at harmonization in the run-up to January 1993, no permanent structure existed to ensure that practices remained both adequate and roughly equivalent, except for veterinary control (and even then, its resources were limited). While the European market was now as integrated as the US market[245], and while European food safety legislation was to a large extent harmonized (possibly more than in the US)[246], there was no equivalent to the FDA and FSIS. We have briefly referred to the discussions, which took place in the US in the years leading to 1906, on which institutional model would be appropriate for food controls, including the view that controls at state borders by state regulators would be sufficient – and, eventually, the creation of federal agencies with a mandate over interstate commerce. The EC/EU situation was and is different – the single market does not make differences between interstate and other commerce (more integration), but the principle of subsidiarity[247] means implementation should as much as possible be done at the Member State level or lower (less integration).

The BSE crisis[248] led to the creation of a new institutional framework[249]. First "in 1997, the Food and Veterinary Office (FVO) was established as a successor of the former "veterinary inspection unit" to carry out inspections to "ensure compliance with EU food safety and animal health rules" (EU 2007 p. 33). Then, in 1999, "within the European Commission, the previously dispersed food units merged to form a part of the Directorate-General for Health and Consumer Protection. This enabled a separation of tasks between those responsible for ensuring food safety, animal health and welfare and plant health, and those in charge of agriculture and food markets" (*ibid.*). With the Food and Veterinary Office reporting to this new DG (called in short "SanCo"), the EU (which superseded the EC with the Maastricht Treaty) now had a new, and original, institutional setup. One "quasi-regulatory" institution with a mandate covering all the food chain, all food products, everywhere in the EU – and an implementation body, not conducting inspections of food businesses and premises directly, but rather inspecting and auditing the way Member States' "competent authorities" do so. Finally, in 2002, was adopted Regulation (EC) 178/2002 called "General Food Law" which "introduced the "farm to fork" approach, i.e. the application of good food safety practices and controls at each and every point in the food chain and the necessity for food to be traceable right back to its original source" and also "provided for the creation of the European Food Safety Authority" and overhauled the Rapid Alert System for Food and Feed (EU 2007, p. 38). The European Food Safety Authority (EFSA) was the last piece in the institutional puzzle, in charge of scientific risk assessment (and thus evaluation of "novel foods" and the like), and the strengthening of RASFF improved the inter-operation of national food safety systems.

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[245] Not necessarily in volumes and percentage of trade, but in freedom of movement for goods, animals etc.

[246] While Member States have retained (at least in some cases) some additional requirements (which, as per ECJ jurisprudence, end up in many cases applying only to their own businesses), EU food safety law covers *all aspects of food safety*, and *all types of products* – which is a significantly higher level of integration than the US case.

[247] As well as strong objective factors such as the difficulty of creating control bodies that would have to function in all EU languages, and of achieving acceptance by the public for controls performed directly by "Brussels". Both obstacles are daunting enough, even were subsidiarity to be weakened.

[248] Additional crises and scandals took place over the 1990s, which also contributed to the changes, e.g. the discovery of dioxin in chicken feed produced in Belgium in 1999 (and subsequent food chain contamination)– see http://www.ncbi.nlm.nih.gov/pubmed/11896663

[249] And, eventually, to the the strict liability regime being "widened to apply to agricultural and fishery products" (Purnhagen 2014, p. 37)

As a result, the EU has an institutional structure for food safety which has some similarities with the UK's[250], in the way it is "two tiered": a top-tier agency (FVO) ensuring some level of consistency and uniformity in practices, and bottom-tier agencies actually performing controls with, for some Member States, a middle-tier of national "Competent Authorities" who co-ordinate and supervise controls that are performed by local authorities (as in the UK).

*Key characteristics of the EU food safety regulatory system – and consequences on inspections*

The contemporary EU food safety regulatory system, beyond the 2002 General Food Law, relies essentially on a set of regulations adopted in 2004, which are known collectively as the "Hygiene Package", and have been regularly updated since then. The "Hygiene Package" generally replaces and supersedes previous "vertical" legislation, and embodies the principles affirmed in the 2002 Food Law. The four regulations are: 852/2004/EU on General Food Hygiene, 853/2004/EU on Specific Hygiene Rules for Food of Animal Origin, 854/2004/EU on Official Control of Food of Animal Origin Intended for Human Consumption, and 882/2004/EU on Official Food and Feed Control[251]. The "Hygiene Package" is complemented by a number of "horizontal" directives and regulations that have remained in force (or been added/revised after its adoption), e.g. 1996/23/EC (monitoring of residues in live animals and animal products). The new regulations did not only supersede "vertical" legislation, but also earlier attempts at "horizontal" regulation, which we briefly discussed above – and, in so doing, brought a greater level of integration in controlling the entire food chain. For instance, in contrast to directive 1993/43/EEC, which was the previous attempt at regulating general food hygiene, regulation 852/2004/EU covers also primary production, "from farm to fork" (a.k.a. "from stable to table"), in a way that the previously existing division between the Agriculture and Consumer DGs did not allow.

It is not relevant for our work to enter here in the details of these regulations, but important to highlight their most important elements. First, the regulations embody the "farm to fork" principle by requiring from all operators to ensure traceability of their products "one step up and one step down" (at least to the immediate supplier and customer) They apply to the entire food chain – they also apply across all sectors and sub-sectors, and to all kinds of operators (producers, processors, traders, transporters, food service). Second, they rely on the full liability of "Food Business Operators" (FBOs), as they designate all establishments and entities dealing with food – and this liability is seen as a fundamental tool to ensure compliance with the regulations (by raising the potential costs of non-compliance, since FBOs are responsible for any harm caused) - as well as secure the legitimacy of the system (since victims are compensated). Third, the regulations internalize the impossibility of "zero risk" – they foresee the conditions in which a recall is mandated, and the ways in which it should be performed, in adequate detail. They do so in a way that provides real incentives for FBOs to proactively initiate a recall if they detect a problem – since their liability is engaged in case they do not perform the recall, but can be at least to some extent mitigated if they do so in a timely manner. Fourth, they require of FBOs not only to comply with hygienic requirements or Maximum Residue Levels (MRLs), but also to put in place and effectively implement permanent self-control systems, in order to ensure that food is constantly and consistently safe at every stage – a requirement that is based on the Hazard Analysis and Critical Control Points (HACCP) approach[252]. Fifth, they openly and clearly formulate *risk* as an organizing principle – on the basis of which

[250] Which one could see as ironic. It should be noted that the FVO was set up before the UK FSA. The similarity is partial, since the split of responsibilities is different: the FSA does some controls directly (Meat Hygiene) and includes scientific risk assessment, whereas the FVO relies entirely on Member States for controls of Food Business Operators (FBOs), and scientific risk assessment is done by EFSA.
[251] In the narrow sense, the "Hygiene Package" designates only regulations 852, 853 and 854, but regulation 882 is very closely linked, and generally considered as part of the "package" by many professionals. It was adopted in the same year, and with the same approach.
[252] A few remarks are needed on this "HACCP requirement". First, flexibility is foreseen for small operations, in particular if no clear "Critical Control Points" can be identified, and "Good Hygiene Practices" (which otherwise are a pre-requisite for HACCP) can be

regulatory instruments have to be chosen, regulatory resources allocated, enforcement responses decided upon. Sixth, they apply this risk-based approach not only to inspections of already operating businesses, but to the pre-operation stage – under the "Hygiene Package", only FBOs producing/processing food of animal origin are subject to mandatory approval before start of operation, all others can start operating after a simple registration (notification). Seventh, and crucially for us, they regulate also *official controls*.

Regulation 882/2004/EU on official controls[253] is of particular importance for us, in more ways than one. In its approach, because it squarely defines *risk* as the fundamental criterion on which food safety controls should be organized. In its reach, because it is a regulation that governs how national inspection bodies should work – and seeks to do so in a way that provides *confidence* that official controls are essentially *equivalent* all over the EU's territory. In its details, finally, because it demonstrates a level of attention to the fineries of inspections and enforcement, to the questions of risk assessment, planning, quality control, staffing levels and training, funding level and sources, methods and tools. This makes it a rather unique document, in that it is vanishingly rare to see national legislation on inspections being this detailed and comprehensive[254].

### Risk – the foundation of official controls' planning and implementation

Point 13 of the Regulation's preamble prescribes that "the frequency of official controls should be regular and proportionate to the risk, taking into account the results of the checks carried out by feed and food business operators under HACCP based control programmes or Quality Assurance Programmes, where such programmes are designed to meet requirements of feed and food law, animal health and animal welfare rules". The Regulation mandates the use of *risk-based planning*, specifically through "multi-annual national control plans in accordance with broad guidelines drawn up at Community level. These guidelines should promote coherent national strategies, and identify risk-based priorities and the most effective control procedures[255]" (Preamble, point 34). In its Article 1, the Regulation then goes on to state that the aims of official controls are "preventing, eliminating or reducing to acceptable levels risks to humans and animals, either directly or through the environment" and "guaranteeing fair practices in feed and food trade and protecting consumer interests" – thus, it keeps the old duality of purpose (safety, and market rules) that we

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accepted as sufficient. The level of flexibility shown *in practice* varies considerably between countries [author's own observations discussing with senior food safety officials in 6 different EU countries: UK, France, Italy, Latvia, Lithuania, Poland], and European Commission guidance on this topic is often not known, and in any case not mandatory as it is only a guidance document (i.e. "for information purposes only" – available at: http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance_doc_haccp_en.pdf). Second, in primary production, the application of all principles of HACCP is not mandatory but the introduction of GHP is compulsory and the elaboration of related hygiene guidelines are suggested. Finally, what the regulation requires is application of HACCP *principles,* not the obtention of a HACCP certificate from a conformity assessment provider.
In primary production, the application of all principles of HACCP is not mandatory but compulsory the introduction of GHP and the elaboration of related hygiene guidelines are suggested.

[253] "Official controls", in the context of this Regulation, include: "audit" (systemic check of whether activities comply with planned arrangements in particular internal quality/safety controls), "inspection" (thorough verification of compliance of operations/products with legal requirements), "monitoring" (planned sequence of measurements/observations to obtain a representative view of the compliance level). While the first two target individual FBOs, the third one is aimed at producing statistical information to assess the regulatory system's effectiveness.

[254] The OECD *Best Practice Principles* of 2014 cover most of these issues (though in limited details, due to the nature of the document), but in all national-level legislation studied by the author (covering well over 20 countries), nearly no law was covered that would cover all these aspects (some draft laws being developed with World Bank Group support, e.g. in Mongolia, would do so, but have not yet been adopted). Though it is practically impossible to *prove* an absence, we can safely say that Regulation 882 is one of the very few examples of legislation covering all these aspects (and doing so in significant detail). The European Commission is now trying to somewhat replicate this approach in the field of non-food products safety with the new "Product Safety and Market Surveillance Package" (still under consideration) - http://ec.europa.eu/consumers/consumers_safety/product_safety_legislation/product_safety_and_market_surveillance_package/index_en.htm.

[255] Which means not only should planning be risk-based, but the choice of instruments be linked to risk as well.

have observed elsewhere, but clearly puts risk prevention or mitigation first. Then, in its Article 3, the Regulation goes on to define more specifically the risk factors that should be taken into account: "identified risks associated" with specifics of the product or operation (inherent risk), "operators' past record as regards compliance", the "reliability" of internal controls and external information "that might indicate non-compliance"[256]. Article 54 further directs that "when deciding which action to take [in case of non-compliance], the competent authority shall take account of the nature of the non-compliance and that operator's past record with regard to non-compliance", which outlines a risk-proportionate enforcement approach not unlike the UK HSE's – and Article 55 also prescribes that sanctions should be "proportionate". In short, risk, risk assessment, risk proportionality are the foundations of the entire Regulation.

### Regulating official controls and ensuring coherence and equivalence across all the EU

This is, of course, the very purpose of the Regulation: ensuring as much uniformity of food safety controls all over the EU. While mitigating risks is the main aim, and risk is the foundation for organization and implementation, uniformity is the direct operational objective. The Regulation attempts to achieve it through a number of prescriptions on methods, capacity and means. First, procedures: "official controls should take place on the basis of documented procedures so as to ensure that these controls are carried out uniformly and are of a consistently high quality" (Preamble, point 14). Second, coordination at all levels: "competent authorities should ensure that where different control units are involved in carrying out official controls, appropriate coordination procedures are in place and effectively implemented" (Preamble, point 15). The same is mandated between "central level" and "regional or local level" in countries where it is relevant (point 16), between different competent authorities including those in charge of "environmental and health protection" (article 4), across Member States (Preamble point 22) etc. Third, the Regulation requires competent authorities to have adequate human capacity (numbers and competence), equipment and access to laboratories (with a number of additional prescriptions specifically for laboratories), and legal powers. Adequate resources are required by point 32 of the Preamble, as well as Article 26. Staff numbers and competence are covered repeatedly, e.g. in Preamble points 11 and 12 and Article 4. Equipment and laboratories access are in Preamble point 11, Article 4, Article 16 etc. The requirements on laboratories are covered in details in Article 12 and in Title III (Reference Laboratories) of the Regulation. Legal powers are in Article 4, and Title VII (Enforcement Measures).

In order to ensure that these different aspects are all being adequately complied with, and with a particular focus on the *planning* and *implementation* of controls, the Regulation foresees a whole system of "control of the controllers". In this two-tier system[257], the Commission controls Member States' Competent Authorities, in particular their implementation of the "multi-annual national control plans" – which should "enable the Commission inspection services to verify whether the official controls in the Member States are organised in accordance with the criteria laid down in this Regulation" (Preamble, point 36). Member States should also submit annual reports to the Commission (Preamble, point 37).Title VI, Chapter I covers "Community Controls". The "Commission experts shall carry out general and specific audits in Member States" (Article 45), it shall "establish an annual control programme" (*ibid.*).

[256] And Article 16 mandates an essentially similar approach for checks of imports. Article 46 prescribes that the frequency of third-countries controls should also be risk-based.

[257] Or three-tier, when national Competent Authorities themselves supervise local authorities which conduct the actual controls.

### A comprehensive understanding of inspections issues

As we have briefly indicated, the Regulation attempts to cover all of the issues relevant to inspections' effectiveness. We have already mentioned the sections dealing with resources, staffing, laboratories, powers. The Regulation also covers the question of *fees*, to be used as one of the sources of funding for official controls – and, in so doing, it builds on previous EC/EU legislation starting from 1985, which enabled to raise fees for veterinary controls[258]. The Regulation also emphasizes the importance of training, and it empowers the Commission to organize EU-wide training to ensure effectiveness and consistency (cf. Article 32 for reference laboratories, Article 51 for control staff)[259]. Thus, the Regulation covers every aspect of inspections: goals, legal powers, risk assessment, planning, tools and methods, resources (incl. staff and equipment), sampling and testing, decision making, reporting, training, coordination, exchange of information – as well as crisis contingency planning, emergency response, recalls etc.

### Tentative conclusion

The EU has tried to not only transform the methods of its food safety regulatory system (with a strong emphasis on *risk*), but to put a lot of focus on improving inspections and making them more coherent and consistent. This has led to a rise in the FVO's importance, including through its audits[260] of Member States[261], and its work on assessing candidate countries' readiness (and advising them on reforms to get ready). To the extent that evidence is available, this appears to have been a real success, in the sense that the overall performance of the system is high (in spite of the limitations in assessing how high, and how well it compares, that we discussed above) – and that it has allowed a far greater integration of the EU market, and accommodated an increase in trade volumes and complexity. Success on consumer trust and confidence is not perfect, but real, particularly considering how difficult the situation was in the 1990s. New Member States have been "brought up" from (in some cases) very problematic situations up to levels of food safety that are generally in line with the older EU Members – as evidenced by FVO audits and EFSA monitoring.

There are, however, important limitations that prevent us from drawing strong conclusions on the effectiveness of the different systems. First, there is insufficient epidemiological data to assess if the system performs indeed better now than in the past, or (as some claim) than the US's (and, if so, to what extent) – and in any case, there are very serious attribution issues. It is unclear how strong is the link between food safety data, and improved (or assumed to be improved) controls. Second, while the inspection regime foreseen by EU Regulation 882/2004 is strongly *risk based* in terms of what aspects of operations should be regulated*, risk focused* in terms of inspections planning, and (to a large extent) *risk proportional*, it fails to incorporate a really comprehensive approach to *compliance.* This means that food safety controls based on the implementation of this regulation, while risk-based, are not necessarily "smart" in terms of incorporating several complementary instruments, or a responsive enforcement approach.

Indeed, throughout the directive, when compliance is mentioned it is primarily from a *deterrence* angle (requirements to have dissuasive sanctions: Preamble point 41, article 55). The FVO harmonization efforts are

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[258] Veterinary inspection fees are important because they play a strong role in the EU's capacity to have far more systematic slaughter inspections than the US (see above on this) – the fees are foreseen in Preamble point 32, and covered in details in Article 27, which distinguishes between areas where fees are mandatory (detailed in Annexes IV and V, essentially: veterinary control of slaughter, and imports) – and other areas, where Member States *may* impose fees. The Regulation also sets a minimum level for mandatory fees, and guidelines for fee-setting overall (including proportionality to complexity/size, possibility to reduce fees when risk is low etc.).

[259] In practice, this has resulted in the *Better Training for Safer Food* programme – see EU 2007, pp. 17 and 38.

[260] See audit programme here: http://ec.europa.eu/food/food_veterinary_office/audit_programmes/index_en.htm and audit reports here: http://ec.europa.eu/food/fvo/audit_reports/index.cfm

[261] EFSA is playing the main role in monitoring – see: http://www.efsa.europa.eu/en/panels.htm, http://www.efsa.europa.eu/en/topics/topic/salmonella.htm etc. But the FVO is also active in some areas, see e.g. http://ec.europa.eu/food/fvo/specialreports/pesticides_index_en.htm on pesticides.

conducted from this perspective as well: ensuring inspections are well targeted, and technically competent – but not that there are serious efforts made to support understanding of requirements and actual compliance levels. To the extent that compliance promotion efforts can make a real difference in economic, social and safety outcomes (something which, as we will discuss further in this research, there are serious grounds to consider), this is a major shortcoming.

## 2.3. Conclusions and relevance for our research

This historical overview has served to show the sheer diversity and path dependence of institutional structures. Even in a field as "science based" as food safety, where official guidelines from the EU (and recommendations from agencies such as UN FAO) push towards an institutional model (single agency or at least greater integration), there is very significant diversity, and often fragmentation[262]. There are also all kind of "national peculiarities" (delegated functions to private sector bodies in the Netherlands, importance of local authorities in the UK, etc.). This means that efforts to make inspections more risk-focused, "smarter" etc. take place in an institutional context that is rarely "optimal", and that in any case was generally not really "designed", and emerged as a result of many historical accidents. When real consolidation takes place, it is often either in the context of dramatic external and internal pressure ("transition crisis" and EU pressure for Baltic states), or over several decades (Netherlands). This both creates an apparent challenge to reform and efficient improvement efforts, as well as an opportunity to examine whether different institutional set ups have a major incidence on results, or whether it is possible to improve the way inspections are organised and conducted regardless of these.

At the same time, though, we have observed a number of trends, from which we can try and extract some lessons – which, though they do not have the strength of statistical observations or demonstrations, can nonetheless shed some lights on the origins and development of inspection functions, and their relationship to the question of risk.

A first common aspect across countries and regulatory areas include the fact that inspection mandates and agencies emerged not so much in relation to quantified, scientifically determined risk – but far more in reaction to risk *perceptions*, breakdowns in trust, emergence of new hazards that generated strong reactions

[262] Modern food safety approaches, as advocated for instance by UN FAO and mandated by the EU legislation on the topic, emphasise the importance of "farm to fork" traceability, and thus of a control system that ensures integration of information and findings along the entire food chain. Considering that distinct agencies under separate ministries typically have difficulties effectively sharing information and coordinating their actions, the European Commission (and in particular the Food and Veterinary Office, part of DG SanCo) has been pushing candidate countries very strongly to create "unified" food safety agencies or inspectorates. As is wont to happen, this pressure has been more or less strong and effective depending on the relative size and/or negotiating positions of candidate countries - and countries have reacted to it in different ways (resisting or embracing it) depending on their own contexts. Thus, Poland entered the EU with fragmented food safety control (trade inspection, hygiene, veterinary service), as well as Slovenia (health and veterinary service - in the meantime, a new unified Food Safety Inspection has recently been created), whereas Lithuania and Estonia created very strongly integrated institutions (Lithuania gathering all control functions related to food safety and animal health, adding a large swathe of the regulatory powers, the laboratory network etc.). Absent strong external pressure, it is far more rare to see countries radically transforming their own administrative structures, given the organisational inertia and status quo bias, and lobbying power of large regulatory enforcement agencies. Thus, in many countries of the Former Soviet Union, there still are at least three agencies (not counting those in charge of plant protection) looking at food safety: the sanitary and hygiene, veterinary and standards services (as most of these countries still make widespread use of mandatory standards in the food sphere). Some countries (e.g. Armenia) have gone towards establishing a single food safety agency, but this has usually been in the context of international negotiations (as Armenia was at the time negotiating a free-trade agreement with the EU), which gave additional strength to an internal reform initiative.

of "dread" (in line with the findings in Slovic 1987) , and also as a result of active "lobbying" by what we could call, following Helsloot and Schmidt (2012), "risk experts".

A second element we have found consistently is path dependence. Creating fully new institutions, revising mandates or resources radically, are all very rare. Even when reforms, mergers etc. do occur, they usually do so on the basis of whichever structures, legal framework and practices existed. Path dependence applies not only to structures, mandates and resources, but to regulatory approaches, and in particular to inspection and enforcement methods and objectives. We will come back to this question in more depth because of its importance in our research perspective.

The third tentative finding from our historical review would be a gradual, incomplete but real tendency to some convergence in structures and methods, at least in some areas, e.g. food safety, where international integration (and competition) is stronger. This convergence appears to incorporate a growing emphasis on *risk* as a fundamental criterion for determining the appropriate enforcement response, focusing inspection resources – and, to some extent, even the adequate level of regulation. This qualified (and far from universal) finding, however, appears to run contrary to some recent research on risk and regulation, and requires further discussion.

### a. Understanding path dependence, and its limits

The importance of path dependence has been well perceived by many authors. In trying to understand different "risk regulation regimes", Hood, Rothstein and Baldwin (2001) consider several explanatory factors, which they group under the notion of "context". They thus look at the extent to which the actual features of different regulatory regimes[263] can be explained through three key elements: "market failure"[264], opinion-responsive regulation, and the interplay of the different interests, lobbies and experts. They find, overall, that even though these different context elements appear to explain *some* features in *some* cases, there are important variations and discrepancies that appear difficult to explain within the chosen models. They then turn their attention to "inherent" aspects of these different regimes, and path dependence[265]. The authors find that the "historical points of departure" influence successive developments, and how "context" elements (e.g. "interest-group activity") play out (p. 140). The difficulty of "introducing radically new legislation or standards" means that "incremental adjustment and patching" is frequent (p. 140-141).

There are several ways in which such path dependence functions. One is, as indicated, the fact that radical changes to laws, standards, rules and institutions are difficult, and correspondingly rare. Another is that the "regulatory community" has in a way an "inner life", and definitely develops over time a certain culture and view of what is appropriate or not (*ibid.*, p. 141-142) – something which our examples above clearly also validate. More broadly, the entire "context" explanation is, in a way, a form of "path dependence" vision to an extent, because many "context" elements have themselves been shaped by historical evolution, in particular how responsive (and with which types of response) the government is to public risk perceptions, and also how interest groups, lobbies and experts view their interests, play them out and influence policy.

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[263] Though the authors call them "risk regulatory regimes" we would suggest that they would be more accurately termed "hazard regulatory regimes", in keeping with the difference between "hazard" and "risk" exposed e.g. by BRDO (2012).

[264] We will not discuss here the question of whether it was pertinent in the first place to adopt this list of "context" elements, but clearly 'market failure' is primarily a *justification* for regulatory intervention (from a purely economically rational standpoint), and not an explanatory factor for the *actual features* of regulation.

[265] Defined here as the idea "that policy and administrative routines tend to be heavily influenced by their historical point of origin, with inertia leading to persistence of original form, patterns of development that are path-dependent and often characterized by sudden abrupt changes rather than smooth adaptation to changing context" (Hood, Rothstein and Baldwin 2001, p. 69).

There are, however, powerful elements that come to (at least partly) counterbalance path dependence. The first is the occasional discontinuity occasioned by sudden high-profile accidents – even though the strength of this factor is unequal[266]. The evolution of science and techniques is a second, sometimes very powerful driver, e.g. by making hazards visible or understood, and/or by giving the tools necessary to detect and control them – as we have seen for instance in the food safety case, at repeated points. Supra-national factors also clearly play a significant role (though exactly *how significant* is not easy to determine), at least in some areas – as we have seen in the food safety sphere, where the EU has pushed quite profound transformations in institutions and methods, and the WTO also introduced new requirements (and litigation mechanisms to try and enforce them). Clearly, these unifying forces are not able to overcome all specificities and historical inheritances – otherwise we would see far more unified food safety inspectorates, for instance. But the creation of the FSA in the UK, the FSMA in the US (and new discussions on potentially merging several agencies), both testify to the reality of such forces. Likewise, the creation and successive development of the HSE demonstrates that evolutions in the society, economy and techniques can lead to quite significant changes – but the ways in which these changes are different and happen at different paces in varying countries shows the importance of historical and context factors.

Assessing the significance of path dependency in terms of effectiveness and efficiency of inspections and enforcement is complex. In some instances, it may relate to issues which end up not being binding constraints in terms of methods, practices etc. – such as the exact split of institutional mandates between several agencies, or whether central or local government is in charge. While these aspects clearly *influence* the choice of methods and approaches, they do not generally prevent change e.g. the adoption of a more risk-based or compliance-promoting model. Where path dependency is more significant is when

### b. Is there (and can there be) a convergence towards risk-based approaches?

In the above case studies and 'snapshots', as well as in the conclusion, we have suggested that there was to some degree a trend towards a 'convergence' of sorts, at least in some regulatory areas – and that this convergence appeared to be in the direction of more "risk-based" inspections. We saw that the prescriptions about risk that can be found in the EU "Hygiene Package", the US FSM Act, or the WTO SPS agreement, were generally consistent with each other – and also corresponded to the definition of risk that is most commonly used in regulatory inspections: the combination of the likelihood of hazard, and its potential severity and magnitude[267]. We did not, however, look closely as to whether (and to which extent) references to 'risk' e.g. in WTO and EU documents were in fact matched by reality of practice. Thus, while there is undeniably a *claim* of increasingly risk-based practices (at least in food safety), it does not follow that this claim is fully backed up by practice, and even less that it is applicable to other regulatory areas.

Some authors have, in fact, radically challenged claims of 'convergence' and questioned whether they are, in fact, "universally applicable foundations for improving the quality, efficiency, and rationality of governance across policy domains", as some of their proponents have claimed (Rothstein, Borraz and Huber 2013). They point out that, as of 2013, "no comparative research has sought to explore whether the emergence of risk-based approaches to governance in the UK has been mirrored in other member state contexts, nor for that matter, at the level of the EC" (*ibid.,* p. 218) – an important gap, which that article and subsequent work aimed at contributing to filling, and which this present research also intends to help address. In their short overview

[266] What has been "termed 'tombstone-ability' – the capacity of a risk to produce deaths or suffering victims through dramatic catastrophes (…) seems likely to augment the force of public opinion in shaping regime content" but "only one of the observed elements of regime content that was way out of line with the opnion-responsive hypothesis involved a 'tombstone-able' risk" (*ibid.*, p. 140).

[267] See BRDO 2012 and World Bank Group 2013 a.

of the cases of France and Germany, in counterpoint with the UK, the authors find (somewhat unsurprisingly, one could add) that "the emergence of risk as an organizing concept of governance varies across countries" (p. 231). More importantly, they find considerable barriers to the adoption of risk-based approaches in France and Germany. In both countries, a combination of cultural and legal factors appear to make such approaches really problematic, and to result in risk-based regulation remaining very limited in scope and depth.

In France, they find that the idea of risk-based regulation[268] runs contrary to several key organizing principles of public policy: "the culturally established commitment or "promise" by the French state to provide security for its population", "the priority given to maintaining "public order;" a principle that is defined in administrative law, has been interpreted by the courts, and (…) underpins a core role of state officials in preventing any event that could create disorder and undermine the authority of the Republic", the "principle of equal treatment for all (…) [which] can conflict with risk-based approaches to setting priorities and allocating scarce resources" and "the concept of the "general interest", which civil servants are expected to represent and defend, under the supervision of the *Conseil d'Etat*" – a role which risk-based approaches, because they result in "more open and deliberative styles of decision making", could threaten (*ibid.,* pp. 222-223). In Germany, they find that barriers to the use of risk-based approaches come from both "the juridified character of German policymaking" and "the fragmented federal system that distributes competences – depending on policy domain – across at least three levels" (*ibid.,* pp. 225-226). On the courts' side, the problem is the difficulty they have found to balance "the state's "duty of protection" from dangers (*Schutzpflicht*)" with the need to accept "some degree of "residual risk" (…) [and their] great difficulty in using "probability-x-impact" frameworks to define the boundary between unacceptable "dangers" and acceptable "risks."" The federal system, in turn, results in the "presence of multiple decision makers with varying philosophical approaches to governing risks and often contradictory interests in the distribution of risks, costs, and benefits" (*ibid.*).

The authors go on to show examples of how these resistances have limited their introduction "even where risk-based approaches have been internationally mandated" – for instance, "in the case of EU-mandated risk-based food safety inspection". In France, "local state services complement the assessment of food safety risks posed by businesses with an additional "fudge" risk factor that takes into account the "sensibilities" of the *département* (…). Such factors can undermine the value of risk-based approaches in protecting public health if the field-services or the *préfet* decides that inspection resources should be directed towards maintaining public order or protecting their own reputation" (*ibid.,* p. 224). Generally, French state authorities "in situations of uncertainty or under pressure from social movements (…) prefer to be risk averse or invoke the precautionary principle, even if it means facing later criticism for over-reaction" (*ibid.*). In Germany likewise, "even internationally mandated risk-based approaches to governance can fall foul of constitutional arrangements for their implementation. One example was resistance by *Länder* to EU rules on risk-based food safety inspection on the grounds that they contravened constitutional expectations" (*ibid.,* p. 226).

There are several reasons why we do not think that these views seriously rebut our perspective on risk-based approaches. First, we are focusing on inspections and enforcement, not on policy- and rule-making – and this is clearly the area where (in spite of shortcomings) there has been the strongest "push" for more risk-based approaches (at least in food safety) at the EU level. Second, we would take a somewhat different view of the same situations that Rothstein, Borraz and Huber describe – namely, that of the "half-full bottle". If one compares the practices in France and Germany to an *ideal* of risk-based approaches, or even to the practice in the UK (which is not "ideal", but clearly far more strongly risk-based), then clearly the assessment will be that France and Germany are "resisting risk-based approaches". If one, however, compares the *current*

[268] Defined by the authors as premised on the "idea that governance cannot, and indeed, should not, aim to eliminate all potential harms or more generally, "adverse outcomes" (…).Rather, in an adaption of Paracelsus' maxim – the likely dose makes the poison – "risk based" approaches pay attention to both the probability and impact of potential adverse outcomes" (*ibid.,* pp. 215-216).

practices in France and Germany with that of a couple of decades *earlier* in the same countries, there is some evidence of *changes* in the direction of gradually *more* use of risk-based approaches, at least in some areas. Thus, taking again the example of food safety, even though inspections in France and Germany are in some areas probably not in full conformity with EU regulations and guidelines (and we would certainly agree, as we will discuss in later sections, that they are *less* risk-based than in the UK), such partial non-conformities are a normal part of "real regulatory enforcement". Considering how much power and clout the EC FVO wields, and of how frequently it audits national systems, it is unlikely (to say the least) that France and Germany could get away with completely avoiding implementation of EU Regulation 882 – rather, there are problems "at the margin", and indeed the margin can be somewhat too wide.

This brings us, in conclusion, to two points: the effectiveness question, and the challenge of overcoming "national cultural and institutional resistances". On the first, an earlier paper (focusing on environmental regulations and their enforcement) by Rothstein, Irving , Walden and Yearsley (2006) concluded that "case studies suggest that they have the potential to improve regulatory understanding and efficiency and overall outcomes. (p. 1063). Subsequent sections of this research will consider other evidence, but we have already seen some pointers suggesting that "risk-averse" systems are not immune to problems, e.g. the *E. coli* outbreak originated in Germany, whereas Rothstein *et al.* (2013) have found resistance from local authorities in Germany to implementing EU-directed risk-based approaches – in all likelihood in the belief that their own system would be more effective, a belief that we now have strong evidence to find mistaken. If indeed there are significant differences in effectiveness between risk-based approaches and others, then the question of how to foster the adoption of these approaches becomes a very important one. From such a perspective, the findings from the 2013 paper suggesting that France and Germany present strong inherent factors making the adoption of risk-based approaches very difficult can cause concern. Without discussing this question in depth here, it is worth pointing to the *limitations* of these barriers. Indeed, clearly, introducing risk-based approaches may be more or less difficult in different countries, and face in some cases very strong resistances – and possibly fail. But there are many examples of reforms in a more risk-based direction taking place in countries where cultural and institutional resistances were considerable, e.g. in Lithuania, one of the cases we will consider in later sections. There are also examples in the very countries taken as examples of "risk resistance" that show that there are limitations to these cultural and institutional factors, and more complexity than first meets the eye. On building safety regulation, for instance, France has a system that is far more risk-based, and far less reliant on state inspections, than the UK – and this system is very much uncontroversial, showing that the demand for more state protection is neither constant nor universal. This system, however, draws on very deep roots, going back all the way to the 1804 Civil Code, and again showing the importance of long-term perspectives[269]. Going into the details of this example is beyond our scope here – it is enough, however, to suggest that what is claimed by actors to be insuperable obstacles to new approaches is sometimes little more than a smoke-screen to shield existing practices from review. If France can have far less state inspections and far more acceptance of risk in one sector than the UK, it means there is nothing absolutely and permanently "determined" in the relative acceptance of risk-based approaches in different countries. Clearly, national political and regulatory cultures are important, as illustrated e.g. in the case of the US by Scholz (1994). But cultures are transient, evolve and change.

[269] A full explanation of the system can be found in World Bank Group 2013 (b) pp. 82-87 and Helsloot & Schmidt 2012 (b) pp. 57-60 and 115-130. In short, state inspections of compliance with building safety norms are close to non-existent in France. Rather, there is a 10-year liability for all operators involved in construction, backed by mandatory insurance for builders and developers. In addition, the stringency of third-party controls required (and of state approvals) is linked to the risk level of the building (or part of the building), and insurance premia are also risk-proportional.

### c. Conflicting directions – steps "forward" and "backward"

A last remark is needed: just as inspections are not an unalloyed good (or bad), evolution of institutions and practices does not follow a uniform path. Bardach and Kagan (1982) show how the powers of the inspectors, if left unchecked, are in some ways even more prone to abuse than policemen's, because of the lower limits on "searches and seizures" (p. 32-33). Inspections can thus tend to abuses of power, but they can also be threatened by ineffectiveness and capture by influential regulated entities (*ibid.*, pp. 42-44).

In the US, what was perceived as capture by "criminal" businesses led to a very strong backlash in the late 1960s and early 1970s – a consumer advocacy report championed by Ralph Nader compared the consultations and cooperative meetings of the FDA with businesses to a situation where the Justice Department would hold regular meetings with the mafia (p. 44). The "reform agenda" in response involved "new regulators, preferably at the federal level", "more comprehensive and explicit regulations", sharply curtailing "administrative discretion and leniency" and enhancing "deterrence by increasing the severity, speed, and consistency of sanctions" (p. 45). The "new-style protective regulation", worried about capture, prescribed an "explicitly legalistic enforcement style" (p. 72), and resulted in blurring the difference between inspectors and police, with a "young regional FDA enforcement official" being quoted as saying: "We're a law enforcement agency, not a service agency" (p. 73). This whole evolution was to lead, in turn, to what Bardach and Kagan called "regulatory unreasonableness", and a considerable backlash *against* regulation and inspectors[270].

The development we are trying to investigate in this research is precisely the next phase of this "back and forth" – the attempt to develop approaches that would strike an appropriate balance between the twin pitfalls of excessive discretion and legalism, of ineffectiveness and unreasonableness. Risk-based approaches are promoted as being the way to reconcile apparently contradictory concerns, but we can see that they are not the product of a seamless evolution, and that conflicting views and perspectives exist, and carry regulation and inspections in different directions, depending on the relative strength of different actors and factors over time.

Having now completed this historical introduction, we will turn our attention to the theoretical underpinnings of risk-based inspection approaches, before moving to consideration of data in order to assess comparative effectiveness.

[270] See also p. 123 for a more positive take by the same authors on the contributions made by the "stricter" approach of the 1970s.