

Food safety regulation in Europe: How to measure performance and effectiveness

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Panel 7.4

Abstract

The paper aims to review the existing empirical literature on food safety regulation in Europe, in order to assess how performance and effectiveness are measured.

The paper explores the main empirical contributions that describe the measurement process that has been applied in the literature to operationalize some key variables. Those variables have been identified through a preliminary literature review. This allowed to draw a general picture of the state of the art in the field of food regulation and to go deeper into unsolved research questions. Furthermore, measurement and operationalization processes are assessed.

The method used is systematic review, which allows replicability and relies on the “*key principles of objectivity and scientific rigor*” (Arthur et al. 2012, p. 218).

The paper eventually discusses the results in order to set the ground for further empirical analysis on the impact that the institutional regime (i.e. regulation, regulators and controllers) has on the effectiveness of food regulation.

Introduction

In both developed and developing countries, food safety has become of major concern in the political agenda of the governments. In response to *food scares*, which has occurred in the last decades, many countries have engaged into a deep policy change all over the world, particularly in Europe.

The spreading of new animal and human diseases (the European “mad cow disease” case has been one of the most shocking and well-known), the use or the contamination of some harmful products for the human and animal health, as well as for the environmental protection, shed lights on the crucial role of governmental policies and regulators. The food safety governance is a complex multi-level system of interactions between institutions - both public and private, local and global - and individuals - citizens and consumers. Food safety regulators are influenced by economic interests, social norms and technological development, and their decisions can have a great impact on public health systems as well as on economic developments.

The main objective of this paper is to review the empirical literature on food safety regulation in Europe, in order to assess how performance and effectiveness are measured. Furthermore, research opportunities in this field are explored. The main research question is: how to measure the performance and effectiveness of food safety?

The paper assesses the main empirical contributions that describe the measurement process that has been applied to operationalize some key variables: food safety and food safety performance, food quality, food authenticity, compliance with regulation. Those variables have been identified through a preliminary literature review. This allowed to draw a general picture of the state of the art in the field of food regulation and to assess measurement and operationalization processes (data collection, methods and data analysis).

As working paper, it is preliminary to develop further empirical analysis on the impact that the institutional regime has on the effectiveness of the food regulation. Indeed, results will be applied in the operationalization process of the outcome in further empirical analysis.

The paper is divided in five sections.

In the first section a general overview of food safety regulation is given, introducing some concepts such as food safety, risk regulation and governance. Furthermore, the factors which affected the evolution of food safety regulatory framework within the EU are explored, together with the compliance process. Indeed, compliance might be crucial for the effectiveness of the regulations with respect to achieving the specified policy objectives.

The second section is dedicated to the method: how the review has been conducted, the eligibility criteria for the articles examined, information sources and the strategy adopted for the selection of the articles.

In the third section the main results of the systematic review are presented: the main characteristics of the empirical contributions, measurement of the key variables, limitations of the analyses and comments.

The fourth section discusses the results in order to set the ground for operationalization in further analysis.

Eventually, some final considerations are given.

Food safety, risk regulation and governance

Food safety regulation is particularly relevant due to the impact it exerts on public health and on businesses of agri-food sector. It also has to be intended within the broader framework of risk regulation. As the work of Righettini (2015) enlightens, safety governance and risk governance are complementary and food safety can be considered as the result of food risk management. Food safety regulation has to do with many policy sectors, including consumers protection and public health, and its main goal is to ensure food chain quality, from producer to consumer (Righettini, 2015). Triggered by several major food crises and scandals (e.g. horse meat, chicken flu, bovine spongiform encephalopathy), European and national food safety policies and regulatory structures have been object of deep reforms. On the one hand, at the European level the European Food Safety Authority (EFSA) has been established in 2002, with the task of overseeing the organization of science and expertise. On the other hand, most member states have set up specialized agencies with different organizational features (Abels and Kobusch, 2010).

In this paper, we adopt Levi-Faur definition of regulation: “*Regulation is the promulgation of prescriptive rules as well as the monitoring and enforcement of these rules by social, business, and political actors on other social, business and political actors.*” (Levi-Faur 2010, p. 9).

Within this framework, governance of a regulatory policy has no single actor or single institution who exerts control over the entire decision making process, but it rather develops through co-decision and interdependence (Righettini 2015, Righettini and Giraudi 2011). Indeed, complexity of governance has to be understood as a result of the convergence around the solution of a regulatory problem among different kinds of actors

(politicians, institutions, businesses, technicians) and different territorial levels (Righettini 2015, Dente 2011).

Di Porto (2011) proposed an interpretative framework of regulation related to risk, identifying four possible configurations of the relationship between risk and regulation: risk as object of the regulation, risk as justification of the regulatory intervention, risk as management principle of administrative activity, and risk as evaluation tool both for the regulation and for measurement of accountability of the regulator (Di Porto, 2011). The presence of risk is what determines the shift from emergency administration to precautionary administration, as well as the necessity for the regulator of establishing goals, priorities and level of risk acceptance. Additionally, risk governance can be seen as the way through which institutional or individual actors face risks, surrounded by uncertainty, complexity and ambiguity (Hermans et al., 2012). This interpretation not only includes the three typical features of risk analysis - assessment, management, and communication - but also goes beyond, considering risk governance as normative prescription to inform all actors involved about how to face risks in a responsible way (Hermans et al. 2012). Contemporary risk governance follows three main principles: communication and inclusion, integration, and reflection (Van Asselt and Renn 2011, Renn et al. 2011, Hermans et al. 2012). Moreover, risk governance has the aim of taking into consideration the entire complex system of actors, rules, procedures and mechanisms connected with all relevant information that is collected, analyzed and communicated about risks and how management decisions are taken (Hermans et al. 2012).

After the revision of the main concepts building the food safety regulation framework - i.e. regulation, risk regulation and governance - this paper overviews the strand of literature related to the regulation of food safety in the European Union, in order to explore the factors which affected the evolution of food safety regulatory framework. Furthermore, the compliance process is explored. Indeed, compliance might be crucial for the effectiveness of the regulations with respect to achieving the specified policy objectives.

Food safety regulation evolved during the last twenty years and food safety assurance systems became more stringent, in response to enhanced *food scares*. Since the end of the 1990s, food safety controls became focused on process-based requirements and have been seen as mechanisms to support consumer confidence in the safety of the food supply (Henson and Caswell, 1999). EU institutions designed complex regulatory patterns to reconcile the tensions between product safety, market integration and national regulatory concerns, through committees, agencies, and private bodies (Vos, 2000). Indeed, many have noticed that there has been a shift from command and control

regulation by the state towards other forms of regulation, such as self-regulation, co-regulation, management-based regulation, and private systems of governance (Havinga, 2006). In particular, the social fields around food safety regulation include three institutions: state, the food industry and producers, and third-parties (Havinga, 2006).

Flynn et al. (1994, 1995, 1997) investigated the nature of food regulation in the UK and they distinguished between two drivers of different styles of regulation: the public interest and the private interest. Their perspective is particularly relevant in order to conceptualize local modes of regulation and central-local state relations within the framework of the *regulationist analysis*. According to these scholars (Flynn et al. 1997, p. 474) “*the interconnectedness of different tiers of the state must be addressed*”, taking into account the centrality of the policy process in multi-level analysis and the role played by actors at different levels in shaping regulation. Indeed, they investigated “*the nature of the regulatory state through an analysis of the construction and implementation of regulatory practice at the local level*” (Flynn et al. 1997, p. 474). Their major findings suggest that the local level is not just an arena of policy implementation, but also of reformulation of regulatory practices and contextualization of regulatory authority, giving major relevance to the spatiality of policy and regulation. The regulatory approach adopted by EU institutions after the bovine spongiform encephalopathy (BSE) crisis can be understood under this spatial perspective, in particular concerning control and inspection: the responsibility is within the member states and the European Commission (EC) monitors the way they undertake their responsibility through the Food and Veterinary Office.

Private safety control systems, standards, and certification programs respond to the needs for safety controls. According to Henson and Caswell (1999, p. 590) there are several factors which influenced the evolution of food safety regulation: “*the criteria employed for establishing regulations, the relationship between public and private food safety control systems, how governments approach regulation, strategic responses by private parties to regulation, and the trade implications of national food safety controls*”.

The interaction between public and private food safety control systems has been widely investigated in the literature (Henson and Caswell 1999, Henson and Hooker 2001, Codron et al. 2005). On the public side, it's possible to identify direct ex-ante regulation mechanisms - standards, inspections, product testing, and specific financial penalties for non-compliance, as well as ex-post regulation in the form of product liability, which “*punishes companies that produce products of insufficient quality through damage awards to those harmed by their actions*” (Henson and Caswell, 1999, p. 594). On the private side, there are self-regulation mechanisms (internal control systems) and different forms of third

parties certifications, which can act “*in both an offensive and a defensive manner*” (Henson and Caswell, 1999, p. 594).

Approaches to public food safety regulation can be different in the “*degree to which they impede freedom of activity*” (Henson and Caswell 1999, p. 595). Food safety standards were the most common form of public food safety regulation and they can be either target standards, performance standards, or specification standards. According to Henson and Caswell (1999) there has been a shift towards performance-based measures, in order to allow suppliers to control food safety in ways that favor efficiency and reduction of compliance costs. Regardless of the specifics of the regulation, however, food businesses undertake “*a standard series of steps to determine whether and how to comply*”. From the perspective of regulatory agencies, “*the question of compliance is essentially one of outcome: are businesses conforming to regulatory requirements?*” (Henson and Heasman 1998, p. 11). Capture theory suggests that firms will try to appropriate the regulatory process in order to gain strategic advantage. Many scholars have indeed explored this strategic behavior of firms (Barrett 1991, Rugman and Verbeke 1998, Porter and van der Linde 1995, Henriques and Sadorsky 1996), highlighting the fact that corporate compliance depends on the expected economic benefits. Indeed, efficiency is a crucial aspect because it affects the costs of compliance itself. Furthermore, the compliance process is crucial to understand the impact of food safety regulation (Henson et al. 1998) and for the effectiveness of the regulation itself, with respect to achieving the specified policy objectives.

In this section, a general overview of food safety regulation has been given. We introduced some concepts such as food safety, compliance, risk regulation and governance, and we assessed the factors which affected the evolution of food safety regulatory framework within the EU.

The second section will be dedicated to the method.

The method: systematic review

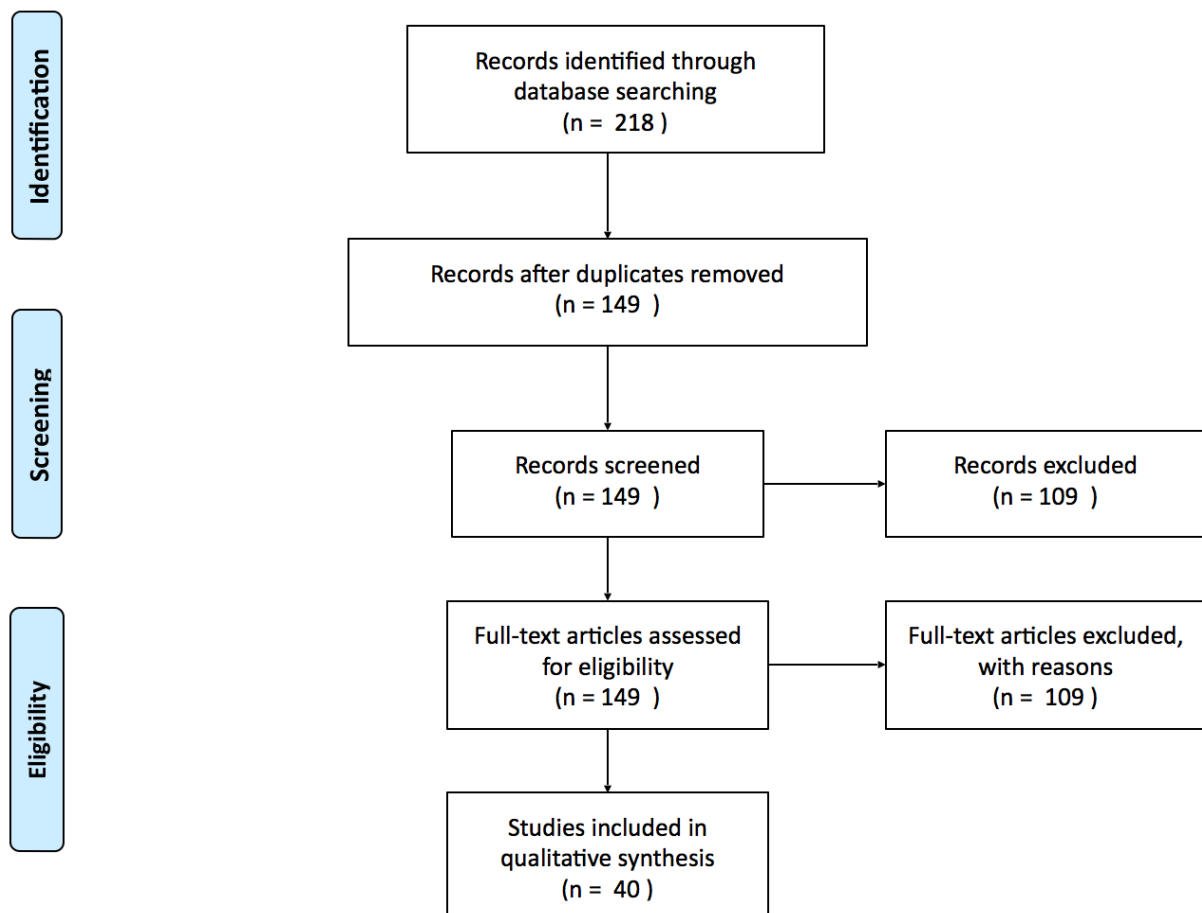
The method used is systematic review, which allows replicability and relies on the “*key principles of objectivity and scientific rigor*” (Arthur et al. 2012, p. 218). A systematic review usually consists of seven steps: research question, protocol, information retrieval and article selection, quality appraisal, synthesis and report writing. “*The research question and objectives, the scope of the review, its parameters and strategy for information retrieval, inclusion/exclusion criteria, methods for searching, coding (data extraction) [...] are all pre-stated in the protocol*” (Arthur et al. 2012, p. 220).

The main objective of this review is to identify how the outcomes of empirical contributions are operationalized and how the key variables are measured. The main research question is: how to measure the performance and effectiveness of food safety?

The paper assesses the main empirical contributions that describe the measurement process that has been applied to operationalize some key variables: food safety and food safety performance, food quality, food authenticity, compliance with regulation. Those variables have been identified through a preliminary literature review. This allowed to draw a general picture of the state of the art in the field of food regulation and to assess measurement and operationalization processes (data collection, methods and data analysis). As working paper, it is preliminary to develop further empirical analysis on the impact that the institutional regime has on the effectiveness of the food regulation. Indeed, results will be applied in the operationalization process of the outcome.

The PRISMA flow diagram has been used to show the strategy for information retrieval, inclusion/exclusion criteria and methods for searching (Fig. 1).

Figure 1 - PRISMA flow diagram



Source: Own elaboration.

Records identified through database searching (Scholar and Scopus) are 218 and additional records have been added through other sources - specific journals and references from other relevant articles.

The key-words' strings used are: "food safety empirical", "food safety performance", "food safety management", "food safety compliance", "food standards compliance", "food quality compliance", "food safety effectiveness". They have been identified through a preliminary review of the existing literature about food safety regulation.

The choice of focusing on empirical literature is due to the main objective of this paper, which is to assess how to measure effectiveness and performance in food safety regulation. Thus, performance, management and effectiveness have been chosen as key-words in the attempt to find as much contributions as possible to their own measurement.

Moreover, compliance has been added as key-word because it might be crucial for the effectiveness of the regulations, with respect to achieving the specified policy objectives.

A first screening took place during records' identification phase, through database searching.

Papers and articles containing in the title the string "consumer/public perception/behavior/attitude" have been excluded, as well as those referring to non european countries (containing words such as "US", "Australia", "developing countries", "China", "Hong-Kong", etc.). These exclusion criteria have been applied also in the second screening phase, when abstracts have been assessed.

Moreover, there is a wide scientific literature on food safety which is not related neither with regulation nor with governance or management issues, but with chemical and biological hazards and evaluation, health and medical issues, etc. Articles published on scientific journals (i.e. chemistry, biology, medicine, information technology, etc.) have been excluded since the beginning, as well as those containing in the title the key-words: "microbial risks/hazards", "chemical risks/hazards", "foodborne pathogens", etc.

After the first screening, records identified were 218, distributed as follows: 37 identified through the string "food safety empirical", 46 through "food safety performance", 51 through "food safety regulation", 39 through "food safety management", 23 through "food safety compliance", 9 through "food standards compliance", 7 through "food quality compliance" and 6 through "food safety effectiveness". Duplicated records were 69, thus records after duplicated removed were 149.

After this preliminary screening, abstracts have been assessed for eligibility. Papers and articles which do not give neither an empirical contribution nor any measurement indication/assessment have been excluded, as well as those which refer to non EU

countries and which have as object of analysis the consumer. Some articles have been included in the grey literature: those which are published in some specific journals such as “Food control” which can adopt a governance/regulatory perspective or a scientific/biological perspective. In this case, articles have been selected on the basis of the abstract. Moreover, full-text articles have been assessed for eligibility. Records screened are 149 while records removed are 109. Thus, articles included in the qualitative synthesis are 40. Table 1 summarizes the exclusion and eligibility criteria.

Table 1 - Screening criteria

EXCLUSION CRITERIA	ELIGIBILITY CRITERIA	SCREENING STAGE
where: non EU countries	EU countries	title / abstract / full-text
who: consumer, citizen	who: businesses, institutions, regulators, bureaucrats, trade associations, experts	title / abstract / full-text
what: microbial risks/hazards, chemical risks/hazards, <i>foodborne</i> pathogens, nutrition, obesity, diseases, health issue, trust / attitudes / behaviors of non eligible subjects	what: food safety performance, food safety effectiveness, food safety management, food safety output, compliance to regulation, transparency, food quality, food authenticity, costs/benefits of regulation	title / abstract / full-text
theoretical	empirical	abstract / full-text
hard science: chemistry, biology, medicine, etc.	social science, economics, management	title / journal
missing explanation of the variable measurement	explanation of the variable measurement, data collection, method, operationalization and analysis	full-text

Source: Own elaboration.

Results

A preliminary review of the existing literature about food safety regulation led to the choice of the key-words’ strings used for the screening through database searching. Moreover, the preliminary review led to the identification of some key variables of which we are interested in, with particular attention in how they are measured.

Literature on food regulation widely refers to food safety and food safety performance (Le Vallée & Charlebois 2015, Tuominen et al. 2003, Garcia Martinez et al. 2006), Food Safety Management Systems (FSMS) and their performance and effectiveness (Kirezieva et al. 2013, Jacxsens et al. 2011, Jacxsens et al. 2010, Luning et al. 2015, Osés et al. 2012,

Kafetzopoulos et al. 2013, Vladimirov 2011, Tomašević et al. 2013, Escanciano & Santos-Vijande 2014), compliance to regulation (Fairman & Yapp 2004, 2005, Zorn et al. 2013, Romano et al. 2004, Herzfeld & Jongeneel 2012, Henson & Heasman 1998), transparency (Deimel et al. 2008, Beulens et al. 2005), food quality and Quality Assurance Systems (QAS, FSQMS) (Carcea et al. 2009, Trienekens & Zuurbier 2008, Rozan et al. 2004, Manning & Baines 2004), food authenticity (Carcea et al. 2009).

Table 2 shows the variables identified, how they have been measured in the literature and some related variables and dimensions/sub-dimensions, while Table 3 shows how those dimensions and related variables have been measured in turn.

Table 2 - Key variables

OUTCOME	OPERATIONALIZATION	RELATED VARIABLES AND/OR DIMENSIONS
FOOD SAFETY	expiry date, presence of GMOs, absence of pesticides, origin of products	
FOOD SAFETY PERFORMANCE	number of recorded international food safety violations of traded raw and minimally processed foods	Food safety chemical risks, microbial risks, food consumption indicator, inspections and audits, food safety risk management
FSMS & FSQMS	FSMS output = f(Broad context; FSMS context; FSMS activities)	CONTEXT, PERFORMANCE, EFFECTIVENESS, INCENTIVES, COSTS, BENEFITS AND DIFFICULTIES OF IMPLEMENTATION
COMPLIANCE		COSTS, BARRIERS, DRIVERS, BENEFITS
TRANSPARENCY	Structural determinants of transparency: supply chain, product and transaction characteristics Behavioral determinants of transparency: cultural aspects and social embeddedness, transactors' behavior and the quality of business relationships between suppliers and customers Observable effects of transparency: indicators of chain performance, perceived transparency	Performance of supply chain as main objective of transparency, measured through dimensions of efficiency, flexibility, responsiveness, quality and safety
FOOD QUALITY	price, guarantees, manufacturer's or distributor's trademark, alliances between brands, umbrella brand, origin or appellation of origin, adverts, packaging	
FOOD AUTHENTICITY	economic adulteration of high value foods; misdescription of the geographical, botanical or species origin; non-compliance with the established legislative standards and implementation of non acceptable process practices; misdescription of name of food and non-compliance with requirements of legal name; adulteration of foods or substitution with lower value ingredients; the misdescription of geographical species, variety and production origin; the non-declaring of certain processes in the ingredients or preparation of food; and incorrect quantitative ingredient declarations	

Source: Own elaboration.

Table 3 - Related variables

VARIABLES/DIMENSIONS	OPERATIONALIZATION
FOOD SAFETY CHEMICAL RISKS	amount of pesticides used in each of the 17 OECD countries, expressed through kilograms of active ingredients per hectare, TDS
FOOD SAFETY MICROBIAL RISKS	performance scores across each of five foodborne illnesses
FOOD CONSUMPTION INDICATOR	reporting and frequency of national food or nutrition intake surveys
INSPECTIONS AND AUDITS	rates of inspections and audits, measured by whether a country had strict risk-based inspection policies and carried out frequent inspections
FOOD SAFETY RISK MANAGEMENT	national food safety response capacity, food recalls, food traceability, and radionuclides standards
CONTEXT IN FSMS	fsms context, activities, output: stereotypical description, performance indicators and broad context (agro-climatic, market and public policy environment, and food safety governance), product, production, organization and chain characteristics
PERFORMANCE OF FSMS	preventive measures, intervention processes, monitoring systems, control strategies, core assurance activities, setting system requirements, validation, verification, documentation and record keeping context factors, core safety control activities, core assurance activities
INCENTIVES TO FSMS IMPLEMENTATION	increase product safety, comply with regulatory requirement, increase product quality, marketing, comply with customer requirement, access to new market (export), reduce production costs
COSTS TO FSMS IMPLEMENTATION	Investment in new equipment, Civil works in the plant, External consultants, Product investigation/analysis, Staff training, Staff time in documenting system, System documentation, Structural changes to plant
BENEFITS TO FSMS IMPLEMENTATION	Increased safety and quality of the products, Increased working discipline of staff, Increased customer confidence, Legal instrument against complains, Increased product shelf-life, Increased ability to access new overseas markets, Increased product sales and prices, Reduced production costs
DIFFICULTIES TO FSMS IMPLEMENTATION	Recouping costs of implementing HACCP, Need to retrain supervisory/managerial staff and production staff, Reduced staff time available for other tasks, Attitude/motivation of supervisory/managerial staff and of production staff, Reduced staff time to introduce new products, Lack of support of inspection service/governmental institutions, Lack of pre-requisite programs/good hygienic or manufacturing practice
COSTS OF COMPLIANCE	local control units (control costs, personnel costs, total food control related income), food control costs per control object (control visits, samples, notifications, administrative burden)
BARRIERS TO COMPLIANCE	money, time, experience, information, support, interest, knowledge, trust, awareness, motivation, formal management systems
DRIVERS OF COMPLIANCE	legislative requirement, industrial standard compliance, environmental protection, insurance requirements, customer pressure, improving business efficiency, employee and investors pressure

Source: Own elaboration.

Food safety and food safety performance have been measured through a series of indicators. A good proxy of food safety can be considered the expiry date, the indication of presence/absence of GMOs, the absence of pesticides and the indication of origin of the product. Particularly, several dimensions of the two variables have been identified and operationalized: food safety chemical risks, microbial risks, food consumption indicator, inspections and audits, food safety risk management (Table 3).

Le Vallée & Charlebois (2015) conducted a benchmarking for food safety performance through a comparative study across 17 OECD countries. Their work is the only comparative study conducted to measure and rank the food safety performance at country level, and data used for the assessment came from publicly available sources from competent authorities - both national and supranational.

Management studies widely explored food safety management systems (FSMS) and some related variables have been considered: context factors, performance and effectiveness, as well as incentives, costs, benefits and difficulties of implementation. Those studies are conducted among businesses, usually through surveys and/or interviews.

Jacxsens et al. (2010, 2011) have selected external and internal food safety performance indicators, in order to assess the microbiological safety level profile for each of the food businesses included in the study (Table 4 and 5). Explanations and motivations of the choice of each indicator are reported as well as the operationalization of each level of performance on a scale (from 0 to 3).

Table 4 - External food safety performance indicators

INDICATOR	MOTIVATION	LEVEL 0	LEVEL 1	LEVEL 2	LEVEL 3
Comprehensiveness of external evaluation and seriousness of remarks	External and independent evaluation of the FSMS, a positive evaluation indicates a good safety performance	Inspection or audit never performed	Inspection of the FSMS performed by national agency, major remarks on various aspects	Audit of the FSMS performed by one accredited third party, major remarks on one specific aspect, minor remarks on others	Audits and/or inspections performed by several accredited third parties and/or national agency, no major remarks or only minor remarks
Type of microbiological food safety complaints and hygiene-related complaints	Presence of a good functioning system for complaint registration and evaluation of complaints is positive	No complaint registration	Various complaints towards multiple problems	Restricted complaints on one specific problem	No complaints

Table 5 - Internal food safety performance indicators

INDICATOR	MOTIVATION	LEVEL 0	LEVEL 1	LEVEL 2	LEVEL 3
Advancedness of product sampling	Regular sampling and different types of samples give accurate and comprehensive indication of the microbiological performance	No samples and no microbiological analyses are performed	Ad hoc sampling and only on final food product	Regular sampling both conducted on final food product and raw material	Structured sampling and conducted on final food product, raw material and environmental samples
Comprehensiveness of microbiological criteria	Using more criteria gives accurate indication of the microbiological performance	No criteria	Only legal criteria used	Combination of legal criteria and requirements and/or specifications	Combination of legal criteria and requirements and/or specifications by external parties and additional company specifications
Type of hygiene and pathogen non conformities	Presence of a good system for non conformities registration and evaluation is positive	No internal product analyze and no non-conformity registration	Several non conformities towards multiple problems	Restricted number of non conformities on one specific problem	No non-conformities

Source: Jacxsens et al. 2011

Garcia Martinez et al. (2006) identified and computed the key performance indicators, benchmarking performance dimensions of food safety (Table 6). In their work, they assessed food system safety performance, i.e. *“the capacity to deliver safe food to consumers and to demonstrate such performance to the satisfaction of private customers and public regulators”* (Garcia Martinez et al. 2006, p. 71).

Table 6 - Food safety performance measurement: key performance indicators

DIMENSIONS	SUB DIMENSION 1	SUB DIMENSION 2	MEASURES
DIMENSION 1. Supply chain management practices	Coordination of the supply chain <ul style="list-style-type: none"> - Importer-exporter contractual arrangements - Importer-exporter information sharing - Importers evaluation of exporters - Importer-customer information sharing - Market orientation - Vertical integration - Vertical coordination - Traceability systems - IT systems - Complaints systems 	Processing and packaging: <ul style="list-style-type: none"> - Packing/repacking infrastructure - Exporter labeling quality 	<ul style="list-style-type: none"> - Nature and duration of contract - Directness of the relationship, in communication of requirements and specifications - Systems in place to assess quality and safety provisions - Varieties supplied and ability of importer to meet customer requirements - Involvement of importer in upstream or downstream processes in the supply chain - Coordination of operations in terms of timing - Importance of quality criteria in selecting produce - Requirements for health, safety and welfare - Requirements for environmental management practices - Safety and quality specification
DIMENSION 2. Importer operational infrastructure	Safety and quality orientation of the supply chain <ul style="list-style-type: none"> - Importer quality certification - Quality orientation - Social responsibility - Environmental management - Safety and quality requirements 	Storage and transport: <ul style="list-style-type: none"> - Exporter storage quality - Exporter transport quality - Importer storage quality - Importer transport quality 	<ul style="list-style-type: none"> - Level of technology/ efficiency of importer infrastructure for (re)packing operations - Quality of labeling

Source: Garcia Martinez et al. 2006

Data have been collected at the firm level, through an audit of the fresh produce importers in Hungary, using firms in a best-practice country (UK) as benchmark.

Kirezieva et al. (2013) measured the Food Safety Management System output, which is function of the broad context, the FSMS context and the FSMS activities. The output of the FSMS can be identified through a stereotypical description and some performance indicators, as well as some broad context indicators such as: agro-climatic, market and public policy environment, and food safety governance characteristics. Indicators and grids have been identified through comprehensive literature study and semi-structured in-depth interviews with experts in fields.

Tomašević et al. (2013) investigated incentives, costs, difficulties and benefits of food safety management systems implementation in the Serbian meat industry, identifying indicators of such dimensions through a survey (Table 3).

Vladimirov (2011) analyses the adoption of an efficient Food Quality and Safety Management System (FQSMS) and expresses measurements of the dependent variable through the set of questions asked to the businesses included in the study (Table 7).

Table 7 - Adoption of an efficient FQSMS

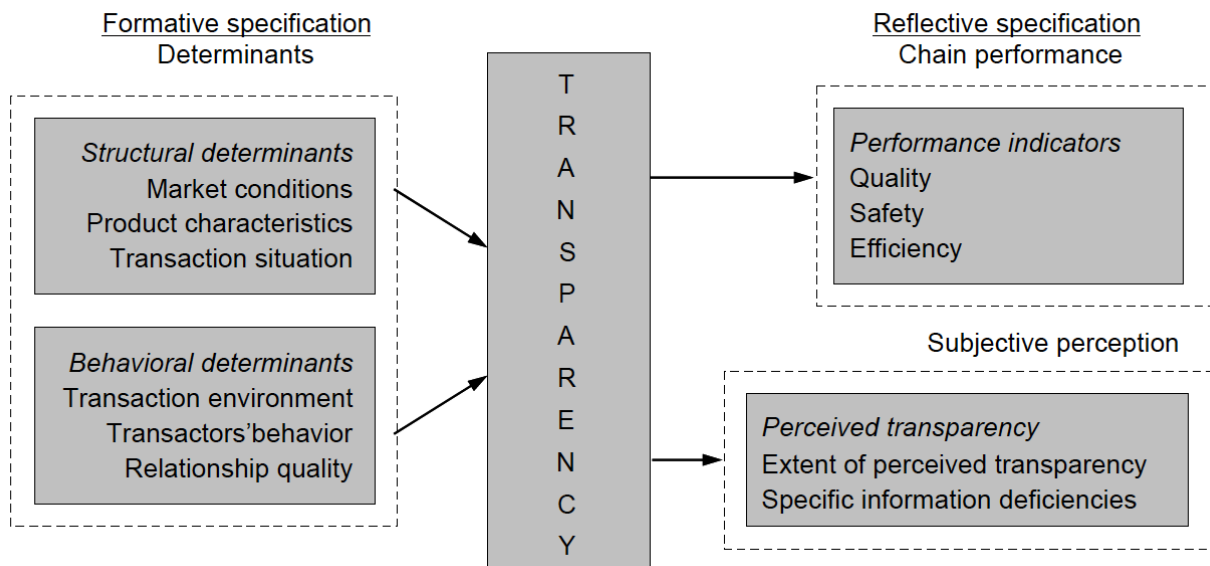
MEANING	DEPENDENT VARIABLE MEASUREMENTS
Manager attitudes toward quality issues	If there were not legal requirements, would you have implemented a food quality and safety management system?
Implementation of food quality and safety management systems and certifications	Did you have implemented already some of the following systems: GHP, GMP, HACCP, other
Regularity of system's review and improvements and frequency of inspectors' important remarks on system	Did you have certified already with some of the following international standards: ISO 9001, ISO 22000, other
Availability of a quality specialist or team and educational programs for staff training on quality	Did you review sufficiently and improve regularly the food quality and safety management system?
Receiving and issuing documents of products' origin/compliance	<p>Did you receive quite often important remarks on the food quality and safety management system by controlling inspectors?</p> <p>Do you have in the company special person or team responsible for the food quality issues?</p> <p>Do you have in the company educational programs on food quality issues for staff training?</p> <p>As a rule, did you receive always documents of origin/compliance from suppliers in respect to: raw materials/food, packing and packaging materials, machines, tools, devices in contacts with food, refrigerators' systems and transport systems for raw materials/food</p> <p>As a rule, did you issue always documents of origin/compliance for each sold by the company food product?</p>

Source: Vladimirov 2011

Another key-variable presented in the literature as a proxy of effective regulation is compliance. Indeed, literature widely discusses compliance with food safety regulation and several dimensions are assessed: costs, barriers and drivers. However, compliance per se is difficult to be measured and none of the empirical contributions included in the review actually explained the operationalization process of the variable. Literature just identifies the major dimensions of compliance, giving measurement details (Table 3). Usually, data are collected through surveys and/or interviews to those subjects who have to comply with regulation: the businesses. Some qualitative studies (Fairman & Yapp 2004, 2005) include interviews with experts, enforcement bodies and trade associations, in order to better understand compliance dimensions, while Zorn et al. (2013) used data from a control body to make quantitative analysis.

Transparency has been object of analysis of Deimel et al. (2008) who proposed a theoretical model, measuring transparency through its determinants and effects (Fig. 2).

Figure 2 - Transparency model



Source: Deimel et al. 2008

The performance of the supply chain is considered the main objective of transparency and it is measured in turn through dimensions of efficiency, flexibility, responsiveness, quality and safety (Table 2).

Furthermore, an issue that has acquired particular relevance in the public debate - due to consumer demands on one side and market needs on the other side - is food quality. In the literature food safety is considered a subset of food quality and it is possible to identify some special intrinsic properties, giving the product a first-rate quality. This is how an appellation of origin is created: *“an appellation of origin is the acknowledgement made by a Regulatory Council - independent and autonomous - which certifies that the product fulfills the technical product specifications - e.g. geographical origin, specific variety or breed, a traditional method of production or elaboration or any special intrinsic characteristic - in order to differentiate the product and guarantee the quality better adapts to consumers’ needs and demands”* (Dopico 2003, p. 22). Therefore, the appellation of origin can be considered a proxy of the food quality of the product and it implies that the product is safe, as well as it has the above mentioned characteristics.

Thus, some scholars have defined food quality and have measured it through a set of indicators, while Carcea et al. (2009) used authenticity as a proxy of food safety (Table 3).

Towards operationalization

Overall, measurement of food safety is conducted through interviews and surveys. Most of the studies included in this review developed indicators and grids to assess food safety performance and FSMS performance from the perspective of the firm. Indeed, few studies involved independent experts, but these schemes of evaluation have been applied as tools for businesses. From a methodological perspective, the measure obtained cannot be considered reliable for a good operationalization of the outcome “food safety”, due to the self-evaluation of the performance by the firms. Moreover, these studies do not take into account the role of the regulators nor of the enforcement bodies (inspectors / controllers, local / national / supranational institutions).

Studies about food quality and authenticity are widely descriptive, focusing on standards implementation and costs/benefits analysis (Trienekens et al. 2008, Rozan et al. 2004, Carcea et al. 2009). Transparency has been assessed just at theoretical level by Deimel et al. (2008) and no examples of empirical measurement are given.

Furthermore, none of the empirical contributions about compliance actually explained the operationalization process of the variable. Indeed, literature just identifies the major dimensions. Moreover, data are usually collected through interviews and surveys conducted among businesses (i.e. the subjects that have to comply with regulation). Those studies do not specify whether there are available database at the institutional level, such as compliance rates, rankings among countries, etc. Measurement does not seem to be possible relying on the existing empirical literature, without objective indicators or benchmarks.

Overall, in the literature there are no comparative studies, neither across countries or regions, with the exception of the study conducted by Le Vallée & Charlebois (2015). The authors measured food safety performance through benchmarking and ranking at country level, using data from publicly available sources from competent authorities - both national and supranational.

This systematic review allowed to draw the picture of the state of the art in empirical literature about food safety regulation and to assess measurement of several key variables. However, results are not satisfactory and contributions cannot be considered reliable for a comparative study on the impact that the institutional regime has on the effectiveness of the food regulation.

Major weaknesses have been identified in the data collection phase: surveys and interviews involving the direct subjects / objects of the regulation do not seem to be convincing to assess the performance of those same subjects. Moreover, even when

interviews are conducted among experts, data are used to build indicators and grids, as tools for further self-evaluation by businesses.

Major gaps can be found in the measurement of compliance (there are neither rankings or benchmarks, indicators or objective measures) and in the absence of comparative studies, particularly in food safety performance measurement. Furthermore, the involvement of regulators (institutions / enforcement bodies) might be crucial in order to assess and measure the effectiveness of regulation and its good performance.

Thus, how to operationalize the outcome “effectiveness of food regulation” is still an open question. A good proxy of effectiveness of regulation might be consumer trust. Further empirical analysis will investigate the relationship between institutional regime and trust, i.e. performance of the regulation. Thus, trust becomes a good proxy for effectiveness of food regulation, i.e. food safety. Literature widely explores consumer trust / perception / behavior about food safety and Eurobarometer surveys addressed Europeans’ attitudes towards food security, food quality and the countryside (Special Eurobarometer 389, 2012) as well as European consumers’ concerns about food related risks (Special Eurobarometer 354, 2010). Despite possible limitations and biases, data are easily comparable and can be used as proxy of effectiveness of food regulation in Europe.

Further empirical analysis will need a new systematic review of empirical literature on consumer trust measurement and related variables, as well as an assessment of available data - Eurobarometer surveys or other available datasets.

Conclusions

This paper aimed to review the empirical literature on food safety regulation in Europe, in order to assess how performance and effectiveness are measured.

Thus, the paper assessed the main empirical contributions that describe the measurement process that has been applied to operationalize some key variables: food safety and food safety performance, food quality, food authenticity, compliance with regulation. Those variables have been identified through a preliminary literature review. This allowed to draw a general picture of the state of the art in the field of food regulation and to assess measurement and operationalization processes - data collection, methods and data analysis.

After a general overview of food safety regulation and the main concepts in the literature (compliance, risk regulation and governance), the method of the systematic review has been described: how the review has been conducted, the eligibility criteria for the articles examined, information sources and the strategy adopted for the selection of the articles.

Then, the main results of the systematic review are presented: the main characteristics of the empirical contributions, measurement of the key variables, limitations of the analyses and comments. Finally, results are discussed in order to set the ground for operationalization in further analysis.

However, results are not satisfactory and contributions cannot be considered reliable for a comparative study on the impact that the institutional regime has on the effectiveness of the food regulation. Thus, major weaknesses and gaps in the literature have been assessed and consumer trust has been identified as possible outcome.

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