Comparative analysis of official controls and voluntary certifications in ensuring food safety compliance: a review

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Abstract

Regulation (EU) 625/2017 emphasizes prevention over inspection, assigning primary responsibility for food safety to the food business operator. At the same time, official control systems ensure compliance with the European Union regulations. In recent years, voluntary third-party assurance programs have emerged as a complement to public regulations. This review explores their role, advantages, and challenges within this evolving regulatory landscape. Private standards have expanded rapidly in response to consumer demand for safer and more ethically produced food. While these certifications offer benefits, they also pose challenges, requiring continuous oversight and potential harmonization to ensure reliability. Some European countries now integrate private standards into official controls, recognizing their potential to strengthen regulatory frameworks. Certified food safety management systems, such as the British Retail Consortium or ISO 22000, can complement official control by improving compliance and efficiency. However, discrepancies between official inspections and third-party audits persist, necessitating careful coordination. To ensure effective integration, competent authorities must monitor the performance of private systems through audits and random checks. Despite some challenges, integrating private systems into official controls could be mutually beneficial. Future advancements will depend on effective collaboration among policymakers, industry, regulatory agencies, and other stakeholders, fostering a more robust food safety system.

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Introduction

The official control system guarantees that the food for consumers is healthy, safe, and compliant with food safety and quality regulations. Food control systems must be current with emerging technologies, function based on risk analysis, and be in line with global best practices and standards established by Codex Alimentarius (FAO, 2022; Sorbo *et al*., 2022; WHO, 2022; FAO and WHO, 2023).

At every stage of production, processing, and distribution, food business operators (FBOs) are subjected to the requirements of food legislation, which European Union (EU) Member States are required to enforce, monitor, and verify [Regulation (EU) 178/2002, article 17] (European Parliament and Council of the European Union, 2002). To achieve this, they must keep up a system of official controls and other monitoring activities encompassing the entire production, processing, and distribution process (Gizaw, 2019). A considerable effort has been made in the last few years to amend laws to reflect the European Parliament and the Commission's increased sensitivity to food safety issues. Actually, the Regulation (EU) 625/2017 is in force (European Parliament and Council of the European Union, 2017), while Regulation (CE) No 854/2004 (European Parliament and Council of the European Union, 2004a) and Regulation (CE) 882/2004 have been abrogated (European Parliament and Council of the European Union, 2004b).

The European legislative framework incorporates the fundamental concepts of food safety culture, indicating a focus on public health issues that may have been absent in the early years of the European Union legislative life (Pettoello-Mantovani and Olivieri, 2022). The regulatory authorities designated under the food control system [known as competent authorities (CA)] help ensure food safety along the food chain and manage food safety hazards, fraud issues, emerging risks, and health emergencies. This work includes oversight and inspection of FBOs, thus collecting data that contributes to a better knowledge of the food chain and a proper management of food safety emergencies.

A change in perspective occurred in the last few decades with regard to food safety. The shift is best described as a transition from relying primarily on inspection to placing greater emphasis on preventive actions. These changes are a part of a larger movement that goes beyond food safety and includes concepts such as quality management and the creation of standards, such as ISO 9000 (ISO, 2024), which had their origins in the 50s. It is common to refer to this shift in thinking as a transition from product controls to process controls. This is in line with the food processing industry's Hazard Analysis and Critical Control Points (HACCP) guidelines. Traceability is a crucial component of this process-oriented strategy, which guarantees that products can be linked to well-regulated processes. A FBO is best placed to devise a safe system for supplying food and ensuring that the supplied food is safe; thus, he/she has primary legal responsibility for ensuring food safety (European Parliament and Council of the European Union, 2002). Moreover, primary responsibility for food safety rests with the FBO, and general implementation of procedures based on the HACCP principles should reinforce the FBO's responsibility (European Parliament and Council of the European Union, 2004c).

Adoption of the private standards is an evolution of the HACCP system within the scope of the FBO responsibility. Standards for food safety, food quality, and the environmental and social elements of agri-food production have been established in recent decades, but significant concerns regarding the function of public and private institutions in regulating food safety have been brought up by the development of these standards.

This paper aims to bring some clarity to the discussion by offering a well-reasoned examination of the impacts and evolution of private food safety regulations. The complex interaction between official controls and voluntary certifications is examined, describing the possible advantages and difficulties of this cooperative strategy.

Official controls

Official controls are carried out by the CA in the EU countries to verify business compliance with the requirements set out in food legislation. Regulation (EU) 625/2017 is the framework regulation setting common rules for carrying out the official controls. A Commission notice on the implementation of Regulation (EU) 625/2017 (European Commission, 2022) compiles further clarifications and best practices in order to contribute to a harmonized understanding and application of the provisions by Member State CA and stakeholders (Antunović *et al*., 2021; Aybar Espinoza *et al*., 2023). Differences in the frequency and methods of controls, outcomes of verifications, at the local, national, and European level, and perception of controls by FBO can be observed (Balzaretti *et al*., 2017; Bovay, 2023). The results of inspections and samplings carried out in previous years are central elements for the development of risk-based plans, which focus mainly on high-risk businesses and product groups. For this reason, official controls are not completely random, and a certain bias is inherent in the system (Lueckl *et al*., 2019).

Even though food law is harmonized in the EU, there is still a certain margin for interpretation, and national differences still exist in its implementation (Lueckl *et al*., 2019; Lugli *et al*., 2024). Variability among inspectors may lead to differences in control performance, potentially influencing the rate of non-compliance (Berking *et al*., 2019). Only harmonization could reduce this influence. Consistency in food control is a legal requirement (European Parliament and Council of the European Union, 2017), and the introduction of a standardized inspection score system is associated with perceived fairness and compliance (Balzaretti *et al*., 2017; Kaskela *et al*., 2019). Most FBOs did not often perceive official food control as being uniform: this kind of opposition should be avoided by increasing the fairness of the system (Kettunen, Lundén, *et al*., 2017; Kaskela *et al*., 2019). Moreover, the sensitivity and knowledge of food control officials may influence the use of enforcement measures, potentially leading to some authorities applying these measures, when necessary, while others may refrain from doing so. This may result in unequal treatment of FBOs (Kettunen, Nevas, *et al*., 2017). If the FBOs, despite the requests of the authorities, do not comply with food safety regulations, authorities shall take effective actions, such as the so-called administrative enforcement (coercive) measures (European Parliament and Council of the European Union, 2017). Many food safety requirements laid down in the European Union and national food safety legislation allow case-dependent interpretation, thus similar cases may result in different regulatory outcomes. The use of enforcement measures can vary among CAs, and inconsistency has been reported in control procedures and inspection practices (Kettunen *et al*., 2015; Läikkö-Roto *et al*., 2015).

Kaskela *et al.* (2019) observed that many FBOs disagreed with the inspectors' grading of non-compliances. This is of concern because such disagreements may have consequences on the credibility of food control and could negatively influence the willingness to correct non-compliances. Many of the topics where disagreements occurred regarding grading can be considered important for food safety, such as the maintenance of premises (Rossi *et al*., 2020). Most FBOs did not perceive official food control as being uniform, and some of them even considered it arbitrary. To facilitate everyday operations at the local level, clarification from the governments regarding the integration of various laws and regulations would be beneficial. This would provide clarity and coherence in the implementation of food safety measures, ultimately enhancing public health protection efforts (Lugli *et al*., 2024). Cross-audits among local food control units are recommended to improve the FBOs' experience of uniformity of food control (Kettunen, Lundén, *et al*., 2017). Moreover, in some cases, the evaluation of non-compliances by an inspector, as being relevant in terms of food safety, may yet vary due to diversity in the educational background of the inspectors themselves (Nevas *et al*., 2013). As non-compliances are documented at each inspection, several authors believe that the efficiency of the controls can be improved (Lueckl *et al*., 2019; Røtterud *et al*., 2020). Jenni and Janne (2016) showed that the official control performed by the official veterinarians (OVs) in high-capacity abattoirs was efficient, although they also agreed that OVs often have to give repeated notifications about the same non-compliances in the same establishments. Moreover, some OVs can work in the same slaughterhouse every day and for a long time. Under these conditions, OVs may become blind to the reality of problems in the abattoirs they are assigned to and do not further implement any control activity. To gain a new perspective, job rotation of the OVs could be profitable and improve the efficiency of official controls as well as the supervision of the CA, periodically performed by a higher-level authority (Jenni and Janne, 2016).

The auditing procedures of the official control in slaughterhouses can vary among European Union countries, and most of them have decided to perform internal audits, where auditors play a key role in overseeing and coordinating official control activities. Auditors also observed that their involvement in audit activities enhanced their understanding of the current state of official controls and their challenges, deepened their expertise, and

enabled them to identify the training needs of OVs (Luukkanen *et al*., 2017; Luukkanen *et al*., 2018; Kosola *et al*., 2022). At the same time, the OVs should receive adequate support from their superiors, especially when actions of a more difficult nature, such as expensive correction of line structures or an increase in the number of OVs, are required (Alban *et al*., 2011).

The CA responsible for food safety has the task of 'establishing control systems and verifying compliance with food law and food hygiene' (European Commission, 2021). The Commission [through the Health and Food Audits and Analysis, formerly known as the Food and Veterinary Office (FVO)] has the power to check that governments are meeting these responsibilities effectively, carrying out controls to ensure that the national authorities in EU countries are fulfilling their legal obligations. The results of the controls carried out by the Commission on the national authorities showed that, overall, they provide levels of compliance that are compatible with the food safety requirements. Nevertheless, Commission controls identified weaknesses in some control systems and highlighted further room for improvement (European Commission, 2023a). Recent "FVO" inspections showed that in some EU countries, the CA does not have the possibility to impose administrative enforcement measures, limiting the efficiency of official controls. Audit guidance and procedures available to OVs are limited in some areas, which does not ensure that all the appropriate points are supervised and result in problems of consistency of controls. The supervision and identification of training needs are not adequate and, as a result, some OVs were not able to identify certain operational hygiene non-compliances, nor enforce their correction (European Commission 2020 and 2023b).

Voluntary certifications

Private standards, which are voluntary by definition, include individual firm schemes (*e.g*., Tesco Nature's Choice, Carrefour) as well as collective national and international schemes [*e.g*., British Retail Consortium (BRC) Global Standard, GlobalGAP, ISO 22000] (Du, 2018; Bomba and Susol, 2020). A multitude of private standards have emerged in this context, covering a wide range of different initiatives and addressing all sorts of consumer interests, including quality assurance, food safety, environment, social or labor conditions, corporate responsibility, carbon footprint, *etc*. (ISO, 2015; ISO, 2018; BRC, 2022; IFS, 2023). Moreover, between voluntary certifications and official controls, the regulated certifications can be placed, especially those of Protected Geographic Indication, Protected Designation of Origin (PDO), and Organic Production. Since then, the public and private certifications linked to the concept of quality productions (European Commission, 2024) are more than 800, most of which were established during the last decade (Becker *et al*., 2008; Boys *et al*., 2015; Dias and Mendes, 2018; Ravaglia *et al*., 2018; Douvaleix *et al*., 2020; Dima, 2021).

In the area of food safety, Regulation (EC) 178/2002 puts the primary responsibility for ensuring that food satisfies the requirements of food law on the FBO. Large players in the food supply chain often rely on certification schemes to be sure that a product meets the requirements and to protect their reputation and liability in the event of a food safety incident. Governments have progressively shifted responsibility for food safety to the private sector, in turn establishing a motivation for private standards. This implies that food firms are responsible for establishing their own food safety control system, while the role of the government is to inspect and verify the audit reports (Marsden *et al*., 2000). For these reasons, businesses are under high pressure to deliver food safety and maintain the integrity of their brands.

The entities involved in the development of private standards have no legal or regulatory power to enforce their implementation (Henson and Humphrey, 2009; Meliado, 2017). Food retailers are more likely to adopt private standards when two conditions are satisfied. The first one is that the retailers have sufficient market power to be able to impose private standards as a condition of access. The second condition is that the benefits of adoption exceed the costs of introducing such schemes. For food businesses, most non-regulatory food safety management schemes (FSMS) are voluntary; however, they often become *de facto* mandatory in a business sense because they are adopted by dominant market players in the food supply chain (Tomašević *et al.,* 2013; Chen *et al*., 2015; Nguyen and Li, 2021), and retailers choose suppliers even based on the compliance with quality assurance standards (Dobson *et al*., 2001; Humphrey, 2012).

The change of buyers' requirements over the years was due to the expectations and demands of safety and quality (Jaffee and Henson, 2004; Panea and Ripoll, 2020). Thus, food safety is no longer defined simply as 'fitness for human consumption', but rather in terms of a wide array of safety attributes (Hassoun *et al*., 2022) that range from research, through experience, to credence attributes. The recent growth in voluntary certification schemes for agricultural and food products was a response to food scares and has become ever more relevant in the context of intense market globalization, an area in which public regulation often failed (Fagotto, 2014). Moreover, it has been reported that public food safety regulations are becoming less detailed, whereas private regulations are often more detailed. For food manufacturers and producers, private retail-driven food safety standards may be similar to public food laws (Havinga, 2006). Being market-driven, private standards take less time to develop and offer more flexibility in implementation: they can be negotiated and amended relatively quickly, providing timely and flexible solutions to respond to new risks more quickly than traditional public regulation (Du, 2018; Weber *et al*., 2018). Private standards go beyond the requirements of public standards because they set a higher standard for particular attributes of food products and are much more specific about how to achieve certain goals.

The key role of standards, whether public or private, mandatory or voluntary, is to transmit credible information on the nature of products and the conditions under which they are produced, processed, stored, and transported (Humphrey, 2008; Henson and Humphrey, 2009; Henson and Humphrey, 2010; Humphrey, 2012). A key question may be whether the use of private food safety certification improves the safety of the food supply. Certification can be considered to ensure that the plant has a better average standard, because maintaining certification implies continuous monitoring of hygiene, operations, and documentation (Trafialek and Kolanowski, 2017; Turku *et al*., 2018). The overall assessment of the HACCP principles, traceability, employee awareness of food safety, and customer complaints in the certified food businesses is better than that in the non-certified ones (Chen *et al*., 2015). Finally, even the positive role of the PDO certification schemes on consumers' utility has been confirmed, as for voluntary certifications. The information conveyed by PDO labels is revealed to be clear and indicative (Fandos-Herrera, 2016; Garavaglia and Mariani, 2017).

Certification schemes can also have drawbacks, such as questions relating to the transparency of scheme requirements and the credibility of claims (particularly for schemes that certify compli-

ance with baseline requirements), potential for misleading consumers, costs and burdens on farmers and producers (particularly where they have to join several schemes to meet buyer demands), and, finally, risk of rejection from the market of producers not participating in key certification schemes, especially for small producers (Henson and Humphhrey, 2010). There is a substantial range of private sector standards, developed by distinct types of organisations to serve diverse purposes and with different functional scopes. Given this large number of standards, it is not surprising that there is a lack of clarity about them. In contrast to this rapid diffusion, only a few studies can be found questioning the trustworthiness of third-party certification and addressing the problems of auditor independence and objectiveness. In some cases, certification is perceived to be just a formal inspection rather than a valid examination of quality standards (Codron *et al.*, 2005; Wiengarten *et al*., 2016). In addition, some authors clearly indicated differences between various certification bodies (Albersmeier *et al*., 2009). A further indication of the weaknesses of auditing practice is the comical rephrasing of GMP audits from "Good Manufacturing Practice" to "Give Me Papers".

Interactions between official controls and voluntary certifications

Public regulations for food of animal origin include mandatory HACCP, inspections (including permanent on-site government inspectors), testing regimes, *etc*. These controls could be public, or private, or a mixture of the two. In this context, the apparent gap between public regulation and private standards narrows substantially. Implementing new systems will require public-private partnerships or recognition of private standards as establishing compliance with public regulations (Smith, 2009; Cartín-Rojas, 2013). Recently, a new relationship between public enforcement authorities and private organizations has been observed, and this includes public recognition of private norms and control systems, inclusion of public prescriptions in private food schemes and controls, and agreements between the public authority and private companies or industry sectors regulating reciprocal obligations on compliance and monitoring (Havinga, 2006; Marx, 2017). Alongside this interaction, in the past decade, the industry-led Global Food Safety Initiative (GFSI) campaigned for governmental recognition of third-party certification schemes.

Regulation (EU) 625/2017 requires taking FSMSs and their audits into account in official food control. Official inspections and third-party audits of FSMSs based on international standards both focus on food safety, which has raised discussions on whether official inspections can be reduced or if the audit results of third-party audits can be part of official food control, considering that official controls must be performed in a manner that minimizes the burden on businesses (European Parliament and Council of the European Union, 2017). Several studies have shown similarities and overlap in official inspections and FSMS audits (Martinez *et al*., 2013; Wright *et al*., 2013; Verbruggen and Havinga, 2015; Turku *et al*., 2018), advocating for the utilization of certified FSMSs in official control (Qijun and Batt, 2016; Dzwolak, 2019; Piira *et al*., 2021).

When CAs are planning their controls, they need to consider the FBO's past compliance and the reliability of their own checks, including those performed by a third party, like in the case of private quality assurance schemes. Based on this information, food operators implementing a voluntary third-party assurance (vTPA) program might benefit from a reduction in the number of inspections (CCFICS, 2018), and the CAs could allocate financial resources to the areas at higher risk, contributing to better coverage (Havinga, 2006; WHO, 2024). This approach is even described in the Codex Principles and Guidelines for National Food Control Systems (FAO and WHO, 2017), which states that "where quality assurance systems are used by FBOs, the national food control system should take them into account where such systems relate to protecting consumer health and ensuring fair practices in the food trade". Public food authorities in countries such as the Netherlands, Canada, and the United Kingdom explored the possibilities to reduce official inspection costs and strengthen food safety in the food industry (Verbruggen and Havinga, 2017).

On the opposite side, some drawbacks should be underlined. First of all, it is important to understand whether the findings of official inspections and third-party audits in food establishments are aligned. A decrease in the frequency of official inspections merely based on the existence of a certified FSMS must be based on the history of compliance (Piira *et al*., 2021). In the study of Turku *et al.* (2018), significant discrepancies between official inspectors' and auditors' findings existed, making the use of audit results challenging. Similarly, Conter *et al.* (2024) showed that the points of view of the CA and the FBOs are different because of different aims. However, most of the FBOs and CA agreed that official inspections and audits frequently overlap, and most of them also agreed that audits of a certified FSMS could reduce the frequency of official inspections (Turku *et al*., 2018).

At present, a major difference from official controls and vTPA systems is that official controls are independent from food businesses, whereas the certification bodies are part of the market economy. From this aspect, some challenges arise in recognizing vTPA programs as supporting the national food safety systems (NFSS). As a matter of fact, the third-party accreditation agencies should be formally recognized by the NFSS. A relationship of trust between the third-party accreditation agencies and NFSS should be created to ensure the transparency of their procedures and results (FAO and WHO, 2018).

In the assessment of a vTPA system by an NFSS, the scope and the criteria of the scheme should be compared with the public standard. Moreover, CAs should periodically test the performance of the private systems. Finally, a negotiation and agreement between NFSS and the scheme owners should be reached. Regarding the involvement of private assurance schemes in public food safety control, many national authorities stress that private assurance should be complementary to official controls, responsibilities of the parties should be clear, a legal base is needed, private schemes should align with legislation, and a certificate should include conformity to food safety legislation. Arguably, the role of CA will shift from direct inspections towards system controls, with a likely impact on the accountability and legitimacy of governmental food authorities. The fact that private standards contribute to consumer safety should not lead to the conclusion that private governance schemes always favor the public interest and should be preferred to government regulation (Fuchs *et al.*, 2011).

Global perspectives and future trends

Globalization has triggered growing consumer demand for a wider variety of foods, resulting in an increasingly complex and long global food chain. Food producers, distributors, handlers and vendors must take primary responsibility to ensure food safety, but

government agencies are the legal enforcers to protect public health and safety. Future achievements in food safety, public health will largely depend on how well policymakers, researchers, industries, national agencies, and other stakeholders manage to interact (Harvey *et al*., 2013; Boqvist *et al*., 2018). In this framework, the integration of private systems in official controls could be a win-win situation for both parties, as it adds to the capacities of both systems. Both public food agencies and private food programs could very well use the resources available to the other party (Hatanaka *et al*., 2005). From the private assurance programs' and third-party certification agencies' point of view, one of the main advantages they get from cooperation with the official control system is their increased legitimacy and authority. This can solve the point related to the cited fact that private schemes are part of the market economy. Certification programs and auditors that are recognized by a public authority strengthen their market position in two ways: i) the industry could be more inclined to get private certification because it contributes to compliance with public regulations or even results in reduced official controls; ii) approved private schemes and auditors become more attractive compared to schemes and auditors that have no public approval.

By the way, the extent of this cooperation can have potential risks. Official authorities can only rely on private food safety controls when public interests are shared by the private actors. In case the interests of private parties deviate from public interests, private controls could not be reliable. Furthermore, conflicts of interest also exist within the private control systems (Zheng and Bar, 2023). For example, the relationship of auditors and certification bodies with the food companies they control is a commercial one. Food companies pay for the auditing and certification services, which depend on the existence of contracts (Tanner, 2000; Lytton and McAllister, 2014; Hu *et al*., 2023). The relationship between certification and auditing services and the food companies they control is based on confidentiality. Typically, audit results are not publicly available and cannot be shared; however, in the case of GFSI schemes, audit reports can be accessed if the FBO decides to make them public. This makes the issue of sharing information challenging. A second cluster of risks is connected to the capacity of the private actors to perform adequate controls. Issues that should be considered are the practice of announcing audit visits (apart from the so-called unannounced audits, which have been increasingly integrated into voluntary certification schemes in recent years) and the lack of sufficiently qualified auditors. Although food safety is in the general interest of food companies within the private certification system, short-term commercial interests may have the upper hand. Recently, it has been stressed that not all FBOs are motivated to prioritize food safety and work on improving food safety. For this reason, the GFSI and private scheme owners introduced the concept of food safety culture in the food industry (BRC 2022; Marconi *et al*., 2023). Finally, governmental agencies can lose track of what happens in practice within the food industry. They need to develop a system of continuous monitoring of the performance of private systems and keep their knowledge up to date in order to prevent regulatory capture.

Conclusions

Auditing has become a crucial tool to ensure food safety systems. Traditionally, internal auditing has been at the forefront of securing food safety standards; however, the last years have seen a drastic shift towards an increased reliance on second-party and third-party audits. The driving force behind this change is not only due to the mounting demands of the public sector, but also because of the broad and comprehensive application of private standards for safety and quality. Over the past few decades, private standards have undergone significant development in tandem with the increased demands placed upon FBOs by EU legislation.

The development of these standards can be traced back to several factors that have driven the need for change, considering recurring food safety crises and scandals. The FBOs have thus been very instrumental in developing better quality assurance systems complementary to public regulation. This development has played a significant role in enhancing food safety systems, more so as the food sector gradually embraces vTPA frameworks to demonstrate its commitment to safety and quality assurance. However, the effectiveness of these schemes is often influenced by different factors, including the nature of the standards, the competence of the auditors, and the robust structure of the audit methodology. With changing market needs and increasing customer expectations, these schemes have tended to become even stricter over time. The imposition of more stringent standards highlights the dynamic interaction between government oversight and market-driven forces.

Notwithstanding these complicating factors, the aim of all food safety stakeholders—public authorities, FBOs, certification bodies—should be common to all: to safeguard food for all consumers. It would mean continued collaboration since it involved the realization of complementary functions by both public and private controls. While official controls and third-party audits have different objectives, official controls being focused on public health and consumer protection, and private standards often emphasizing consumer trust, the mutual recognition of these systems is fundamental to overcoming potential conflicts and redundancies. Alignment of official food safety regulations with voluntary standards can establish a more efficient and transparent food safety system.

In the future, it is crucial for governmental entities, the food sector, and certification organizations to maintain an ongoing cooperation to enhance these systems and guarantee that both regulatory structures and voluntary standards evolve in response to the challenges associated with global food safety. This process will require the promotion of increased transparency, the assurance of the credibility of third-party evaluations, and the creation of frameworks for continual monitoring and evaluation.

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