Italian adaptation to Regulation (EU) 2017/625 on food official controls: a case study

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Abstract

Foodborne diseases can be prevented by implementing a food safety system that manages food chain risks from producer to end-user, from a One Health perspective. In 2017, the European Parliament and the European Council adopted Regulation No. 625 on official food controls and other official activities performed to ensure the application of food and feed laws and rules on animal health and welfare, plant health and plant protection products. Italy issued a national law, Legislative Decree No. 27/2021, to adapt and adhere to European standards. We aim to describe the adoption and implementation of the new Legislative Decree by an Italian Food Hygiene and Nutrition Service, specifically focusing on the amendments introduced by Articles 7 and 8, namely the establishment of the second expert opinion and dispute procedures, and their integration with the promulgation of Article 70 of Legislative Decree No. 150/2022. These modifications aim to reduce the number of minor offenses that proceed to trial.

Introduction

Food contamination may determine the development of foodborne diseases, posing serious concerns for public health. Every year, contaminated food causes 600 million illnesses and 420,000 deaths (World Health Organization, 2015). Nevertheless, foodborne diseases can be avoided and controlled by implementing a food safety system from the production chain to the end user. Hence, national and international surveillance system implementation is fundamental (World Health Organization, 2017). In recent years, Italian public health authorities, particularly in the Emilia-Romagna region, have strengthened surveillance systems against infectious diseases, including foodborne illnesses (Di Federico *et al.*, 2024; Palandri *et al.*, 2020; Veronesi *et al.*, 2019). In the European Union (EU), the competent authorities (CA) are the organizations of a member state responsible for the management of food official controls and other official activities (European Parliament and Council of the European Union, 2017; Rossi *et al.*, 2020). To ensure food safety among the member states, in 2017, the European Parliament and the Council of the European Union revised and updated their regulation on food official controls with Regulation No. 625/2017. Before the latest regulation update, the European regulation on food hygiene was primarily guided by the "hygiene package", consisting of several EU regulations, including Regulation No. 852/2004 on the hygiene of foodstuffs, Regulation

No. 853/2004 on specific hygiene rules for food of animal origin, and Regulation No. 882/2004 on official controls to ensure the verification of compliance with feed and food law, animal health, and animal welfare rules (European Parliament and Council of the European Union, 2004a, 2004b, 2004c – respectively, Regulation No. 852/2004, Regulation No. 853/2004, and Regulation No. 882/2004).

These regulations establish comprehensive hygiene requirements across the food production chain, from farm to fork. Legislative Decree No. 193/2007 transposed Regulation No. 882/2004 into Italian law, defining the responsibilities and powers of official control bodies (OCBs) (European Parliament and Council of the European Union, 2004c). OCBs are responsible for verifying compliance with food safety and hygiene regulations and include local health authorities, the anti-adulteration and health units, and the port authority, each tasked with specific oversight roles in different aspects of food safety. The procedure for detecting and contesting non-compliance under Legislative Decree No. 193/2007 involves several steps. When a non-compliance is identified, the OCB issues a report detailing the irregularities found. The operator is then notified and given an opportunity to present their observations or corrective measures within a specified period. If the non-compliance is confirmed, the OCB may impose sanctions, depending on the severity of the violation. The decree ensures that these procedures are conducted transparently and that operators have the right to appeal against the decisions made by the OCB (Italian Republic, 2007). The new EU Regulation No. 625/2017 expands the scope of official controls to the entire agri-food sector to verify compliance with agri-food chain rules on food and feed safety and integrity throughout production, processing, distribution, and use (European Parliament and Council of the European Union, 2017; Albisinni, 2019; van der Meulen, 2019). This includes ensuring animal health and welfare, the use of genetically modified organisms, organic production, and labeling (Albisinni, 2019). Regulation No. 625/2017 introduced several novelties, providing comprehensive risk-based control rules and an integrated information technology (IT) system that allows CAs a more modern approach to tracking trade practices.

The Integrated Management System for Official Controls handles and automatically exchanges data, information, and documents related to the agri-food chain through a network that links systems for collecting and notifying non-compliance and alerts across various sectors (Albisinni, 2019; Menditto *et al.*, 2017). Thus, EU countries are required to perform official controls and verify that business operators operating in the agri-food chain comply with agri-food chain standards, including rules on products entering the EU from third countries. These standards govern the safety and quality of food and feed, as well as plant and animal health and welfare (Menditto *et al.*, 2017). To standardize control activities, the regulation defines the methods of execution and the requirement to produce documented procedures. It details the responsibilities of the CAs, describing the types of controls to be performed according to documented procedures and at a risk-based frequency. The regulation further outlines official control methods and techniques, including official sampling (European Parliament and Council of the European Union, 2017; van der Meulen, 2019).

A significant innovation introduced by the regulation is the right to a second expert opinion for food sector operators (FSO) whose livestock or goods are subject to testing or diagnosis as part of official controls. In case of disputes between the CAs and the operators, based on the second expert opinion, the operators may request a documentary review of the initial analysis and additional analysis performed by a different official laboratory (European Parliament and Council of the European Union, 2017).

According to EU legislation, national regulations issued in response to EU regulations aim to harmonize and integrate existing national laws with European standards, often involving the repeal or amendment of conflicting national laws. Italy implemented Legislative Decree No. 27/2021 to update food safety official control guidelines and align the national regulatory framework with European regulation (Italian Republic, 2021). European Regulation No. 625/2017 introduced several changes to food official control legislation. Accordingly, two regulatory aspects of the Italian Legislative Decree No. 27/2021 concern the institution of the second expert opinion (Article No. 7) and the subsequent hypothesis of the dispute between the CA and the FSOs (Article No. 8). These institutions allow operators to submit non-compliance results issued by the CA to a further assessment (European Parliament and Council of the European Union, 2017; Italian Republic, 2021).

Thereafter, Italy released Legislative Decree No. 150/2022 to reform the Italian civil justice system and make the civil justice process more efficient, modern, and accessible (Italian Republic, 2022). Article 70 of Legislative Decree 150/2022 contains recommendations about the management of crimes relating to food safety. The purpose of Article 70 of Legislative Decree 150/2022 is to introduce modifications to Law No. 283/1962, aimed at reducing the number of minor offenses that proceed to trial. In particular, the new Article 12-ter establishes a procedure for the extinction of contraventions through compliance with specific prescriptions issued by the CA. This process allows offenders to avoid criminal prosecution by fulfilling corrective actions and paying a financial penalty. The goal is to streamline the judicial process and alleviate the burden on the courts by resolving minor infractions through administrative means (Italian Republic, 1962; Italian Republic, 2022). Procedures supplied by Legislative Decree No. 27/2021 intersect with those provided for by Legislative Decree No. 150/2022.

Given the new European and Italian legislation, the present study illustrates research conducted within the Local Health Authority of Reggio Emilia aimed at updating food control procedures. This update is undertaken in consideration of new regulatory aspects concerning second expert opinions and disputes between CA and BOs.

Case Study

Background

As previously stated, with Legislative Decree No. 27/2021, Italy updated food official control guidelines according to Regulation No. 625/2017. Legislative Decree No. 27/2021 is a 20-article regulation that disciplines food sector and food industry activities, including industries that produce food contact materials (FCM). This Legislative Decree governs the official activities of the CA on food safety, specifying the meaning of non-compliance cases. As detailed in Article 5 of Legislative Decree No. 27/2021, non-conformities are classified into two categories: minor non-conformities, which do not pose an immediate risk to human or animal health and well-being, and major non-conformities, which do pose such an immediate risk (Italian Republic, 2021). Moreover, it regulates not only FSO's duties and culpabilities but also their right to a second expert opinion (European Parliament and Council of the European Union, 2017; Italian Republic, 2021).

As stated in Article 2 of Legislative Decree No. 27/2021, the Italian Ministry of Health, the regions, the autonomous provinces of Trento and Bolzano, and the local health authorities are the designated CAs to plan, program, execute, monitor, and report on official controls and other official activities, as well as to proceed with the adoption of the executive actions and the related administrative sanctions (Italian Republic, 2021). Inside the local health authorities, the CAs designated are the Local Food Hygiene and Nutrition Service (FHNS) and the Veterinary Public Health Service. The first one is responsible for all food industry and food-related activities, except for animal-derived food and animal health, animal feed, and zootechnics, which is up to the second one (Italian Republic, 1978, 1992, 1993). Each Local Health Authority has an FHNS, which is the CA regulating the food control system, which crafts, enforces, and regulates food laws and policies to maintain food safety (Italian Republic, 1998). The FHNS has the fundamental task of protecting communities' health in relation to food and nutrition aspects. The FHNS staff includes medical specialists in hygiene and preventive medicine, nutritionists, prevention technicians, and administrative workers (Azienda Unità Sanitaria Locale –IRCCs di Reggio Emilia, 2024). In the case study, the FHNS is included in the Public Health Department within the Local Health Authority-Scientific Institute for Research, Hospitalization and Healthcare (Azienda USL-IRCCS) of Reggio Emilia. Reggio Emilia is an Italian province with 531,891 inhabitants (in 2022), in Emilia-Romagna, a region of Northern Italy, located in the Po Valley (Italian National Institute of Statistics, 2024).

Constitution of the working group

A working group was assembled *ad hoc* to perform a thorough analysis of the new legislation along with a comparative evaluation of the existing procedures. Concerning food official controls, the FHNS of Reggio Emilia has four inside procedures (IP) and one management procedure (MR). In detail: i) the IP applied to the sampling of foodstuffs and intended surfaces for the verification of microbiological criteria; ii) the IP applied to the sampling of formulations and foodstuffs of plant origin for the detection of residues of phytosanitary products; iii) the IP defines the procedures to be adopted in the case of criminal and administrative measures in the areas of supervision under the jurisdiction of the FHNS; iv) the IP applied to sampling for official control of foodstuffs and FCMs intended for chemical and radiometric analysis; v) the MR describes the sampling activity within official controls.

The final output of the working group was the revision and update of both IPs and MR.

A flow chart was implemented to summarize the activities related to the official control's new procedures, second opinion, and dispute phases. A model Gantt diagram was set up to clearly report and verify the timing of the different daily activities related to non-conforming outcomes management.

Analysis of the second expert opinion and dispute procedures described in the regulatory framework

According to Legislative Decree No. 27/2021, official sampling must be done during the official controls that the CA carries out at the FSO. "Official sampling" refers to a method used in the context of official controls and other official activities that involves collecting a matrix and creating a sample in order to confirm its conformance in a controlled environment or gather information for a risk assessment. The sampling methods for laboratory analyses, tests, and diagnoses are detailed in Article 20 of Legislative Decree No. 27/2021; annexes of the decree provide detailed technical specifications and guidelines for implementing the controls described in the main articles. These include procedural standards for inspections, sampling methods, criteria for assessing compliance, and protocols for reporting and documentation (Italian Republic, 2021).

This sampling procedure always involves collecting a fixed number of aliquots. Aliquot means each of the equivalent parts into which the official sample is divided. An aliquot can be made up of multiple sample units (Italian Republic, 2021).

Some of them are necessary to guarantee the FSO's right to a second expert opinion and dispute. The Legislative Decree No. 27/2021's attachments specify the required number of aliquots, which is often one. When appropriate, relevant, and technically possible, two more aliquots will be created: one for the second expert opinion and one for dispute (Italian Republic, 2021).

During the sampling, a report is drawn up. The sample must be analyzed by an official laboratory. Official laboratories are defined by the Italian Ministry of Health as detailed in Articles 9 and 10 of Legislative Decree No. 27/2021. The aliquot for the second expert opinion is delivered to the FSO together with a copy of the sampling report, while the one for the dispute is handed over and stored by the official laboratory together with the first-instance aliquot. The results of the analysis are sent to the FHNS (Italian Republic, 2021).

Every phase of FHNS official controls, from the sampling to the second expert opinion and dispute, and timings in accordance with the new Italian legislation are illustrated in the flow chart (Figure 1). Given the results, the CA evaluates the outcome. If the outcome is compliant, the procedure is dismissed. If the outcome is non-compliant, the FHNS promptly sends the notification to the FSO involved, the official laboratory, and law enforcement, if involved. In addition, within 48 hours, the CA notifies the non-compliant outcome through the IT platform for the Rapid Alert System for Food and Feed (European Parliament and Council of the European Union, 2002).

Within 15 days of receiving the non-compliant outcome, the FSO can request a second expert opinion. The CA must provide a copy of the documentation of the activities carried out during the sampling and during the official laboratory analysis as soon as possible (Italian Republic, 1990).

Within the time limits set by the CA, the FSO provides the "second expert opinion" of the documentation produced by a qualified and officially appointed part-expert. Sideways the documentary second expert opinion, the FSO may perform, at its own expense, a second sample analysis at an accredited laboratory. The accredited laboratory must be different from the official first-instance laboratory. The second expert opinion must be sent to the CA. The latter judges the documentation provided and communicates the outcome to the FSO as soon as possible. If the outcome is compliant, the CA dismisses the practice. If the outcome is non-compliant, the CA rejects the second expert opinion and fines the FSO. Within 30 days from the rejection of the second expert opinion, the FSO can request a dispute to the CA. The CA has to send the necessary documentation to the Italian National Institute of Health (ISS). Within 30 days from the acquisition of the documentation, ISS shall forward the outcome of the dispute to the FSO and the CA. Within 30 days from the request for the dispute, the FSO may request from ISS a third laboratory analysis of the rate, at its own expense. Within 60 days, ISS shall notify the results of the analysis to the FSO, the CA, and the first-instance laboratory. If the outcome is compliant, the CA dismisses the practice. If the outcome is non-compliant, the CA rejects the dispute (Italian Republic, 2021).

Analysis and update of the procedures in use on sampling activities within official controls in accordance with the legislation in force

In addition to creating the flowchart, which was integrated into the new procedure and summarizes all noteworthy aspects of the new legislation, the working group also implemented an *ad hoc* Gantt chart as a tool to aid in the daily management of analyses with non-conforming outcomes (*Supplementary Figure 1*). In order to record every non-compliant case, the FHNS operator that runs the inquiry is supposed to fill out four fields inside the model: FSO, matrix type, date of sampling, and date of analysis results reception. By filling out the previous fields, the Gantt diagram automatically fills in the fields concerning the starting and ending dates of each non-compliancy management phase. This tool aids the FHNS operator in keeping track of the deadlines imposed by Legislative Decree No. 27/2021 and described in the previous flow chart. On the right part of the diagram and in the "progress" column, the operator keeps track of the progress of the inquiry. The time bar turns from green to red as time goes by.

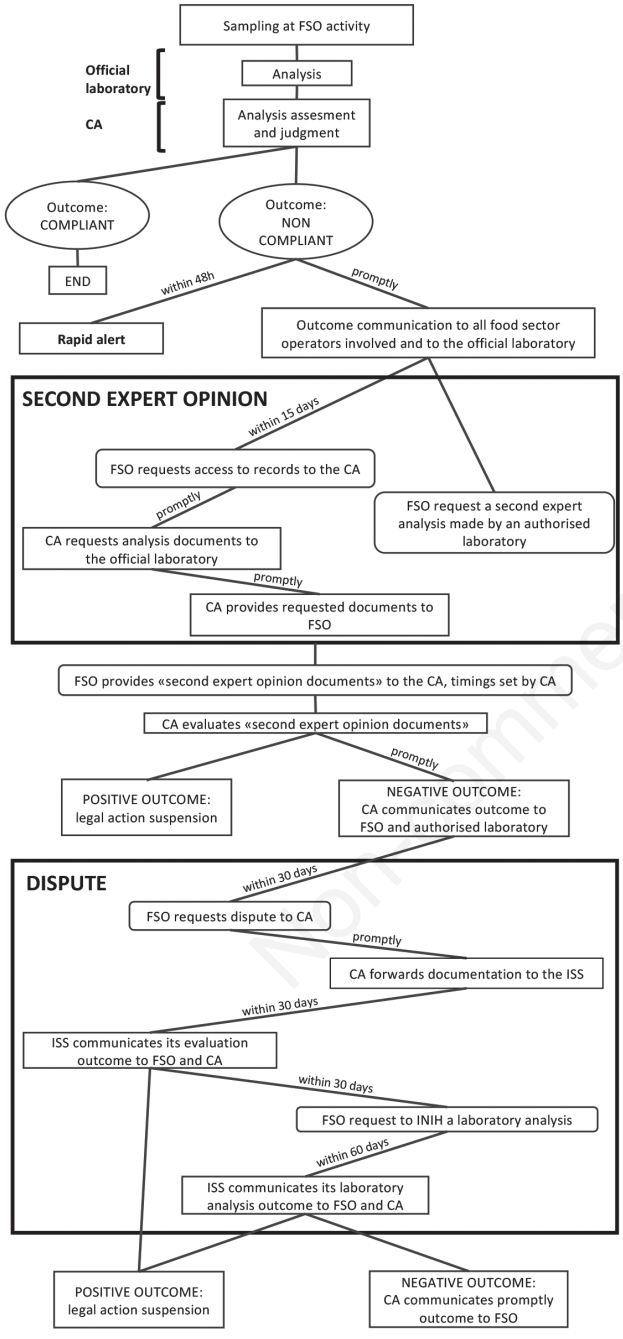

Figure 1. Flow chart describing phases of official controls, second expert opinion and dispute; timings are detailed. FSO, food sector operator; CA, competent authority; ISS, Italian National Institute of Health. (Italian Republic, 2021).

Discussion

Comparison of Regulation 625/2017 adoption among member states of the European Union

Before the enactment of Regulation 625/2017, FSO had the ability to contest decisions made by CAs, reserving their right to request a review of analyses (European Parliament and Council of the European Union, 2004d - Regulation No. 854/2004). However, with the introduction of Regulation 625/2017 and Legislative Decree No. 27/2021, the provisions of the previous regulations (EC 882/2004 and 854/2002) were replaced. Notably, the new legislation introduced two significant innovations: the "second expert opinion" and the "dispute" mechanisms (European Parliament and Council of the European Union, 2004c, 2004d – respectively, Regulation No. 882/2004 and Regulation No. 854/2004).

Several countries, including Spain, France, and Germany, adopted Regulation 625/2017 without adaptations (Spanish Agency for Food Safety & Nutrition, 2023; Germany Federal Ministry of Food and Agriculture, 2024; France Ministry of the Economy, Finance and Industrial and Digital Sovereignty, 2024), while the Food Safety Authority of Ireland (2022) published a guidance document. Unlike some other European member states that adopted Regulation 625/2017 without adaptations to their national legislation, Italy's Legislative Decree No. 27/2021 incorporated distinctive features regarding the execution of disputes and specified timeframes. In Italy, the "dispute" mechanism grants FSO the right to request a documentary review of initial analyses by ISS, whereas Regulation No. 625/2017 allows the review to be conducted by another official laboratory. Moreover, while Regulation 625/2017 does not provide specific timeframes, Italy's Legislative Decree No. 27/2021 imposes strict deadlines, necessitating additional clarifications through ministry addenda to ensure consistent interpretation (Italian Ministry of Health, 2021, 2022, 2023). However, some deadlines were not efficiently clarified by the ministry addenda inducing difficult interpretation. In our case study, the working group attempted to interpret the second expert opinion and dispute timings as detailed in the flow chart (Figure 1). The Gantt diagram was built accordingly.

Challenges in harmonizing Legislative Decrees No. 27/2021 and No. 150/2022

Implementing Legislative Decree No. 27/2021 posed challenges due to the concurrent enforcement of Legislative Decree No. 150/2022, which regulates legal actions concerning food safety non-compliances (Italian Republic, 2022). The integration of their timelines remains ambiguous, particularly regarding the initi-

ation of legal actions by CAs in relation to the "second expert opinion" and "dispute" phases. Despite the provisions outlined in Legislative Decree No. 150/2022, clarity on the sequence of actions to be taken by CAs is lacking. Notably, while Legislative Decree No. 27/2021 received clarifications through the ministry addenda, similar guidance has not yet been provided for Legislative Decree No. 150/2022. The working group suggestion is to pursue legal action against the FSO after the "dispute" phase. However, depending on the severity and complexity of the situation, we reserve the right to report the matter to the authorities simultaneously with the notification of non-compliance. In such cases, we will provide the information currently available to us and indicate that a comprehensive collection of all relevant data is ongoing.

Conclusions

As the local CAs for food safety, Reggio Emilia's FHNS embraced the changes introduced by Legislative Decree No. 27/2021 by establishing a dedicated work group and developing supportive tools for daily operations. The work group encountered challenges that were primarily related to interpreting timing directives and harmonizing Legislative Decree No. 27/2021 with Legislative Decree No. 150/2022. In response, aiding tools were created, and internal MR was updated to support FHNS operators. To facilitate everyday operations at the local level, clarification from the Italian government 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.

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Online supplementary material:
Supplementary Figure 1. Gantt diagram model; aid tool in the management of non-compliances.