



HEALTH PROMOTION

The responsibilities of a commercial intermediation company as a new food business: the case of a typical regional Italian food

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Keywords

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Summary

According to Regulation (EC) 178/2002, “any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food” must be classified as a “food business”. A food business operator (FBO) is “the natural or legal person responsible for ensuring that the requirements of food law are met within the food business under their control”. We analyzed the case of an Italian wholesale commercial intermediation company, purchasing a typically carbohydrate-rich local product from producers and reselling it to retailers, although never physically possessing it. In the marketing process, the company misleadingly emphasized the product’s protein content, providing inaccurate

nutritional information on the label, thus committing food fraud. Moreover, as required by European law, sanitary guarantees on the operating methods and traceability were not provided. To ensure food safety, every food business is subject to the obligation of registration (Regulation EC 852/2004), preparation of the self-control plan according to the principles of the HACCP system and traceability obligations (Regulation EC 178/2002). This case highlights the current general poor culture in food safety. It shows the urgent need for awareness-raising and training interventions to improve behaviors and clarify the qualifications and responsibilities of all parties involved, including FBOs and competent authorities, to prevent health risks and food fraud.

Introduction

The accountability of the food business operator (FBO) is a key point of the current European food legislation. Indeed, they bear the primary responsibility for ensuring food safety.

In particular, Regulation (EC) No 178/2002 (“General Food Law”) [1], identifies the FBO as the natural or legal person responsible for ensuring compliance with the provisions of the legislation in the food business under their control. This approach is grounded in Recital 30 of the same Regulation, which states that: “A food business operator is best placed to devise a safe system for supplying food and ensuring that the food it supplies is safe; thus, it should have primary legal responsibility for ensuring food safety”. The same Regulation introduces the fundamental principle of an integrated supply chain approach, encompassing all stages of production, processing and distribution; specifically, for the final stage of the supply chain, it defines placing on the market as “the holding of food or feed for sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves”.

The EU regulatory framework evolved until the entry into force of the “Hygiene Package” in 2006, which

definitively consolidated and standardised the general principles of food safety legislation at the European level. In this context, Regulation (EC) 852/2004 [2] reaffirms that FBOs must ensure hygiene requirements at all stages of food production, processing and distribution by applying self-control, according to the principles of the HACCP (Hazard Analysis Critical Control Points) system. Self-control derives from the above-mentioned empowerment of the FBO and corresponds to the obligation to keep its production under control.

Among the FBO's obligations is also the guarantee of product traceability, defined in Regulation (EC) No 178/2002 [1] as “the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution;”. The ‘Hygiene Package’ then extended this obligation to all agri-food products, making it possible to identify any product at any stage of the production cycle.

Lastly, Article 6 of Regulation (EC) 852/2004 [2] regulates the obligation of registration, stipulating that FBOs must notify the Competent Authority for Food Safety of every food business under their control carrying out any food production, processing, transport, distribution, sale and administration activity, and any

significant change in activity so that the Competent Authority has up-to-date information at its disposal at all times.

The identification and qualification of the FBO, however, are relevant critical issues in light of the increasing complexity and extension of the agri-food supply chain, including the sales phase, the fragmentation of processes, the variety and number of actors involved, and the complexity of both ownership and logistical steps [3]. In particular, the rapid expansion of e-commerce in the food sector has brought to light the complexities and gaps inherent in the definition culture of the roles and responsibilities of operators involved in online food trading, including Internet service providers [4]. Among the obligations falling on the FBO, the most neglected has been identified as the one relating to the traceability of food products. A study published by Mettevi M et al. [3] identified among the main barriers to fulfilling the obligation of traceability the increasing complexity of food chains and the lack of specific personnel training.

This non-compliance has also been linked to the growing risk of food fraud offences, the prosecution of which, however, is made particularly complex by the large number of actors involved in the chain, many of whom frequently do not physically possess the foodstuff. In this context, Manning highlighted in a study published in 2016 [5] that, in order to mitigate the issue of food fraud, it would be advisable to implement an ongoing development of data centralisation systems, in particular ensuring that separate databases can be coordinated to add value through collective data analysis, and secondly, ensuring that there are appropriate deterrent mechanisms in place so that food fraud mitigation moves from a fraud detection to a fraud prevention stance [6].

Roth et al. [7] identified globalization as a factor associated with the difficulties in fulfilling the obligation of traceability of food products and the risk of committing food fraud. The global relevance of these issues and the need to develop new approaches that can be used by Control Authorities to verify and ensure the safety and traceability of food, as well as to protect producers and industry from unfair competition, are evident. Such actions can only increase consumers' trust in the purchased food [8].

In order to illustrate the aforementioned increasing complexities related to the articulations of the food chain and the qualification of FBOs, a case study will be described, handled through the collaboration of various Authorities and control bodies for compliance with food legislation [9], such as the Food Hygiene and Nutrition Services of the Local Health Authorities operating in the Northwest area of Italy, under the coordination of the Italian Ministry of Health. The case concerns a food brokerage company failing to comply with the main obligations falling on the FBO as provided by EU food legislation. Specifically, those related to registration, self-control procedures, and traceability of food products. Additionally, this company marketed under its own brand typical regional bakery products, whose traditional recipe involves a predominant carbohydrate

component, with nutritional values on the label reformulated in favour of the protein component, which was found to be false during the investigations.

Materials and methods

The investigation focused on the food chain structure and the specific roles of the involved FBOs (Tab. I). The processes that supported the findings of non-compliance to food safety European legislation and the consequent administrative contestation applying Italian laws by Competent Authorities will be highlighted. Finally, criticisms in current identification of new types of FBOs and education about FBOs obligations described by food safety European legislation will be discussed.

Results

In 2021, investigations concerning the falsification of nutritional values reported on laboratory analysis of typical regional bakery products marketed under the same brand name in different types were initiated by the Italian Judicial Authority.

As a result, the owner of the food company whose brand appeared on the labels of the bakery products under investigation was identified as responsible, resulting in charges of commercial fraud.

Regarding the production and distribution chain of these products, it was also ascertained that the aforementioned company, after an initial phase of direct production in a laboratory managed by the company owner, which later became an intermediary only, would then delegate production to another company primarily engaged in bakery activities. However, it provided recipes, raw materials, boxes, and other packaging materials, including rolls of original labels to be affixed to the packaging of the finished product. The bakery was responsible for all product processing, from dough formation to baking and packaging of the finished product, including batch production. During the investigations, the bakery stated that it conducted no internal quality checks, neither on the raw materials received from the intermediary's suppliers nor on the finished product, following an agreement between the parties that delegated this responsibility to the ordering company, identified as the intermediary. Additionally, no formal contract had been concluded between the intermediary and the bakery.

Initially, product storage was entrusted to a logistics company or an agricultural cooperative's warehouse.

The logistics company directly handled the distribution to retailers nationwide, while the warehouse manager entrusted the packages to a courier for delivery to the end customers. Subsequently, investigations revealed that the sole director of the intermediary company with intermediary activities had changed the shipping and delivery methods of bakery products to customers, managing the collection directly with the courier, who in

Tab. I. Time scan of case study events: main activities conducted by the Official Control Authorities.

Date	Event
June 2021	Search at the residence of the legal representative of the company with intermediary activity, seizure of false laboratory analysis reports, inspection at the bakery, checks on the registered office of the company with intermediary activities, and on the activity cessation of one local unit from October-November 2018.
21 December 2021	Partial conclusion of investigations on the production and marketing among the Italian territory of typical regional bakery products with the same brand bearing false nutritional values on the label.
08 August 2022 and 06 September 2022	Further inspection at the bakery: verification of production methods and product supply agreed with the company with intermediary activities.
15 September 2022	Identification of irregularities on the address of the registered office and on the local unit with productive activity subject to notification.
29 September 2022	Inspection at the logistics company: assessment of new methods of shipping products prepared by the sole administrator of the food company acting as an intermediary.
11 November 2022	Information collection report (under the Art. 13 L. 689/1981 and Art. 137 Reg. (EU) 625/2017) in the presence of the legal representative of the company with intermediary activity.
15 November 2022	Information collection report (under the Art. 13 L. 689/1981 and Art. 137 Reg. (EU) 625/2017) at the associated firm of accountants indicated as the registered office in the Company's Chamber of Commerce record with intermediary activity in the presence of the legal representative of the company with intermediary activities.
23 November 2022	Notification of complaints of administrative violations and setting of the deadline (Art. 6 c. 7 Legislative Decree 193/2007 and Art. 138 Reg. (EU) 625/2017) to the legal representative of the company with intermediary activity.

turn delivered directly to the recipient indicated by the intermediary each time. The intermediary coordinated the activities of the various companies involved.

Among how the products were sold, it was ascertained that the company with intermediary activities had a website and Instagram page, but also that the products were sold on numerous other sites dedicated to the sale of 'healthy, dietetic, protein' and 'sports nutrition' products. With regard to the checks carried out on the registration of establishments and traceability of food products, as required for all food businesses by Article 6 of Regulation (EC) 852/2004 [2] and Article 18 of Regulation (EC) 178/2002 [1], it had emerged that the registered office of the intermediary, a crucial address in cases of a potentially unstructured intermediary commercial activity, corresponded to the address of a corporate and tax consultancy firm.

The latter reported that he had not been assisting the intermediary for some time, contrary to what the intermediary's owner asserted (stating that he deposited accounting records with invoices and transport documents (DDTs) at this firm). In order to alternatively obtain such documentation useful for verifying the traceability of the products, further investigations were carried out at the producing bakery. The first DDTs examined, with the bakery's name as the sender addressed to the intermediary and destined to the courier, did not indicate the quantities of the products or their final destination, indicating that the intermediary formally purchased the commissioned products from the bakery and defects in the traceability path of the products.

It also emerged that the only local unit with production activity where an industrial oven had been installed and registered as required by Regulation (EC) 852/2004 [2] had been inactive since the end of 2018, although the cessation had not been notified to the competent

Local Health Authority (ASL) as required by the aforementioned Regulation.

At the time of the inspections, moreover, the establishment was still listed in the Chamber of Commerce records, an official information document that includes personal, legal, and tax information of Italian companies registered in the business registry, specifying production and trade activities of bakery products.

These findings highlighted the food business's failure to fulfil the obligations of registration and traceability of food products required by European legislation.

Regarding the contestation about food fraud, the intermediary argued that the products had changed in denomination, composition, and labelling. It also reported that it had not received any reports regarding human health safety profiles from consumers. However, the Official Control Authorities responsible for the investigations noted that the intermediary had not provided them with documentation regarding the new formulation of the products nor demonstrated compliance with the falling obligations on the FBO according to European legislation on food safety.

Further investigations conducted by the Food and Nutrition Hygiene Service of the A.S.L. in accordance with European legislation on official controls [9] had allowed the collection of information directly from the intermediary company's manager, regarding:

- the predominant characteristics and the type of consumer to whom the own-brand products were intended, respectively "protein and gluten-free characteristics" and "people who engage in sports or have intolerance problems";
- the individual responsibility in formulating the recipes, represented by consultants identified by the intermediary itself; the process of selecting ingredients based on the characteristics outlined in

the technical sheets and other documentation; the implementation of internal checks at accredited laboratories to assess the nutritional values of the products;

- the operating methods of the bakery, which received the recipes and production procedures for the individual types of products from the intermediary and carried out production and packaging;
- a further establishment used as a food distribution platform, which was the subject of a recent notification (which had not been received by the competent territorial authority at the time the information was collected) and for which the self-control plan based on HACCP principles was being prepared;
- the documentation related to product traceability and labelling, particularly nutritional labelling, which the intermediary claimed to be held at their residence rather than at the registered office specified in the Chamber of Commerce extract of the company; it was also reported that transportation documents and invoices were issued directly and that the predominant clientele consisted of other businesses rather than individual consumers, such as gyms, shops, and pharmacies;
- the product traceability procedure, represented by a database prepared and updated daily by the intermediary, shows the invoice number of the finished products that the intermediary purchased from the bakery and the relevant lot and expiry date numbers associated with the invoice numbers of the sales by the intermediary to the final customers; concerning the traceability of the raw materials sold by the intermediary to the bakery, the manager reported that he reported the lot number on the sales invoices;

Furthermore, the intermediary company's manager had put forward several reasons for:

- the lack of registration of the commercial intermediary activity, represented by the fact of "not directly producing anything";
- the failure to draw up a self-control plan based on the principles of HACCP for the commercial intermediary activity, consisting in the fact that he did not see or produce the products directly but only provided the bakery with the recipes and labels to be affixed to them; the bakery was directly responsible for identifying deadlines and was also mentioned on the labels as the producer;
- the failure to communicate the cessation of production activities was due to their unaware of this obligation under Article 6 of Regulation (EC) 852/2004 [2].

Following the investigations carried out, the Food and Nutrition Hygiene Service proceeded with the administrative contestation, as provided for by the Italian sanctioning system [10], and set deadlines [9] aimed at resolving the non-compliances contested by the manager of the commercial intermediary company, violations of Articles 5-6 of Regulation (EC) 852/2004 [2] and Article 18 of Regulation (EC) 178/2002 [1] for the reasons described below:

- the failure of the FBO to fulfill the obligation of registration and notification of significant changes in activities related to the food chain as provided for in Article 6 of Regulation (EC) 852/2004 [2], preventing local competent authorities from having updated information regarding the company and offering them poor collaboration: indeed, the cessation of activity of the local production unit, the change in the conduct of the food business activity through the sale of raw materials to the producing bakery and the purchase of finished products from it, and the performance of an activity attributable to commercial intermediation had not been notified; furthermore, even the Chamber of Commerce extract was not updated in terms of registered office, email contact, production units, and related activities; the intermediary's personal computer kept at home had been identified by the intermediary as the "place" for storing documentation related to product traceability, but the home address had never been formally communicated to the competent authorities as a facility connected to the company's activities;
- the lack of procedures based on the principles of the HACCP system for food distribution activities, in the application of Article 5 of Regulation (EC) 852/2004 [2], the commercial intermediary company of food products must be classified as a food business, even though it does not directly produce food, simply because it distributes them, moreover with its brand and identifying mark. As a food business, the intermediary must, therefore, have its self-control plan, including procedures and systems to ensure the traceability of the food handled;
- the absence of an effective traceability system provided for in Article 18 of Regulation (EC) 178/2002 [1]: the examination of a sample from one of the databases held by the intermediary, some invoices, and the related product labels examined, had highlighted the failure to update the product name and the lack of correspondence between the products actually sold recorded in the database and the description of the products listed in the purchase invoices from the bakery and sales invoices to customers; the database indicated invoice numbers but not product quantities, the latter being specified only in the invoices; the invoices, however, lacked batch numbers and expiration dates; the labels of the products with a new name indicated a minimum term of conservation and not an expiration date, unlike the previous formulations, but the database still mentioned the expiration date (no longer applicable to the newly formulated products) among the data required by the traceability system; finally, a discrepancy was noted in the data entry criteria used to record incoming products in the database compared to those for outgoing products, as the specification of the company name to which the products were sold was not provided.

The manager of the commercial intermediary activity filed an appeal against the aforementioned contestations,

reaffirming that they only engage in the sale of raw materials and finished products without intervening in the production, packaging, and transportation phases, and therefore believing that they are not subject to the obligations of OSA as provided for by European food legislation. They denied the need to communicate the cessation of production activity at the local unit registered under Article 6 of Regulation (EC) 852/2004 [2], adding that such omission does not cause any harm or potential danger to consumers, nor does it prejudice any official controls [9], considering that production does not take place in an "unknown" or "non-updated" facility. They also stated that they had prepared a self-control plan based on HACCP principles, although they believed that this requirement was only necessary for operators managing the production and delivery of food products; in this context, they emphasized the professionalism of the consultants selected for recipe formulation and raw material selection, as well as the internal checks carried out regarding the quality standards of the production, logistics, and transportation companies. Finally, they attributed the contested issues regarding the traceability system to material errors and reported that they had taken steps to resolve them. However, the competent ministerial authority formally supported the aforementioned appeals.

Discussion

The case described provides insights into the growing challenges related to the awareness of the qualifications of the FBO and their obligations and, consequently, the competent authorities' correct qualifications of such figures.

In particular, when the FBO's activity does not explicitly involve direct handling of food products, its awareness of having to qualify as such may not be immediate. This includes the increasingly complex management of distribution and indirect sales phases (online trade, mere logistics activity and trade in pre-packed non-perishable products). However, even in these cases, the operator qualifies as a FBO and is bound by all the obligations that food legislation imposes, including registration through notification, the preparation of a self-control plan consistent with its activities, product traceability and, in the event of suspected/confirmed non-conformity of the product distributed, cooperation in product recall or withdrawal procedures, and collaboration with authorities and other operators involved.

The Italian Ministry of Health has managed this issue through a formal Communication addressed to all control authorities already in 2012 [11], referring also to the "Guidance document on the implementation of certain provisions of Regulation (EC) 852/2004 on the hygiene of foodstuffs" issued by the European Commission on 16/02/2019 [12]. This communication clarified that "even the company operating in the field of commercial intermediation, which deals with the movement of food products between suppliers and

between these and retailers – without necessarily involving the handling of food products or their storage at the company's premises, which may consist only of an office – is subject to the registration obligation. "It reiterates that "the intermediation activity therefore fully falls within the definition of a food business operator whenever it is connected to one of the stages of food production, processing, and distribution".

The Communication also evaluates the definition of "supplier" offered by Regulation (EC) 178/2002 [1] as generic, as it can refer indiscriminately to both the owner and the holder of the goods, since products, once they leave the production facility, can undergo different ownership and logistical stages. Therefore, the owner of the holder of the goods may not coincide with the physical holder of the same. It clarifies that "food business" means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food". Regarding the registration obligations, it further explains that "the unit to be registered is represented by the offices where commercial documents are kept" and that "the owner of the business is required to submit the SCIA (Certified Notification of Start of Business) in the municipality where these offices are located, declaring that it is an intermediary activity". It concludes that such an FBO is not subject to the general and specific hygiene requirements provided by current regulations but to the traceability, withdrawal, and recall obligations under Regulation (EC) 178/2002 [1].

It is noted that the European legislator, about the notification obligation, refers to "every establishment" under the control of the FBO [2] and not generically to the food business defined in Reg. (EC) 178/2002 [1] as "any public or private entity, with or without profit, which carries out any of the activities connected to one of the phases of food production, processing, and distribution." This clarification may imply an intention to make the competent authorities aware of detailed data regarding the composition of the food business. However, it may also introduce interpretative challenges, especially for FBOs that do not have physical premises where they carry out their activities, as can happen in the cases described above. An explicit clarification in this regard is provided by the recent amendment of Regulation (EC) 853/2004 [13], which introduced the definition of "intermediary operator" as "a food business operator, including traders, other than the first supplier, with or without premises, who carries out its activities between production areas, relaying areas or any establishments." However, the definition was introduced with specific reference to the live bivalve mollusc chain [13]. Therefore, there is speculation about the opportunity to introduce specific regulatory enhancements (at least at the European level) regarding the e-commerce sector of food products, which is rapidly expanding, to enhance transparency and reliability. This could be achieved, for example, by clearly defining the roles and responsibilities of different operators, including Internet service providers, in the online food trade sector [4].

This is also aimed at reducing the risk of fraudulent activities occurring. Among the priority obligations of the FBO identified by the European legislator is also that of guaranteeing the traceability of foodstuffs by means of declaring to the competent authorities, upon request, the data relating to the suppliers of the products and the persons to whom the goods have been delivered. This is done in order to reconstruct every stage of the food's journey through the supply chain. However, even concerning this obligation, there is evidence of a lack of awareness and training for stakeholders [14, 15].

Self-monitoring in the phases following primary production must include the application of both Good Manufacturing Practices (GMP) and procedures based on the principles of the HACCP system. This system aims to identify, control, and mitigate food safety hazards using a concrete analysis of each process stage. FBOs must retain and provide, upon request, to the competent authorities' documentation proving the effective application and updating of procedures suitable for their purposes and consistent with operational reality. Even an FBO acting solely as an intermediary in food trade is obligated, as argued above, to establish, implement, and maintain one or more permanent procedures based on the principles of the HACCP system. Moreover, the same FBO must justify (with a documented qualification procedure) the choice of suppliers and storage and transportation companies and indicate based on what agreements (physical, chemical and microbiological specifications) the products subjected to commercial intermediation are purchased.

Consumer information profiles also emerged from the case. In this context, the European legislator has established that all foodstuffs placed on the market must bear the mandatory information on the label, including the possible presence of allergens, the conditions of use and storage, and the expiry date; in particular, the European legislation [16] emphasises the primary responsibility of the owner or manager of the brand under which the product is marketed, but also refers to the concurrent responsibility of the distributor who sells or offers for sale products whose non-compliance with the regulations in force may be presumed.

Lastly, it is important to have a network organisation between competent authorities, clearly distinguishing roles and responsibilities. In Italy, the current Legislative Decree 27/2021 art. 2 designates the Ministry of Health [17], the Regions, the Autonomous Provinces of Trento and Bolzano, and the Local Health Authorities, within their respective competencies as competent Authorities to carry out official controls in food businesses and to ascertain and contest administrative sanctions for violations concerning food, feed, animal health and welfare, animal by-products, plant protection products and pesticides. The same article provides that 'the Ministry of Health, in its capacity as Competent Authority, may avail itself of the NAS (Antisofistication and health nucleus of Carabinieri, guaranteeing the coordination of assessment activities with the control activities carried out by the other territorially competent authorities'.

In conclusion, for Article 2 of Regulation (EC)

178/2002 [1], "any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food", including a wholesale intermediary company that purchases food from producers and resells it to retailers, even without physically possessing the products, must still be qualified as a "food business" solely for the fact of carrying out a food distribution activity. Especially if, as in the case at hand, the brand displayed on the finished products belongs to the intermediary company. According to mandatory regulations, such a company is subject to the obligations of:

- registration (health notification) under Article 6 of Regulation (EC) 852/2004 [2];
- establishment of a self-monitoring plan according to the principles of the HACCP system referred to in Article 5 of Regulation (EC) 852/2004 [2];
- traceability and recall obligations under Articles 18 and 19 of Regulation (EC) 178/2002 [1].

A significant gap in food safety culture persists even two decades after the adoption of EU food regulations. The very recent Regulation (EU) 2021/382 [18] addresses this point by introducing a new chapter aimed explicitly at raising stakeholders' awareness on the issue to increase awareness and improve the behaviours of all involved parties, including competent authorities. Implementing training interventions for OSAs and their staff can be a useful strategy to enhance awareness and the significance of associated responsibilities.

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Authors' contributions

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