

# Official controls regarding artisanal ice cream shops: public health policies and consumer protection in the Italian and European legislative frameworks

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## Abstract

*Ice cream is a widely enjoyed food that is especially popular during summer. To ensure it is safe and ready-to-eat for consumers, legislation imposes a series of obligations for food business operators, and for competent authorities that have to carry out official controls, including official sampling. This article reviews the general and specific requirements applicable to the premises where ice cream is produced, concerning aspects related to health notification obligations and to implementing and maintaining procedures based on the principles of the Hazard Analysis and Critical Control Point system. The review extends to results stemming from the most recent official control activities conducted in Italy, and to future perspectives on control methods that will have to be compliant with the provisions of the new EU Regulation 625/2017 applicable from 2019.*

## Introduction

Italy's ice cream is a popular and worldwide appreciated food. In its production, large food industries need to be particularly careful about ensuring effective conditions for making ice cream also intended for export (e.g. hygiene and thermal conditions during storage and transportation, suitable packaging materials, accuracy of label translation in the language of the country of destination), while the skills of artisanal makers must also be able to yield

a ready-to-eat (RTE) food that is often more enjoyable because of organoleptic traits that owe to make use of locally sourced raw materials. Particular attention must be paid to production and distribution of the artisanal products, as quality must be carefully respected and guaranteed from the standpoints of hygiene and sanitation, as with other RTE foods (1).

Increasing consumption of ice cream in the 19th century was accompanied by a proportional increase in incidence of food-borne diseases (FBDs) (2). This was such

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a pressing issue that, at the time, ice cream poisonings could represent pathological conditions with lethal outcomes. Notably, according to historians, these poisonings were related to ingestion of toxic vanilla or galvanisation caused by release of toxic substances (including metal alloys) in freezers with which the ice cream was directly in contact. Even today, the scientific literature reports numerous cases of FBDs related to ice cream consumption; among these are outbreaks of *Salmonella enteritidis* infection in homemade ice cream (3), *Salmonella typhimurium* in cake batter ice cream (4), *Escherichia coli* verocytotoxins in ice cream produced in a Belgian farm (5), and *Listeria monocytogenes* in ice cream consumed in the United States (6, 7). In addition, there are documented cases of FBDs related to consumption of ice cream served in hospitalised patients (8), as well as cases of staphylococcal enterotoxigenesis (9). The presence of *Bacillus cereus*, a producer of emetic toxins, has also been documented (10).

Ice cream, therefore, represents a substrate that, owing to intrinsic chemical-physical characteristics (pH, activity water, nutrient content), allows microbial growth even if stored at low temperatures, which have a bacteriostatic effect (11). Further potential hazards are represented by secondary contaminations due to contact with improperly sanitised vessels, tools or machines, or to micro-organisms transmitted by infected operators (e.g., *Staphylococcus aureus*, hepatitis A virus) (12). These types of contamination may also occur in a domestic context (13). As this is a milk-based food matrix, in the context of an in-depth evaluation of contaminants at the source, the risk related to the presence of mycotoxins in the main ingredient must not be neglected, as already stated for dairy products (14-16).

With regard to the presence of chemical contaminants, results from a recent study

investigating the presence of heavy metals in industrial and artisanal ice cream samples are of particular interest (17). Total absence of arsenic and mercury was verified in all the samples studied. With reference to industrially produced ice cream, despite the total absence of cadmium, presence of chromium (58%), lead and tin (18%) were detected. Notably, the lead values were above the limit of 0.02 mg/kg set by the sector legislation and, therefore, the samples were deemed non-compliant. With regard to artisanal ice cream, no positive results emerged for lead and tin, but traces of chromium (26%) and cadmium (10%) were found.

The European Food Safety Authority (EFSA) has also expressed scientific opinions on the risks to human health related to the presence of cadmium (18) and arsenic (19) in foodstuffs, establishing tolerable daily intakes, but not specifically considering milk-based products.

### **General and specific requirements, self-monitoring and notification**

All food industries are subject to the provisions of the Hygiene Package (EC Reg. No. 852/04, 853/04, 854/04, 882/04) and must comply with general and specific requirements and notify the territorial competent authority (CA) their activities (20-23).

The principal minimum requirements, generally applicable across all food businesses, including the ice cream workshops, provide that:

- structures are to be kept clean and maintained in good repair and condition;
- the layout, design, construction, location and size of food premises are to allow for the hygienic performance of all operations and to avoid or minimise airborne contamination;
- adequate numbers of suitably located

washbasins, designated for cleaning hands with hot and cold running water and adequate changing facilities for personnel are to be provided;

- suitable and sufficient means of natural or mechanical ventilation must be guaranteed;

- prevention actions have to be implemented to prevent animals and pests from causing contamination and to avoid accumulation of dirt, contact with toxic materials, shedding of particles into food and formation of condensation or mould growth on surfaces.

To comply with the specific requirements, also applicable within the premises of artisanal ice cream preparation, it is necessary that:

- workplaces are designed and located to allow hygiene practices, avoiding cross-contamination;

- surfaces, walls, doors and floors are kept in good condition, easy to clean and disinfected;

- cleaning and disinfection equipment and equipment for washing food are provided, with hot and cold drinking water supply;

- windows and the other openings are equipped with anti-insect barriers.

Furthermore, a food business operator (FBO) must put in place, implement and maintain one or more permanent procedures, based on the principles of the Hazard Analysis and Critical Control Points (HACCP), providing for:

- identification of any hazard that must be prevented, eliminated or reduced to acceptable levels;

- identification of the critical control points (CCPs) at the steps at which control is essential to prevent or eliminate a hazard to reduce it to acceptable levels;

- establishing critical limits that separate acceptability from unacceptability for the prevention;

- application of effective monitoring procedures and related corrective actions

when monitoring indicates that a CCP is not under control;

- codification of procedures for the regular verification of the effective functioning of the system, together with appropriate documents and records adequate to the nature and size of the food business. In this specific case, for example, the preservation of ice cream at a specific temperature generally represents a CCP to be monitored with a predetermined frequency: if the food has not been stored within the expected temperature range (values between -15°C and -18°C), because of electrical blackout or a malfunction of ice cream display stands, the FBO will have to adopt a specific corrective action (eg. food destruction or food redirect for other uses), to document the non-conformity detected and to implement consequent actions to avoid the event repeating (eg. devices for remote temperature monitoring equipped with alarm system).

To better define the hazards, specific risks and correct hygiene practices of food companies belonging to the artisanal ice cream sector, appropriate manuals of Good Hygiene Practices, validated by the Italian Ministry of Health (MH), can be a useful consultation tool for subsequent drafting of HACCP plans (24, 25).

The FBO must notify the Local Health Authority—the CA—about his proposal to start a business activity previously subjected to a health authorisation issue. This is done in accordance with the backdrop of the general and specific requirements established by the European Community legislation (20-23), for any additional requirements possibly provided by regional or local regulations, and for developing procedures inspired by principles of the HACCP system. In Italy, from 1 July 2017, a single notification model has been used for the purpose of health registration (26-28). This is issued following presentation of a Certified Notification of Commencement of Business (SCIA) and transmitted through the Unique Branches

of Productive Activities managed by the municipal administrations (29, 30). The notification model is arranged in accordance with criteria aimed at allowing unambiguous categorisation of the activities of a food business in the national territory and to use specifically structured information systems to enable extraction of homogeneous data related to similar activities. The new categorisation takes into account the provisions of Master List Reg. (EC) No 852/04, expanded by the working group of Registry and nomenclature of the Ministry of Health, to allow aggregation of food businesses in macroareas (31); specifically, “production of handcrafted ice cream” fall within the macroarea “bakery and pastry products, ice cream and RTE foods.”

### **Results analysis deriving from official control activities**

Official controls on food safety, which must be performed cognizant of properly updated documented procedures, can be conducted through different techniques and methods as required by the EC Reg. n. 882/2004 (23). These include monitoring, surveillance, verification, audit, inspection and sampling for analysis. No control is carried out with random criteria, but rather must take into account a precise orientation of the control policies, agreed upon interinstitutional coordination between the different authorities, and be subject to specific training and updating of health personnel designated to official controls.

In the complex system of official controls on food safety, the CAs are represented by the MH (central CA), the regions and autonomous provinces (regional CA), and the local health units (local CA) (32).

Local CAs, through services directorates responsible for controls (food hygiene and nutrition services and veterinary services) must carry out annual local planning of the

official controls, taking into account the provisions of the Multiannual Control Plan, a national plan aimed at rationalising controls and optimising use of available resources. Local CAs should also consider findings arising from implementation of the specific risk assessment and the risk categorisation of food businesses (33). Therefore, “risk-based” local planning, for aspects related to the frequency and modalities of control management, must take into account the provisions of guidelines for official control (34). The European Community legislator also proactively verifies the effectiveness and appropriateness of official controls, generally conducted on the basis of a top-down principle and useful for, among other aspects, assessing correct application of operating procedures specifically designed for the type of control carried out. Audits on effectiveness can be performed before or after the control, or when it is in progress. This latter type of verification, conducted *in situ*, can be considered as a supervision activity, useful for evaluating the technical skills of control staff. It represents a verification typology the local CA commonly uses to assess compliance of methods and techniques that the health personnel in charge of territorial control adopts.

In the current state system, the official controls are a provision falling within Minimum Health Assistance (LEA), which is within the Collective Prevention and Public Health Actions guaranteed by the Italian National Health Service (NHS) (35). In this regard, the flows conveyed through the new Health Information System (NSIS) assume strategic importance. These data include information assets of the healthcare services contained within the LEAs, and represent a reference tool for measuring quality, efficiency and appropriateness of the NHS. Among the various objectives of the NSIS are: allowing the MH to promptly dispose of data related to official controls carried out by the CA every time a request

comes from the European Commission, the Member States or third countries; fulfilling the information obligation towards the European Community (EFSA) and national bodies; and allowing appropriate assessment and management of health risk through processing of data (36). In addition to the data derived from the official control activities conducted by the CAs (number of checks, type of checks, number of measures, penalties), the results stemming from the official samplings also take on importance. The data deriving from the analytical activity conducted by the official laboratories are conveyed by the same laboratories within the NSIS food system through FOODEX coding, related to the type of matrix taken and parameters searched (37).

Milk-based ice cream falls under a specific codification of “dairy ice cream and similar.” This group includes any type of dairy ice cream and other frozen or semi-frozen products made with dairy or imitation-dairy ingredients. The FOODEX coding, which generally represents an integral part of the official food sampling reports, concerns: the type of specific analyses (chemical, microbiological, dioxins, mycotoxins, additives, aromas, enzymes); codification of the food matrix (or materials and objects intended to come into contact with food); the point of the production chain in which the sample is collected and the country of the production; the sampling strategy (random, targeted, suspicious, following ordinary planning); the type of processing or treatment the food has undergone; and identification data of the FBO in whose company the sampling is carried out. Additional data are required if sampling food matrices deriving from organic circuits or if the analytical investigations are related to the search for residues of plant protection products. After further checks, processing and validations, the MH will relay the corresponding data flows collected through the NSIS system to the EFSA.

It is useful to consider the annual report of the National Integrated Control Plan (PNI) issued by the MH and for the year 2016 (38). This report aggregates data concerning the results of the monitoring and control of food and beverages. As part of the inspection activity, with specific reference to the pre-existing macro-category, “producers and packers selling mainly at retail” (39), which includes all craft activities and ice cream shops, in 2016, 34,389 units were checked, of which 8,124 had infractions. The 2016 PNI highlights how the infringements detected were attributable to issues of general hygiene, personnel, structures and related to the HACCP plan (failure to arrange specific procedures or apply the plan’s provisions). The infractions reported are those whose reporting is provided by the “A Model”, attached to the Ministerial Decree dated 8 October 1998 (39), and that refer to the current hygienic inadequacies, or minor or major non-conformities. In order to reduce non-conformities, more frequent hygiene techniques training could be carried out, more on-site interventions could be performed by the consultants chosen by the FBOs and, within the maintenance plans, high frequency intervention could be set. The recently published PNI report concerning data related to year 2017 states that, given the patchy compilation of the tables, it was not possible to evaluate the data and provide a comparison with the previous years (40).

For completeness of information, it is necessary to consider that, prior to transmission of the SCIA, the FBOs must register their activity in the “business register” at the Chambers of Commerce using ISTAT classifications of the activities that take into account national codifications that refer to European economic activity nomenclature (41). In this context, “ice cream laboratories,” which include activities dedicated to preparation of all types of ice cream and some preparations traditionally associated with ice cream parlours (e.g.,

granita, fruity, milkshakes, yoghurt) particularly represent a sub-category of the widest codification of “ice cream parlours and pastry shops.”

In this scenario in which, until now, there has been a non-homogeneous classification of the same type of activity, the MH, in disseminating the data derived from the PNI of 2015, has already highlighted how some regions have “spread the data in a non-homogeneous way.” For example, the Umbria region has already transmitted data taking into account Master List 852, adopting different criteria from those provided for by the classification pursuant to the Decree of 8 October 1998 (38), which other notifying regions continue to use instead.

### **Control methods: future perspectives**

Taking into account the provisions of the current guidelines in accordance with EC Reg. 882/04 (33), the Local CAs must every 2, 3 or 5 years carry out official controls in food businesses that produce artisanal ice cream, depending on the risk categorisation. To determine the risk category, it is generally necessary to use checklists investigating the establishment’s features (new, recent, fairly recent or outdated ice cream parlour); general maintenance conditions (good, fair, scarce or insufficient); company size (small, medium or large); scope of marketing (local or regional); professionalism in management operations, as well as the health-hygiene training of employees (high, fair, poor or insufficient); the HACCP plan and related application degree; and the company’s historical data that must take into account the previously identified non-conformities or irregularities.

It follows that, if the ice cream shop is located in the lower risk zone, the next official control will be carried out — unless otherwise scheduled or for other reasons — in no sooner than 5 years, which is a reasonably

long time frame that takes into account the workforce and specific attributed risks.

Among the official control methods, as previously stated, the sampling of foods also includes the research for microbiological parameters in ice cream, including *Enterobacteriaceae*, *Listeria monocytogenes*, *Salmonella spp*, *Staphylococci coagulase positive*, staphylococcal enterotoxins and mould. Some of these parameters must be investigated only if the collection is carried out during distribution and not in preparation, or vice versa. Considering these factors, and being mindful that the FBO bears the primary responsibility in matters of food safety, careful implementation of the official controls allows regulation of the artisanal ice cream shop sector, which, like all entrepreneurial activities, earns profit directly proportional to the correct *modus operandi* of the food producer.

The evolution of the sector legislation, which focuses on preventive aspects and the FBO’s acquiring awareness of actions and behaviours for avoiding spread of FBD, has led to adoption of diversified approaches. These depend on the type of official control conducted in accordance with EC Reg. 882/04 (23). The set of methodologies and tools used in Italy for implementing official controls, subsequent verification of effectiveness, and reliable laboratory analytical techniques, represents concrete application of the provisions of harmonised European Community legislation. Furthermore, the general and specific aspects of food safety, together with adoption and implementation of HACCP procedures and ongoing training of food staff, guarantee acceptable levels of consumer protection, even in the context of a complex system of official controls conducted by the health authorities that, in Italy, are considered satisfactory (42), and regarding checks carried out during the import phase (43).

Although a recent detailed analysis of the PNI highlights a trend characterised by a decreased number of official controls and

increased number of non-compliances (44), we have moved from a national situation characterised by documented presence of faecal contamination indicators found in artisanal ice cream in the last century (45) to a current context in which microbiological analysis for food safety criteria (which provide the legal acceptability of a foodstuff placed on the market) show how most RTE products analysed are in compliance according to Commission Regulation (EC) No 2073/2005, even if in some cases there could be an excess of processing hygiene criteria (46), which are generally applicable to samples taken at production stage. This appreciable improvement has also materialised because of development of new production technologies (e.g., temperatures of blast chillers used in ice cream parlours) and acquisition of awareness of the importance of the role played by the operators involved in various aspects of producing and handling foodstuffs. In such a situation, improper behaviours adopted by staff often bring about situations of potential criticality (47, 48), and may also involve the presence of allergenic substances (49), which, because of cross-contamination, can be detected in the finished product (50). Additionally, to assess the consistency and effectiveness of official controls, sector studies have analysed the feedback provided by the FBOs subject to official controls on food safety. Most of the respondents have considered the controls important and are satisfied with the quality, especially when noticeable cooperation between the parties is established. However, uniformity in how the control is conducted is not often perceived and, in 25% of cases, control is considered arbitrary. Therefore, conducting a “cross-audit” between different inspection staff to improve and standardise control techniques is recommended (51).

It will certainly be necessary to promptly reconsider some detailed aspects concerning the procedures for conducting official

controls on food safety. This should be done taking into account the entry into force of the new EU Reg. 625/2017, applicable from 14 December 2019 (52), and aiming to assess compliance with legislation in the areas of food safety, integrity and health, and at all stages of production, processing and distribution. This also includes standards aimed at guaranteeing fair business practices and protecting consumers’ interests and access to information. The new regulation also concerns the manufacture and use of items that will come into contact with food. This, in specific sectors, may represent a non-negligible risk, considering the different types of applicable machinery, equipment and tools (e.g., batch freezers, pasteurisers, containers, spatulas, portioners) and the possibility of migration of potentially problematic contaminants into the food matrix. The Community Rapid Alert System for Food and Feed, through product traceability, allows withdrawal or recall of food from the market in the case of non-compliance (53).

Given the context analysis and the results obtained from the sector data, consumers evidently benefit from safe and controlled RTE food throughout the entire supply chain, from the field to the table, where handcrafted ice cream represents a flagship item for quality and excellence in the local context.

## **Riassunto**

*I controlli ufficiali in materia di sicurezza alimentare nelle gelaterie artigianali: le strategie di Sanità Pubblica e la protezione dei consumatori nel contesto legislativo italiano ed Europeo*

I gelati rappresentano un alimento molto apprezzato il cui consumo nel nostro Paese è elevato soprattutto nel periodo estivo. Per garantire al consumatore un alimento sicuro e conforme sotto l’aspetto igienico-sanitario, il legislatore impone una serie di obblighi per gli operatori del settore alimentare ed una serie di controlli condotti dalle autorità competenti, che comprendono anche campionamenti ufficiali. In questo articolo vengono

richiamati i requisiti generali e specifici applicabili alle imprese alimentari nelle quali avviene la produzione di gelato artigianale, gli aspetti relativi agli obblighi di notifica sanitaria e di predisposizione, attuazione e mantenimento di procedure ispirate ai principi del sistema HACCP, i risultati derivanti dalle più recenti attività di controllo ufficiale condotte in Italia e le prospettive future circa i metodi di controllo che dovranno essere aderenti a quanto previsto dal Reg. UE 625/2017 in applicazione dal 2019.

## References

1. Caggiano G, De Giglio O, Lovero G, et al. Detection of *Listeria monocytogenes* in ready-to-eat foods sampled from a catering service in Apulia, Italy. *Ann Ig* 2015; **27**(3): 590-4.
2. Geist E. When ice cream was poisonous: adulteration, ptomaines, and bacteriology in the United States, 1850–1910. *Bull Hist Med* 2012; **86**(3): 333-60.
3. Seo KH, Valentin-Bon IE, Brackett RE. Detection and enumeration of *Salmonella enteritidis* in homemade ice cream associated with an outbreak: comparison of conventional and real-time PCR methods. *J Food Prot* 2006; **69**(3): 639-43.
4. Zhang G, Ma L, Patel N, et al. Isolation of *Salmonella typhimurium* from outbreak-associated cake mix. *J Food Prot* 2007; **70**(4): 997-1001.
5. De Schrijver K, Buvens G, Possé B, et al. Outbreak of verocytotoxin-producing *E. coli* O145 and O26 infections associated with the consumption of ice cream produced at a farm, Belgium, 2007. *Euro Surveill* 2008; **13**(7): pii=8041. <https://doi.org/10.2807/ese.13.07.08041-en>.
6. Chen YI, Burall LS, Macarasin D, et al. Prevalence and level of *Listeria monocytogenes* in Ice Cream linked to a listeriosis outbreak in the United States. *J Food Prot* 2016; **79**(11): 1828-32.
7. Chen Y, Luo Y, Curry P, et al. Assessing the genome level diversity of *Listeria monocytogenes* from contaminated ice cream and environmental samples linked to a listeriosis outbreak in the United States. *PLoS One* 2017; **12**(2): e0171389.
8. Rietberg K, Lloyd J, Melius B, et al. Outbreak of *Listeria monocytogenes* infections linked to a pasteurized ice cream product served to hospitalized patients. *Epidemiol Infect* 2016; **144**(13): 2728-31.
9. Fetsch A, Contzen M, Hartelt K, et al. *Staphylococcus aureus* food-poisoning outbreak associated with the consumption of ice-cream. *Int J Food Microbiol* 2014; **187**: 1-6.
10. Messelhäusser U1, Kämpf P, Fricker M. Prevalence of emetic *Bacillus cereus* in different ice creams in Bavaria. *J Food Prot* 2010; **73**(2): 395-9.
11. Giaccone V, Colavita G. Principi di microecologia degli alimenti. Milano: Edizioni PVI 2015: 18-24.
12. Kramer J, Cantoni C. Alimenti, microbiologia e igiene. Milano: Tecniche Nuove, 2011: 372.
13. Montagna MT, De Giglio O, Quaranta A, et al. Prevention of foodborne diseases and home safety. *Ann Ig* 2013; **25**(3): 191-200.
14. Napoli C, Marcotrigiano V, Pagliarone CN, et al. Micotoxins in foodstuffs: regulations and maximum tolerated levels. *Ig Sanita Pubbl* 2009; **65**: 607-20.
15. Montagna MT, De Giglio O, Napoli C. Mycotoxins in foodstuffs: Italian regulations in the European framework. *Ann Ig* 2012; **24**: 475-89.
16. Montagna MT, Napoli C, De Giglio O, et al. Occurrence of aflatoxin M(1) in dairy products in southern Italy. *Int J Mol Sci* 2008; **9**(12): 2614-21.
17. Conficoni D, Alberghini L, Bissacco E, et al. Heavy Metal Presence in Two Different Types of Ice Cream: Artisanal Ice Cream (Italian Gelato) and Industrial Ice Cream. *J Food Prot* 2017; **80**(3): 443-6.
18. European Food Safety Authority. Cadmium in food. Scientific opinion of the Panel on Contaminants in the Food Chain. *EFSA Journal* 2009; **980**: 1-139.
19. European Food Safety Authority. Scientific opinion on arsenic in food. EFSA Panel on Contaminants in the Food Chain (CONTAM). *EFSA Journal* 2009; **7**(10): 1351.
20. Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs.
21. Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for on the hygiene of foodstuffs.
22. Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.



23. Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. Official Journal of the European Union, L 165, 30 April 2004.
24. Federazione Italiana Pubblici Esercizi – FIPE. Confcommercio Imprese per l'Italia. Manuale di corretta prassi operativa: ristorazione, gastronomia, gelateria, pasticceria. GU Repubblica Italiana, Serie Generale 6 novembre 2013, n. 135.
25. Associazione delle Industrie del dolce e della pasta italiane – AIDEPI. Guida di corretta prassi igienica e HACCP nella fabbricazione dei prodotti di gelateria. 2009.
26. Legge 7 agosto 2015, n. 124. Deleghe al Governo in materia di riorganizzazione delle amministrazioni pubbliche. GU Repubblica Italiana, Serie Generale 13 agosto 2015, n. 187.
27. Decreto legislativo 25 novembre 2016, n. 222. Individuazione di procedimenti oggetto di autorizzazione, segnalazione certificata di inizio di attività (SCIA), silenzio assenso e comunicazione e di definizione dei regimi amministrativi applicabili a determinate attività e procedimenti, ai sensi dell'articolo 5 della legge 7 agosto 2015, n. 124. GU Repubblica Italiana, Serie Generale 26 novembre 2016, n. 277.
28. Legge 6 agosto 2008, n. 133. Conversione in legge, con modificazioni, del decreto-legge 25 giugno 2008, n. 112, recante disposizioni urgenti per lo sviluppo economico, la semplificazione, la competitività, la stabilizzazione della finanza pubblica e la perequazione tributaria. GU Repubblica Italiana, Serie Generale 21 agosto 2008, n. 195 (Suppl. Ord. n. 196).
29. Legge 30 luglio 2010, n. 122. Conversione in legge, con modificazioni, del decreto-legge 31 maggio 2010, n. 78, recante misure urgenti in materia di stabilizzazione finanziaria e di competitività economica. GU Repubblica Italiana, Serie Generale 30 luglio 2010, n. 176.
30. Decreto del Presidente della Repubblica 7 settembre 2010, n. 160. Regolamento per la semplificazione ed il riordino della disciplina sullo sportello unico per le attività produttive, ai sensi dell'articolo 38, comma 3, del decreto-legge n. 112 del 2008, convertito, con modificazioni, dalla legge n. 133 del 2008. GU Repubblica Italiana, Serie Generale 30 settembre 2010, n. 229.
31. Ministero della Salute. Implementazione dell'anagrafe degli stabilimenti registrati ai sensi del Reg. CE 852/04. Nota DGSAF 9875-P- del 15/05/2013.
32. Decreto Legislativo 6 novembre 2007, n. 193. Attuazione della direttiva 2004/41/CE relativa ai controlli in materia di sicurezza alimentare e applicazione dei regolamenti comunitari nel medesimo settore. GU Repubblica Italiana, Serie Generale 9 novembre 2007, n. 261 (Suppl. Ord. n. 228). Rettifica GU, Serie Generale 6 febbraio 2008, n. 32.
33. Presidenza del Consiglio dei Ministri. Conferenza permanente per i rapporti tra lo Stato, le Regioni e le Province autonome di Trento e Bolzano. Intesa, ai sensi dell'articolo 8, comma 6, della legge 5 giugno 2003, n.131, tra il Governo, le Regioni e le Province autonome di Trento e Bolzano sulla proposta del Ministero della Salute concernente il Piano Nazionale Integrato (PNI) 2018-2018. Rep. Atti n. 177/CSR del 18/12/2014.
34. Presidenza del Consiglio dei Ministri. Conferenza permanente per i rapporti tra lo Stato, le Regioni e le Province autonome di Trento e Bolzano. Intesa, ai sensi dell'articolo 8, comma 6, della legge 5 giugno 2003, n.131, tra il Governo, le Regioni e le Province autonome di Trento e Bolzano sul documento concernente "Linee guida per il controllo ufficiale ai sensi dei Regolamenti (CE) n. 882/2004 e 854/2004". Rep. Atti n. 212/CSR del 10/11/2016.
35. Decreto del presidente del consiglio dei ministri 12 gennaio 2017. Definizione e aggiornamento dei livelli essenziali di assistenza, di cui all'articolo 1, comma 7, del decreto legislativo 30 dicembre 1992, n. 502. GU Repubblica Italiana, Serie Generale 18 marzo 2017, n. 65.
36. Conferenza permanente per i rapporti tra lo stato le regioni e le province autonome di Trento e Bolzano. Accordo quadro tra il Ministro della Sanità, le regioni e le province autonome di Trento e di Bolzano per lo sviluppo del nuovo Sistema informativo sanitario nazionale. Accordo ai sensi dell'art. 4 del decreto legislativo 28 agosto 1997, n. 281. Provvedimento 22 febbraio 2001. GU Repubblica Italiana, Serie Generale 18 aprile 2001, n. 90.
37. Ministero della Salute. Direzione generale per l'igiene e la sicurezza degli alimenti e la nutrizione. Linee guida per la raccolta dei dati di vigilanza e controllo alimenti e bevande mediante il sistema NSIS-Alimenti versione 2017.1 – gennaio 2017.

38. Ministero della Salute. Relazione annuale al PNI 2016. Publication data 30/06/2017.
39. Decreto Ministero della Sanità 8 ottobre 1998. Modificazioni alle appendici 2 e 3 del decreto del Presidente della Repubblica del 14 luglio 1995 contenente l'atto di indirizzo e coordinamento alle regioni e province autonome sui criteri uniformi per l'elaborazione dei programmi di controllo ufficiale degli alimenti e bevande. GU Repubblica Italiana, Serie Generale 24 ottobre 1998, n. 249 (Suppl Ord n. 178).
40. Ministero della Salute. Relazione annuale al PNI 2017. Publication data 06/08/2018.
41. Istituto Nazionale di Statistica (ISTAT). Classificazione delle attività economiche Ateco 2007 derivata dalla Nace Rev. 2. Metodi e Norme n. 40. 2009.
42. European Commission. Health and consumers directorate – General. Food and Veterinary Office. Final report of a specific Audit carried out in Italy from 04 to 12 October 2010 in order to assess the Official Control Systems in place for food hygiene, traceability, labelling, food contact materials and food additives in the context of a general audit. DG(SANCO) 2010-8591.
43. European Commission. Health and consumers directorate – General. Food and Veterinary Office. Final report of a specific Audit carried out in Italy from 07 to 14 September 2010 in order to evaluate import controls on food of plant origin in the context of a general Audit. DG(SANCO) 2010-8586.
44. Panunzio MF, Caporizzi R, Lagravinese D, et al. The official control beyond the official control. How to plan and schedule controls starting from risk assessment along the agro-food supply chain. *Ann Ig* 2015; **27**(2): 497-501.
45. Maifreni M, Civilini M, Domenis C, et al. Microbiological quality of artisanal ice cream. *Zentralbl Hyg Umweltmed* 1993; **194**(5-6): 553-70.
46. Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs.
47. Mullan BA, Wong CL. Hygienic food handling behaviours. An application of the Theory of Planned Behaviour. *Appetite* 2009; **52**(3): 757-61.
48. Finch C, Daniel E. Food safety knowledge and behavior of emergency food relief organization workers: effects of food safety training intervention. *J Environ Health* 2005; **67**(9): 30-4.
49. Regulation (EU) No 1169/2011 of the European parliament and of the council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.
50. Marcotrigiano V, Lanzilotti C, Rondinone D, et al. Food labelling: regulations and public health implications. *Ann Ig* 2018; **30**(3): 220-28.
51. Kettunen K, Lundén J, Lääkkö-Roto T, et al. Towards more consistent and effective food control: learning from the views of food business operators. *Int J Environ Health Res* 2017; **27**(3): 215-29.
52. Regulation (EU) 2017/625 of the European parliament and of the council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation).
53. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. *Official Journal of the European Communities*, L 31, 01 February 2002.