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The Framework of Hygiene Inspections in the Food Sector in Greece-Implementation of HACCP Principles and Penalties in Case of Non-Compliance

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Abstract

The effective environmental health control on the food sector is concerned to be of vital importance in order to avoid the adverse effects on human health of food-borne diseases. EU legislation includes the rules that guarantee the achievement of the goal for hygienic food production. In order to ensure food hygiene and safety, it is necessary to perform audits to all stages of food production chain as a follow-up. This article deals with the food hygiene controls in the food sector in Greece, implementation of HACCP based principles procedures including the proper flexibility rules and penalties in case of non-compliance.

Keywords: Environmental health control; Food hygiene; HACCP implementation; Flexibility; Penalties

Introduction

Worldwide people suffer from diseases caused by food consumption on a daily basis. The so-called food-borne diseases are caused by pathogens and/or toxic chemical substances [1]. The effective food hygiene control is concerned to be of vital importance in order to avoid the adverse effects on human health and the negative economic consequences of food-borne diseases [2]. Bacteria, viruses, and parasites can pose a serious risk to public health if strict food hygiene procedures are not followed. Well-known examples include illnesses linked to salmonella in poultry; listeria in dairy, meat and fishery products, and BSE in cattle [3].

In USA food-borne diseases affect one in three people each year [4]. In European Union, a total of 5.196 food-borne outbreaks, including waterborne outbreaks, were observed for the period of 2011–2012 [5]. Food safety is one of the main priorities of European Union [6].

EU community policy safeguards health along the whole food chain every part of the food production process from

farming to consumption by preventing food contamination and promoting food hygiene, food information, plant health and animal health and welfare [3]. European legislation includes a great number of rules that guarantee the achievement of the goal for safe and hygienic food production. In order to ensure food hygiene and safety, it is necessary to perform audits to all stages of food production chain as a follow-up. It is essential to consider that every element can have a potential impact on food safety from primary production to the final delivery of the food to the consumer [7].

EU Community food law is based on the principle of primary responsibility of food businesses at all stages of production, procession and distribution within the businesses under their control [8]. In this way, business operators ensure that food complies with the requirements of the legislation in areas of relevance to their activities. Food law is complemented by a wider range of more specific legislation on food hygiene [EU Hygiene Package] [9].

Member States implement food legislation, monitor and verify the compliance to legislation of food business operators at all stages, maintain a system of official controls and other activities including public communication on matters relating to food safety and hazard, the inspection of food safety and other monitoring activities covering all stages of the chain [8].

The competent authorities of the Member States monitor and control the overall and effective compliance to food legislation requirements at all stages of the food chain (farmers, food and feed producers, importers, intermediaries, distributors, public and private catering companies, etc.). They also define the system of penalties for breaches of food law [6]. These penalties must be effective, proportionate and dissuasive.

Food Hygiene Inspection in Greece: Brief History

Since the beginnings of the legislative function of the newly established Greek State, care has been taken to address the

healthcare problems of the country [10]. In 1929, the Athens School of Healthcare was established by the government of Eleutherius Venizelos (1928-1932), following a proposal by the Health Organization and the League of Nations for the education of medical doctors and lower healthcare personnel (purge inspectors).

Greek Law n. 4333/1929 provides the issue of health legislation by the Health Ministry and Law n. 6008/1934 on regional healthcare service organizations, including among other, responsibilities for the control and supervision of the production, sale and consumption of food [11].

Compulsory law 2520/1940 on environmental health legislation provides the publication of specific food hygiene control legislation, pursuant to which has been adopted the food hygiene inspection number 2805/1960 legislation, which provides characterizations for food, classifies them according to the impact on human health and provides for administrative measures and penalties [11].

Until the entry into force of the European Food Law the competent authorities for the food hygiene control was the Public Health Directorate of the Ministry of Health [12] and for the food control of animal origin was the veterinary Administration of the Ministry of Agriculture. At the establishment of the Hellenic Food Authority (EFET) the above competencies have been received by the EFET, which together with the Ministry of Rural Development and Food, are the central competent authorities in the food sector in Greece [13].

In accordance with European legislation, the competent authority is the central authority designated as competent for the organization of official controls or any other authority to which this competence has been delegated [6]. Official control is any form of control carried out by the competent authority of each State to verify compliance with food law.

Official controls shall be carried out at any of the stages of production, processing and distribution of food and include inspections in businesses, concerning the use and storage of food, any process, material, substance, activity or action, and transportation related to food. An inspection is the examination of each food item to ensure that these items meet the legal requirements of the legislation [7].

The physical check may include the characteristics of the food itself, the control of the means of transport, packaging, labeling and storage temperature. Physical control also includes sampling for analysis and laboratory testing and any other checks required to verify compliance with food law [6].

Stages of hygiene inspections and competent food hygiene control authorities in Greece

Food hygiene inspection on the stage of primary production: On 29 April 2004, Food Hygiene Regulation (EC) 852/2004 came into force, which determines the general hygiene requirements that food business operators should comply with. The approach of the Food Safety Regulation

throughout the food chain sets the hygiene requirements from the primary production stage [14].

Primary production operations covered by the legislation of the regulation include:

- The transport, storage and handling of primary products at the place of production, provided that this does not substantially alter their nature
- Transport of live animals when judged necessary for the achievement of the objectives of the Regulation
- In the case of plant products, fishery products and wild quarries, transport operations from the place of production to an establishment for the delivery of primary products, the nature of which have not been significantly altered.

As far as possible, food business operators should ensure that primary products are protected from cross-contamination, taking measures that they will subsequently undergo [14]. Food business operators must comply with appropriate Community and National legislation on the control of hazards in the primary production and associated operations, including:

- (a) Measures to control the contamination through air, soil, water, feeds, fertilizers, veterinary products, plant protection products and biocides, and their storage, handling and waste disposal, and
- (b) Measures concerning animal health and welfare and plant health which affect human health, including programs for the monitoring and control of zoonosis and zoonotic agents. Primary goods are products from the soil, livestock, hunting and fishing.

Primary products include, inter alia, products of plant origin (e.g. seeds, fruits, vegetables, herbs, mushrooms), products of animal origin (e.g. eggs, raw milk, honey, fishery products, live bivalves mollusks), products of plant or animal origin collected from nature as mushrooms, berries, snails, etc. [15].

In Greece, the Ministry of Rural Development and Food (MRDF) is the Central Competent Authority for the organization of official feed and food controls in primary production sector and that in the stage of first processing of primary goods, in which the products undergo operations do not constitute processing operations that make the products transmuted [16].

Food hygiene control from the stage of first processing to final supply

Food hygiene control is part of the official food controls carried out by the competent authorities [16]. The organization of official controls is a task of the Central Competent Authority. According to the current National Health Law "Environmental Health Inspection is the detailed examination by the competent public health Services for food and beverages, as well as objects, premises and facilities that are considered to have health interest in order to limit the transmission of infectious agents and to identify any adverse effects on public health" [17].

In Greece, Hellenic Food Authority (known as EFET) is the Central Competent Authority for the organization of official food controls at the stages of the first processing phase in the meat sector and the processing and distribution of all other food in the sector of animal origin food, the competent services health veterinary carry out control slaughterhouses, cutting, standardizing meat, meat preparations, freezing meat, fish, packaging, refrigerationfreezing and crushing of live bivalve mollusks and fishing vessels, snails and frogs, milk and pasteurization, standardization-packaging of eggs and egg products, standardization of honey and refrigeration warehouse chambers, in accordance with current veterinary legislation [18]. In the context of the implementation of National Legislation [16] for businesses like mass catering, retailers, retailer manufacturers, distributors, warehouses, etc., the food hygiene inspection is being conducted at this stage by the Regional Public Health Directorates and has the form of environmental inspection of establishments and the macroscopic level of the food (Figure 1).

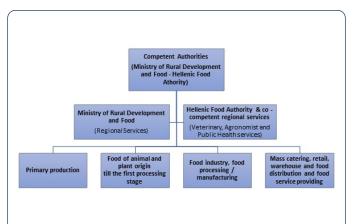


Figure 1 Official control system in the food sector in Greece.

Food Hygiene in the View of Food Business Self-Control

HACCP based procedures

International agencies are acting to the achievement of the goal of better public health protection. One of the principal

Table 1 Greek Guides to good practice approved by EFET.

actions has been the development of HACCP based regulations by Codex Alimentarius Commission [19]. HACCP principles are generally considered and internationally recognized as a useful tool for food business operators to control the hazards that may occur in food [20]. According to the Regulation of the European Parliament (EC) 852/2004 on food hygiene, food business operators should establish and maintain procedures based on the principles of hazard analysis and critical control point [14] In order to assist food business operators to better understand the food hygiene rules and how to implement them in specific sectors, guides at a national level have been issued (Table 1) [21].

HACCP based procedures are mandatory for all food business operators, with the exception of the producers of primary products [19]. The recital of the above-mentioned Regulation, states that the requirements for the implementation of the HACCP principles should take into consideration the principles determined by Codex Alimentarius and should be sufficiently flexible such as to be applicable in all circumstances, including small businesses [14].

In particular, it should be recognized that in certain food businesses it is not possible to identify critical control points, that in some cases good hygiene practices may substitute the monitoring of critical control points, because establishment of critical limits does not imply the need to set a numerical limit in any case, as well as the archiving of documents, must be flexible so as not to overburden the very small businesses [22]. Following the adoption of Regulation (EC) 852/2004, the Directorate General for Public Health and Consumer Protection of the European Commission issued guidelines on the implementation of HACCP principles, especially in small food businesses (small retail outlets, cafes, bars, etc.). Recently, the European Commission published an announcement to the newspaper of European Union (C278/01/2016) concerning the implementation of food safety management systems, that covers HACCP pre-requisite programs and the procedures based on HACCP principles, including facilitation/flexibility for application to certain food businesses [20].

S.NO	National Guides to good practice for food
1.	Guide for mass catering
2.	Guide for bakeries and food businesses that distribute and place on the market bread and bakery products
3.	Guide for water bottling enterprises
4.	Guide for Athens municipal retail market
5.	Guide for establishments of storage and distribution of chilled, frozen foods and dry grocery
6.	Guide for supermarkets

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7.	Guide for Thessaloniki municipal retail market
8.	Guide for food establishments in hotels
9.	Guide for street stalls
10.	Guide for butcheries
11.	Guide for enterprises of products that are maintained on the basis of their heat treatment.
12.	Guide for School Canteens
13.	Good Hygiene Practice Guide for Flour Milling Industries
14.	Guide for the total management of the pest control in food companies
15.	Guide to Good Hygiene Practice for the confectionery production
16.	A generic guide to implementing a system based on HACCP principles in small dairy businesses
17.	Guide to Good Manufacture Practice for Food Contact Materials
18.	Guide to Good Practice for cottage industry establishments

HACCP and prerequisite requirements

The general hygiene legislation defined in Annex 1 and 2 of Regulation (EC) 852/2004 as complemented by the specific requirements of the Annexes to Regulation (EC) 853/2004 for food business operators of animal origin are the so-called prerequisite programs in an international context. In combination with the principles defined in Regulation (EC) 178/2002 (general food safety principles), they constitute the legal basis for the European Food Safety Management System [20]. Overall, the Food Safety Management Systems (FSMS) consist of prevention, preparedness and self-monitoring systems for managing food safety and hygiene in business.

- Good hygiene practices and good manufacturing practices, which are commonly called pre-requisite programs.
- Procedures based on HACCP principles (Establishment of a multidisciplinary group, product description, and designation of intended use, flow diagrams, drafting a list of hazards, identification of critical control points and critical limits, surveillance of corrective actions, verification, and documentation).
- Other management policies and bidirectional information exchange (traceability).

Flexibility during implementation of the procedures based on HACCP principles, according to Hellenic Food Authority

Prerequisite programs on food hygiene requirements: The prerequisite programs provide the basis for the effective implementation of HACCP principles and must be prior to the adoption of the procedures [22]. They include specifications concerning the infrastructure and equipment, raw materials and safe food handling, pest control and sanitation procedures, water quality, compliance with the cooling chain, health and personal hygiene of staff as well as training.

They are separated into basic constructional prerequisites (e.g. building infrastructure, equipment, maintenance, etc.)

and functional requirements [23]. Operational Prerequisites (OPRP's) are the points where certain hazards could be controlled by more comprehensive general core control measures (e.g. personal hygiene, cleaning and disinfection, keeping the cooling chain, heat procession). Allergy control programs and traceability could be considered as pre-requisite programs [20]. Hellenic Food Authority, in order to implement procedures with the appropriate flexibility issued guidelines categorized the food businesses as follows:

Category 1: Businesses in which food is directly supplied to the final consumer or take place only low-risk simple processes at the level of preparation and manufacturing at their disposal. A large population is not considered to be the target. In these businesses, all hazards could be controlled by the application of hygiene requirements, whether accompanied by good practice guides or not. However, when it is necessary for food safety (e.g. keeping the cooling chain) it should be ensured the implementation of the necessary monitoring and verification.

For the businesses of category 1, there is no critical control points accrued. Indicatively, the businesses that are included in category 1 are the following: Grocery stores, dairy-pastry and bakery shops, the sale of frozen products, Coffee/Dried fruits/drink shops, fruit shops, kiosks, canteens, refectory, mobile canteens, nightclubs, cafeterias – cafes-bars, etc.

Category 2: Food businesses in which food is handled in accordance with procedures that are widely known and often included in the standard professional training of the responsible personnel in these sectors (whether at wholesale or retail level). These businesses usually serve a larger population than the previous category. In these businesses, the compliance with the requirements of the legislation is demonstrated by the observation of the guides for good practice approved by the competent authority.

In the absence of an approved guide by the competent authority, businesses must establish and implement their own self-regulatory system while encouraging the development of relevant guides. Butchers, poultry, confectionery, bakeries, pasta makers and sellers, supermarkets, fish shops, refrigerated warehouses, restaurants, mass caterers, etc.

Category 3: Businesses with many common features, a linear production process, and a high-risk hazard, usually serve a larger population than the previous category or and specific population category. In this case, generic sectoral guides could be adopted to implement a HACCP system. (e.g. European guide for bottled water, the national guide for small dairy businesses). Companies that make use of these guides have developed a thorough hazard analysis.

In this case, companies develop and implement a HACCP system, adapting it to the specifics and characteristics of each facility. Producers of food products of animal origin (meat products, dairy products and fish products), vegetable products (cereals, juices, etc.), food production (ready meals/catering, dough and pastry products etc.), hospitals, institutions have been mentioned [24] (Table 2).

Table 2 HACCP based procedures on the flexibility principles according to Hellenic Food Authority.

HACCP based procedures	Prerequisite programmes (PRP's)	Good practice guides/generic HACCP plan	Generic guides/ HACCP-specific plan
Category 1	*	*	
Category 2		*	*
Category 3			*

Uniform penalty system for food sector in Greece

With the adoption of Law 4235/2014, measures, procedures, and sanctions are enacted to implement EU and

national food legislation with a uniform character throughout the food chain [25]. Compliance measures shall be introduced by the competent authorities to businesses or holdings, which do not comply with the requirements of food law aiming to their strict compliance. Actions by competent authorities are provided in the case of non-compliance that constitute or jeopardize public health (immediate compliance measures, referral to justice, administrative penalties). Also, actions are provided in the case of non-compliances that do not constitute or jeopardize public health (conducting re-inspections for the validation of non-compliance corrective actions).

Administrative penalties involve the imposition of administrative fines in cases of non-compliance for primary production and related work, general and specific plant hygiene requirements, non-self-control based on HACCP principles, unsafe food, the operation of food businesses that do not hold the essential license, more specific non-compliances as well as any other non-compliance in the food sector [25].

The competent authorities shall introduce criminal penalties in cases of refusal, obstruction or impediment of the official controls, in the case of businesses that produce, import, store, distribute or supply food to the final consumer, which in the determination of the competent authorities, are harmful to health and in cases of businesses that over a period of two years succumb more than twice to the same non-compliance. Also, criminal penalties shall be introduced for specific nonconformities (e.g. genetically modified food) [25] **(Table 3)**.

Table 3 Administrative penalties in the case of non-compliance in the food hygiene sector.

Law. no 4235/2014 – Administrative penalties in the food sector				
Type of non-compliance	Amount of fine			
Obstruction/denial of official control	1000 – 30.000 €			
Non-compliance with the general requirements of the Regulation (EC) 852/2004 in the field of primary production	300 – 3000 €			
Non-compliance with the general requirements of Regulation (EC) 852/2004 and specific hygiene requirements of Regulation (EC) 853/2004 for food of animal origin	500 – 5000 €			
Non-compliance with HACCP implementation procedures	500 – 5000 €			
Unsafe food	500 – 60000 €			
Business operation without permission or start announcement	1000 – 20.000 €			
Violation of licensing terms/opening announcement	1000 – 20.000 €			
Non-compliance with staff training	500 – 5000 €			
Non-compliance posing a serious risk to public health	61000 – 5000000 €			

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Conclusion

Food hygiene and safety is an important Public Health issue which involves a wide range of diseases [19]. Although governments globally are striving to improve food safety as much as possible, the emergence of food-borne illnesses remains an important issue at a global level (1). Although governments globally are striving to improve food safety as much as possible, the emergence of food-borne illnesses remains an important issue at a global level [26].

Food hygiene aims to take the necessary preventive measures at all stages of the production, procession, handling, and disposal of food, in order to avoid foodborne illnesses for consumers by microorganisms, toxins and chemical substances [27].

The basic principle introduced by Regulation (EC) No 852/2004 concerning the contribution of food business operators to the insurance of good hygiene practices at every stage of the production. Process and as well as legislative implementation of HACCP principles to all food businesses after first processing are important steps in achieving the goal of food hygiene [14]. These procedures can be implemented through guides to good practice, generic guides or HACCPspecific plans, depending on the suitability of each hazard control tool. In particular, in food businesses that do not process food, hazards can be controlled only by applying prerequisites for food hygiene. It is noticed that European food legislation does not contain any requirement for quality certification, based on HACCP principles, followed by businesses for hazard control. Any such action is a private initiative, as Community legislation provides for a single assessment of the competent control authorities in the context of official control [22].

Food hygiene control in Greece has been established at all stages of the food chain, as defined in the multiannual integrated National Control Plans drafted by the Central Competent Authorities (Hellenic Food Authority and Ministry of rural development and food), from the initial stage of their production to final food disposal [28]. The competent authorities must be well coordinated in order to uniformly apply the official controls in the food sector and the uniform sanction system, as well as to avoid inspection duplications [29]. Also, the competent authorities ensure that the personnel which conducts the official controls has the appropriate training in the field of competence and the necessary opportunities for inter scientific cooperation in order to implement the rules of legislation for the achievement of the goal for safe and healthy food [6].

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