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Hazard analysis approaches for certain small retail establishments in view of the application of their food safety management systems

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Abstract

Under current European hygiene legislation, food businesses are obliged to develop and implement food safety management systems (FSMS) including prerequisite programme (PRP) activities and hazard analysis and critical control point principles. This requirement is especially challenging for small food retail establishments, where a lack of expertise and other resources may limit the development and implementation of effective FSMS. In this opinion, a simplified approach to food safety management is developed and presented based on a fundamental understanding of processing stages (flow diagram) and the activities contributing to increased occurrence of the hazards (biological, chemical (including allergens) or physical) that may occur. The need to understand and apply hazard or risk ranking within the hazard analysis is removed and control is achieved using PRP activities as recently described in the European Commission Notice 2016/C278, but with the addition of a PRP activity covering 'product information and customer awareness'. Where required, critical limits, monitoring and record keeping are also included. Examples of the simplified approach are presented for five types of retail establishments: butcher, grocery, bakery, fish and ice cream shop.

Keywords: food safety management, small food retailers, prerequisite programme, hazard analysis and critical control point

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Summary

The European Commission (EC) requested that the European Food Safety Authority (EFSA) provides a scientific opinion on hazard analysis approaches within food safety management systems (FSMS) for small retail establishments, specifically a butcher shop, a grocery, a bakery, a fish shop and an ice cream shop as summarised in the flow diagrams (Section 3.3). Given the difficulties these small retailers have in developing and implementing effective FSMS, including prerequisite programme (PRP) activities and hazard analysis and critical control point (HACCP) principles, the EC specifically requested (1) the formulation of guidelines on how to identify the most relevant biological hazards and, if relevant, chemical (including allergens) and physical hazards at each step in these enterprises; (2) the provision of guidance on methodology for hazard ranking (within HACCP), and the selection of the most appropriate method(s) for each type of retail activity; (3) the provision of guidance on how to select, implement and validate the most efficient approaches to control the hazards identified (considering critical control points (CCP), PRPs, critical limits and monitoring systems); and (4) to use the guidelines developed in (1)–(3) to identify and rank the hazards in each of the five retail establishments and to describe appropriate control activities for the hazards identified (including PRPs, control points and CCPs) and, where appropriate, indicate critical limits and monitoring systems.

The primary methods used to develop this scientific opinion included a review of the relevant scientific and grey literature, including previous EFSA opinions, such as the EFSA BIOHAZ Panel opinion on the development of a risk-ranking toolbox, and expert discussion within the working group. The latter was informed by guidelines and information provided on good hygiene practice (GHP), HACCP and FSMS by EC, Codex Alimentarius, Food and Agriculture Organization of the United Nations (FAO), etc. Based on the literature review, the history and legislative framework of FSMS, with particular focus on HACCP, were initially examined and the constraints to implementing effective FSMS in small retail food businesses identified, including food safety culture/climate, staff expertise and turnover, cost, documentation/record keeping, development of CCPs, verification of the FSMS and supplier control. It quickly became apparent that retail is only one step in the agri-food chain and often the critical control activity, e.g. cooking occurs at a different stage in this chain. Thus, for example, if a butcher shop receives beef carcasses contaminated with *Salmonella* spp., the butcher can undertake activities such as correct chilling, cleaning, storage of raw meat separate from ready-to-eat (RTE)/cooked and other activities to control growth and cross-contamination, thereby preventing an increase in risk to the consumer, but will not be able to apply an intervention that will eliminate the *Salmonella* organisms. Food safety should therefore be practised at all stages in the food chain and food processors should only source raw materials from producers with fully operational and inspected (e.g. using audit certificates) FSMS.

The literature survey was also used to identify and describe biological, chemical and physical hazards. Allergens were considered in addition to other chemical hazards as they are a major and ever increasing issue for food businesses and affect a sensitive subpopulation, whereas other chemical hazards impact the whole population. PRP activities and HACCP principles were then described.

Given the problems for small retail businesses in developing and implementing effective FSMS, the overriding principle in answering the Terms of Reference (TORs) was to develop guidelines for a hazard analysis approach (hazard identification, ranking and control options) that were easy to understand and implement. Thus, when answering the TORs, the current (classical) approach was first described and, based on the same principles, a simpler, more user-friendly, but equally effective hazard analysis methodology/approach was developed ('simplified' approach). In hazard identification, for example, flow diagrams summarising the stages involved in the retail establishment were used in both approaches. However, the new simplified approach did not require a detailed description of the activities at each stage but instead used the flow diagrams to guide the development of a 'Small Food Retailer Food Safety Management System (SFR-FSMS)' presented as a table. The development of tabulations throughout this opinion represents the new simplified approach to food safety management for the target retail establishments. Moreover, it was considered sufficient for the retailer to know whether or not a biological, chemical or physical hazard or allergen might occur at each stage without necessarily describing each specific hazard in detail, but instead realising that a failure to undertake key control activities, such as correct chilled storage or separation of raw from RTE/cooked products, etc. could contribute to increased exposure of the consumer to the hazard.

Classical qualitative, semi-quantitative, and fully quantitative methods for hazard ranking are described. In the classical approach, hazard ranking is used to inform the type of control activities required; hazards ranked as high require a specific intervention at a CCP to control them. In contrast,

it is considered, based on the hazard analysis, that all the hazards that occur in the food retailers targeted in this opinion could be controlled using PRPs. Thus a simplified approach, that does not require hazard ranking, is presented.

The next stage in the development of the 'SFR-FSMS' was to assign PRPs to control the hazards that may occur at each stage, as identified in the flow diagrams. These PRPs were based on those described in the Commission Notice 2016/C 278/01, but with the inclusion of an additional PRP 'product information and customer awareness' (PRP 13). Most PRP activities are based on qualitative and not quantitative parameters and thus are evaluated as being 'acceptable' or 'unacceptable'. Cleaning, for example, may be based on visual inspection. Other PRPs (e.g. cooking or chilling) are based on quantitative parameters (e.g. temperature) and their correct application may be assured by setting critical limits that must be achieved to ensure food safety. In the simplified approach the former PRPs based on qualitative parameters do not require record keeping but for the latter based on quantitative parameters, monitoring is required to ensure critical limits are achieved and records should be kept to demonstrate compliance. In the final section (Section 3.3) the 'simplified approach' was applied to the five target small food retail establishments.

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1. Introduction

1.1. Background and Terms of Reference as provided by the European Commission

'In accordance with Regulation (EC) No 852/2004 on hygiene of foodstuffs, all food business operators (FBO) must comply with general hygiene requirements (Good Hygiene Practices, GHP) laid down in the Annexes I (primary production and associated operations) or II (other FBOs) of the Regulation. In addition, FBO, other than primary producers, must put in place, implement and maintain a permanent procedure or procedures based on the Hazard Analysis and Critical Control Points (HACCP) principles (Article 5).

The GHP, together with good manufacturing practices (GMP) and traceability provisions are considered as prerequisite programmes (PRPs), which, together with the procedures based on the HACCP principles, must result in an integrated food safety management system (FSMS) for each business operator. A risk-based approach covering sector-relevant (micro-)biological, chemical and physical hazards is essential.

The establishment and implementation of such FSMS requires knowledge and resources which is not always available in small food enterprises. The Regulation explicitly refers to the need of flexibility for the application of procedures based on the HACCP principles in case of small businesses. In particular, it is necessary to recognise that in certain food businesses, it is not possible to identify critical control points (CCPs) and that, in some cases, GHP or PRPs in general, can replace the monitoring of CCPs (recital 15). The nature and the size of the food business must be taken into account when verifying compliance with the procedures based on the HACCP principles (Art 5(4)(a)).

Food retailers (e.g. restaurants, butchers, bakeries, caterers, groceries, pubs, etc.) are often small enterprises and therefore flexibility as well as scientific input to apply a risk-based FSMS is very much needed for the retail sector.

The Commission already published in 2005 a Guidance document on the implementation of procedures based on the HACCP principles, and facilitation of HACCP principles in certain food businesses. Recently, the Food and Veterinary Office (FVO) of the Commission Directorate General Health and Food Safety carried out a desk study, fact-finding missions and consultations of Member States and private stakeholders' organisations on a state of play of the implementation of HACCP in the European Union (EU) and areas for improvement. The FVO Report provides several suggestions for improvement, including guidance on hazard analysis and setting of CCPs.

Flexibility on FSMS starts from the principle that each food business needs to comply at least with relevant PRPs and carry out a hazard analysis using a risk-based approach. In such hazard analysis, hazards identified as major risks in the specific food establishment may result in CCPs, while less important hazards may be controlled by the PRPs.

On 9 January 2015, EFSA published an external scientific report on risk ranking for prioritisation of feed and food-related issues (EFSA supporting publication 2015:EN-170). The report reviews methodologies for ranking of risks on the basis of their anticipated human health impact. Based on the characteristics of the individual methods and the method categories, an overarching framework (decision tool) was developed for the selection of the appropriate method(s) for risk ranking. Several of the reviewed methods have been used in hazard analysis carried out within the frame of identifying important hazards for procedures based on the HACCP principles, e.g.

- Risk matrices:
  - Chapter on 'Semi-quantitative risk characterisation' in 'Risk Characterization on microbiological hazards in food', WHO, FAO Microbiological Risk Assessment Series 17 (ISSN 1726-5274)
  - Jacxsens L, Devlieghere F, Uyttendaele, M, 2009. Quality management systems in the food industry. ISBN 978-90-5989-275-0.
- Decision tree:
  - See Diagram 2 of the Annex to the Codex Alimentarius 'General Principles of Food Hygiene' (CAC/RCP 1-1969)

In order to facilitate the implementation of FSMS by certain retailers, typically small enterprises, it is appropriate to develop generic hazard analysis using the most appropriate methodology for risk ranking. Such hazard analysis should include at least hazard identification, hazard assessment (risk

ranking) and the selection of most appropriate control measures. Five specific retail activities, from which a generic flow chart is provided in the appendix, have been selected as examples for providing guidance on hazard analyses for these activities, subject to adaptation to each individual retail establishment.

The Opinion could also provide input for the EU position at the planned revision of the Codex Alimentarius 'General Principles of Food Hygiene' (CAC/RCP 1-1969), including the Annex on HACCP.

Terms of Reference

EFSA is asked to provide a Scientific Opinion on a hazard analysis approach for certain small retail establishments in view of the application of their FSMS. In particular, starting from generic flow diagrams with processing steps for respectively a butcher shop, a grocery, a bakery, a fish shop and an ice cream shop in the appendix to the mandate, EFSA is requested:

1) To formulate guidelines on how to identify the most relevant biological hazards and if relevant chemical, including allergens and physical at each step in the enterprises;
2) To provide guidance on methodology for hazard ranking (within HACCP) and select most appropriate method(s) for each type of the selected retail activities;
3) To provide guidance on how to select, implement and validate the most efficient approaches to control hazards (considering CCP, PRPs, critical limits and monitoring system);
4) Using the guidance developed in TOR 1, 2 and 3, to identify and rank the hazards in each of the five retail establishments and to describe appropriate control activities for the hazards identified including PRPs, control points and CCPs and, where required, indicate critical limits and monitoring systems.

When carrying out the analysis and making recommendations, EFSA should consider that mostly these small retailers are limited with regard to knowledge and resources. EFSA should take into account proportionality to the nature and size of the enterprise as laid down in Regulation (EC) No 852/2004.'

1.2. Interpretation of the Terms of Reference

The Terms of Reference (TORs) have been interpreted to include: (1) the development of generic guidelines to identify the hazards that should be controlled within a FSMS in retail establishments; (2) the development of guidance for hazard ranking in the frame of FSMS; (3) the development of guidelines for the effective control of hazards through PRP and/or HACCP type systems; and (4) the application of these guidelines (1–3, above) to hazard identification, ranking and control in five small retail establishments including butcher, grocery, bakery, fish and ice cream shops.

Food safety hazards include biological, chemical and physical hazards. Although the primary focus of this opinion is on biological hazards, the latter are also covered.

Biological hazards include bacteria, viruses, parasites and fungi. For each of the five retail establishments the biological hazards that may occur at each step in the processes used (as identified in the flow diagram) are identified. Control options are presented, including an explanation as to whether these should be part of the PRP or HACCP plan.

Chemical hazards include contaminants, veterinary drug residues, pesticide residues, cleaning chemical residues, allergens, additives and migration from food contact materials. For the purposes of this opinion the broad categories of chemical hazards are identified but information on specific chemicals/compounds is not provided. Allergens are discussed separately.

Physical hazards include those intrinsically present in the food, for example bones of parts thereof in fish and meat products, etc., and extrinsic physical hazards such as metal, glass, wooden splinters, etc. As with the chemical hazards, the broad categories of physical hazards are presented including the step(s) in the process where they might occur and potential control activities provided.

Retail is defined by Regulation (EC) No 178/2002[1] as 'the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets'. Small/micro businesses are usually independently owned and operated with limited size in terms of staff and turnover. The exact

[1] 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. OJ L 31, 1.2.2002, p. 1–24.

definition varies depending on the country and function of the definition: small businesses are defined by EC Recommendation 2003/361 on the basis of staff head count and turnover or balance sheet total. Thus 'small' businesses are defined as having less than 50 employees, a turnover or balance sheet total of €10 million or less. 'Micro' businesses are defined as having less than 10 employees (but in many cases may have as few as two to three employees), with a turnover or balance sheet total of €2 million or less. A business or firm that is part of a larger group should be included in the head count, turnover or balance sheet data from that company. The small retail establishments (butcher, grocery, bakery, fish and ice cream shops) covered by this opinion are typically 'micro' business.

The nature of the small company can also be defined by the qualities they generally share: they serve local customers; have a limited share of the available market; are owned by one person, or by a small group of people; are managed by their owners who deal with all management issues, usually with little other help; and they are independent businesses not parts of, or owned by, larger companies (Taylor, 2001).

1.3. Additional information

1.3.1. Introduction to the assessment

In order to minimise the risks associated with the consumption of food, every part of the food chain must be controlled to prevent or, where prevention is not possible, to minimise contamination. This control is achieved using FSMS. Each FSMS is company/enterprise-specific and is the result of the implementation of various quality assurance and legal requirements (Jacxsens et al., 2011). A preventive FSMS should provide a proactive rather than a reactive approach to food safety through continuous management system monitoring, verifying and making corrections before a hazard occurs. FSMS implemented in companies include PRPs including good agricultural practices (GAPs), GMPs, and GHPs as well as HACCP based on national and international as well as public and private standards and guidelines (CAC, 2003; Jacxsens et al., 2009).

A FSMS in a retail business should be focused on the continuous identification of hazards and the implementation of specific activities to achieve active managerial control of the risk factors contributing to foodborne illness. However, developing, applying and updating FSMS (PRP and HACCP) at the retail stage of the food chain present several difficulties including a lack of understanding, inconsistencies between guidance documents, lack of resources (especially in small and micro retail enterprises), inconsistency in inspection/audits, a lack of flexibility, inadequate training, difficulties in identifying critical control points (CCP), and issues with monitoring, corrective actions and record keeping. Moreover, even when a PRP and HACCP plan are in place, their successful implementation is reliant on the shared attitudes, values, beliefs, and hygiene behaviours of the staff (Griffith et al., 2010). Thus PRP and HACCP effectiveness is dependent on a strong business food safety culture (Wallace et al., 2012, 2014).

1.3.1.1. History and legislation

The concept of HACCP dates back to the 1960s when the Pillsbury Company developed this system to assure the safety of food for astronauts on the first manned space flights. The current HACCP approach for food businesses was defined by the Codex Alimentarius Commission (CAC), which is responsible for implementing the Joint Food and Agriculture Organization (FAO) of the United Nations and World Health Organization (WHO) Food Standards Programme. On 14 June 1994, HACCP was introduced into European Food Legislation (Council Directive 93/43/EEC on the hygiene of foodstuffs).

Current food safety legislation is designed to ensure the safety of food and protect consumers. Thus, regulations such as EC 178/2002 (the general principles and requirements of food law), EC 852/2005 (hygiene rules),[2] EC 853/2004 (hygiene rules for food of animal origin),[3] EC 854/2004 (official controls on products of animal origin intended for human consumption),[4] EC 882/2004 (official controls performed to ensure the verification of compliance with feed and food law, animal health and animal

[2] Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs. OJ L 139, 30.4.2004, p. 1–54.

[3] Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin. OJ L 139, 30.4.2004, p. 55–205.

[4] 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. OJ L 139, 30.4.2004, p. 206–320.

welfare rules),[5] EC 2073/2005 (microbiological criteria for foodstuffs)[6] and EC 1881/2006 (setting the maximum levels for certain contaminants in foodstuffs),[7] regulate food safety in the food chain from farm to retail. The general approach to food safety is based on HACCP (Article 5 of Regulation (EC) No 852/2004 requires food business operators (FBO) to put in place, implement and maintain a FSMS based on HACCP principles) and good hygiene conditions and practices based on a PRP that covers such areas as cleaning and disinfection/sanitation, maintenance of equipment and buildings, personnel hygiene and training, pest control, plant and equipment, premises and structure, services (e.g. ice, steam, ventilation, water, etc.), storage, distribution and transport, supplier control, waste management and zoning (physical separation of activities to prevent food contamination).

1.3.1.2. The challenges in implementing PRPs and HACCP in small and micro retail establishments

Although the fundamentals of PRPs and HACCP have been defined for many years, implementation of effective FSMS in some food businesses still presents a challenge (Fielding et al., 2005; Sun and Ockerman, 2005; Celaya et al., 2007; Violaris et al., 2008). Even though the inability to control food safety hazards inevitably results in customer complaints, recalls, and foodborne outbreaks (Hedberg et al., 2006; Lianou and Sofos, 2007), partial implementation of FSMS is common with many food businesses lacking a full PRP and HACCP system. Common failings include a lack of PRPs (e.g. Celaya et al., 2007), inadequate CCPs (e.g. Fielding et al., 2005; Hielm et al., 2006; Domenech et al., 2008), insufficient monitoring systems (Walker et al., 2003a), poor compliance with procedures (e.g. Azanza and Zamora-Luna, 2005) and the absence of documentation (Nguyen et al., 2004) (based on Luning et al., 2011). In extreme cases, the PRP and/or HACCP plan may be reduced to a 'tick-the-box' exercise (Wallace et al., 2014).

The development and implementation of effective PRPs and HACCP, as part of the FSMS, is dependent on overcoming a complex mix of managerial, organisational and technical hurdles (Taylor, 2001). Large food companies, with significant financial, technical and managerial resources, are more likely to have operational HACCP plans (Gormley, 1995; Mortlock et al., 1999). In contrast, small and micro companies are less likely to invest in hygiene and food safety. Indeed, one study suggested that for companies with less than 50 staff, HACCP implementation decreased proportionally as the number of employees reduced (Panisello et al., 1999). The major challenges to the effective implementation of FSMS in small or micro food businesses will now be discussed.

Motivation including food safety culture/climate

Motivation is a key factor in the development and implementation of effective FSMS. Jacxsens et al. (2015) identified inspection and audits as major motivational factors in the application of effective FSMS but the type of inspection in the food retail sector (e.g. small retailer shops, bars and restaurants, catering activities) does not provide the same motivation to implement effective food safety systems as that provided by the auditing and inspection large companies face when supplying major retail customers or other large businesses. Furthermore, for most small companies the adoption of a PRP and HACCP requires owner/managers to embark on a completely new system of managing food safety. They have little motivation for such change, largely due to their belief that they already produce safe food. Thus, whilst change in larger companies has been mainly customer driven, this has had little impact on smaller operations, many of whose customers are the end user. The only pressure to apply a PRP and HACCP in small and micro food businesses, including retail establishments, has been from legislation which, given the low rate of prosecution in most European countries, has not proven to be a sufficiently strong motivator for change. It is also evident that the typical owner/manager has yet to be convinced that HACCP is either effective or practical in the context of their businesses.

The food safety culture or climate is also important. Food safety climate is defined as employees' (shared) perception of leadership, communication, commitment, resources and risk awareness concerning food safety and hygiene within their current work organization (De Boeck et al., 2015).

[5] 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. OJ L 165, 30.4.2004, p. 1–141.

[6] Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs. OJ L 338, 22.12.2005, p. 1–26.

[7] Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs. OJ L 364, 20.12.2006, p. 5–24.

Several studies have reported that the food safety culture within the food business is critical if a FSMS is to be effectively implemented (De Boeck et al., 2015).

Staff expertise and turnover

Any knowledge deficit in PRPs and/or HACCP will inevitably result in weaknesses in the developed system. Similarly, the way that FSMS team members interact and share knowledge will impact on food safety. It is therefore important to understand the way that FSMS teams work together to make decisions about food safety and HACCP (Wallace et al., 2012). Thus, effective implementation of PRPs and HACCP requires training. Decisions about PRPs and HACCP application within FSMS teams are dependent on both the collective knowledge of the team members, i.e. the knowledge that each individual member of the team brings, and the holistic team knowledge (Cooke et al., 2000). The requirement for training is reflected in the current legislation as EC 852/2004 states that 'successful implementation of the procedures based on the HACCP principles will require the full cooperation and commitment of food business employees. To this end, employees should undergo training'. However, small businesses often lack the financial and human resources to facilitate training. For example, letting an employee attend a course that requires their absence from work for 3 days may not be feasible (Mossel et al., 1999). Even when FSMS training is provided, high staff turnover inhibits effective implementation (Luning et al., 2011). Low pay may affect motivation and language barriers may also be an issue (Walker et al., 2003b).

Cost

Many food businesses have cited cost, including employing a consultant, staff training, etc. as a major factor inhibiting the effective implementation of FSMS. For small food businesses such as small retail establishments, this may represent a heavy financial burden, a situation compounded if the retail establishment is located outside a major urban centre and some distance from training providers. Moreover, small FBOs often consider food safety as a public good and associated costs should be paid by outside agencies and not borne by them (Taylor, 2001). Thus, they seek financial assistance from the government or other agencies for developing and implementing their PRP and HACCP system.

Documentation and record keeping

The requirement for documentation is an ongoing issue with FSMS, including PRPs and HACCP. For many, especially small and micro businesses, paperwork of any kind is a burden with verbal communication, the usual communication method in the successful management of their businesses (Nguyen et al., 2004). Thus, arguably, FSMS for small retail establishments should focus on ensuring food safety with the minimum documentation. This requires a realistic approach to controlling food safety hazards which focus on 'effective control' in a FSMS and not on a requirement for a minimum number of CCPs that are formally monitored and recorded.

Development of CCPs

Where CCPs are necessary, there is confusion about critical limits, monitoring and validation. This is often compounded by inconsistent and conflicting advice from consultants, the regulatory/inspection function and trade organisations. CCPs should be based on parameters that can be objectively measured (e.g. temperature). As with other aspects of the PRP and HACCP, the development and implementation of CCPs is reliant on the provision of training for FBOs. In addition to providing knowledge, training may also empower and motivate FBOs, giving them control of food safety rather than a sense of being pushed into change by external forces (Taylor, 2001).

Verification of FSMS

Auditing is commonly used to verify that the FSMS is being implemented on a continuous basis. However, owner/managers usually use visual inspection for ongoing confirmation that the system is running according to plan. Thus, documented verification may be perceived to be a pointless, double checking exercise. This is especially true for micro businesses where the owner is the self-employed manager. In addition to such routine auditing, the PRP and HACCP plan also require periodic review to demonstrate that they are meeting their objectives of facilitating the production of safe food. The technical expertise and costs associated with such an activity are outside the scope of most micro businesses.

Assuring the safety of food raw materials and supplier verification

Large companies invest considerable time and resources in assuring the safety of food raw materials from suppliers. This involves demonstrating compliance with detailed specifications, certificates of analysis and on-site audits, all of which pose logistical and technical difficulties for small and micro FBOs. Moreover, many of these FBOs rely on negotiation through telephone/e-mail contact and buying from middlemen who are themselves micro businesses with little formal food safety control. Even companies trying to follow standard vetting procedures can face difficulties if they lack the required knowledge (Taylor, 2001).

1.3.1.3. Food safety control along the entire agri-food chain

Food safety is not the sole responsibility of one participant in the food chain (e.g. the retailer at the end of the chain) but has to be practised at all stages. Farmers and growers need to have FSMS in operation that prevent or, where this is not possible, minimise contamination of the food or raw materials they produce. Food processors should only source raw materials from producers with fully operational and inspected (with audit certificates, etc.) FSMS. They also have a legal obligation to ensure hazards are not introduced or associated risks increased during processing and, if possible, interventions are applied to eliminate any hazards that may be present in the food. Retailers are also legally obliged to ensure the food that they sell is safe and to avoid any practices that may increase the risk associated with a given hazard. This principle of a food chain approach is embedded in EU Regulation 178/2002, general food law. Consumers also have a role in food safety. Although outside current food safety legislation, consumers should ensure the food is stored, handled and prepared in a manner that ensures it is safe for consumption. This stage in the food chain is especially important as it often includes interventions (such as cooking) capable of eliminating pathogenic bacteria that inevitably contaminate a small percentage of foods and survive the processing and retail stages. Retailers should provide the consumer with information to assure food safety during storage, handling and preparation of the product, for example using a leaflet or verbally. Relevant information may originate from national food safety authorities and include optimum storage temperature, shelf life, cooking instructions, etc.

1.3.2. The different types of hazards

This section provides an overview of possible hazards which may be biological, chemical, physical or allergens.

1.3.2.1. Biological hazards

Biological hazards include human pathogenic bacteria, yeasts, moulds, viruses and parasites. A classification based on the ability to grow or develop within a food product is presented in Table 1 (based on EFSA BIOHAZ Panel, 2012).

Table 1: Classification of biological hazards in a food product and examples (non-exhaustive list)

Type of biological hazard	Example (non-exhaustive list)
May grow if the food product is incorrectly stored	*Listeria monocytogenes, Salmonella* spp., pathogenic *Escherichia coli, Yersinia enterocolitica, Clostridium perfringens*
Do not grow in the food product	*Campylobacter jejuni,* viruses, parasites
Growth of hazards in food is required for production of toxins or toxic metabolites	*Clostridium botulinum, Bacillus cereus,* coagulase-positive *Staphylococcus aureus*

In most cases, bacteria and their toxins are normally considered under biological hazards, while the presence of mycotoxins from mould growth is usually referred to as a chemical hazard (Mortimore and Wallace, 2013).

Parasites also represent a biological hazard. Many different parasites may be transmitted to humans through contaminated food and water. The most common foodborne parasites are protozoa such as *Cryptosporidium* spp., *Giardia duodenalis*, *Cyclospora cayetanensis* and *Toxoplasma gondii*; roundworms such as *Trichinella* spp. and *Anisakis* spp.; flukes such as Opisthorchiidae; and tapeworms such as *Diphyllobothrium* spp. and *Taenia* spp.

1.3.2.2. Chemical hazards

Food items sold in small retail shops can contain different types of chemical hazards. These include natural toxins, environmental contaminants, food additives, process contaminants, food contact materials and residues from pesticides, veterinary drugs and disinfectant agents.

Potential chemical hazards occurring in food items in small retail shops can be present due to their occurrence in the raw materials, chemical contamination during storage and/or chemical contamination during processing.

Chemicals may be present in raw materials due to environmental contamination. Examples of such environmental contaminants are metals and organic substances. Raw materials may also contain natural toxins such as mycotoxins, plant toxins and marine biotoxins. In raw materials, residues from veterinary drugs and pesticides could be present from compounds that are prohibited or misused, as well as compounds present in higher concentrations than allowed (Arvanitoyannis and Varzakas, 2008). Also food additives and chemicals released from food contact materials could be present in raw materials or ingredients in concentrations higher than permitted, or due to the use of inappropriate contact materials or prohibited food additives. In addition, disinfectant residues could potentially be present in raw materials delivered to small retail shops.

Chemical contamination of food items during storage in small retails shops may occur from other chemicals present in the shops, e.g. pest control products stored inappropriately (Arvanitoyannis and Varzakas, 2008). In addition, there may be contamination from the outdoor environment, e.g. from traffic or neighbouring industries.

Chemical contamination during processing may also occur due to residual disinfectants used for cleaning knives and machines, formation of new chemicals (e.g. acrylamide during baking at high temperature) or use of contaminated water during ice making (fish shop) or washing/spraying (fish, fruit, vegetables).

Table 2: Classification of chemical hazards based on their origin in the food chain

Type of chemical hazard	Example (non-exhaustive list)
Natural toxins	Mycotoxins, histamine, marine biotoxins, tropane alkaloids
Chemicals used in the food chain	Residues of pesticides, residues of veterinary drugs, residues of disinfectants, too high levels of food additives, chemicals released from food contact materials
Environmental contaminants in raw materials	Metals, dioxins and polychlorinated biphenyls
Process contaminants	Acrylamide, polycyclic aromatic hydrocarbons, chemicals contaminating water
Contamination from non-food chemicals in the shops or from outdoors	Pest control products stored inappropriately. Chemicals from traffic or neighbouring industries

1.3.2.3. Physical hazards

Physical hazards can be defined as hard, sharp foreign objects that are not expected to be present in the food product and may be intrinsic or extrinsic (Table 3). Physical hazards may cause injuries in the mouth, teeth, pharynx and/or throat or can lead to asphyxiation in a worst-case scenario. Intrinsic physical hazards may be 'naturally' present in the food, but are not expected in processed food. Extrinsic physical hazards are usually a contamination from the production environment (Lelieveld et al., 2003). The material and size of these foreign bodies are important factors to consider. According to the US Food and Drug Administration, particles of a hard material with size between 7 and 25 mm are the most hazardous (US FDA, 2005).

Table 3: Classification of physical hazards based on their origin in the food chain

Type of physical hazard	Example (non-exhaustive list)
Intrinsic hazards	Fish and meat bones/bone fragments, fruit stones (olives, peaches, etc.)
Extrinsic hazards	Hard plastic or metal from production and measuring equipment, glass from lighting in production areas, wooden splinters from pallets, etc.

1.3.2.4. Allergens

Food allergies involve immune responses to specific foods (mostly protein compounds) (Perry et al., 2006). Food allergens, which may be classified as declared or undeclared allergens (Table 4), pose a risk to a limited number of sensitive consumers but are harmless to most consumers regardless of the amount ingested. When ingested by sensitive consumers, the symptoms can range from mild to severe and life threatening (Sicherer and Sampson, 2006). Food allergies are estimated to affect about 2% of the adult population in industrialised countries and their prevalence is reported to be higher in infants and children (6–8%) (Poms et al., 2004; Mills et al., 2007). Over 180 allergenic food proteins have been identified to date, with a few major allergens occurring in common foods (e.g. egg, milk, fish, crustaceans, peanut, soybean, wheat and tree nuts) (Mills et al., 2007). However, due to the growing complexity of food formulations and food processing, foods may be unintentionally contaminated via allergen-containing ingredients or cross-contamination. Therefore, allergens are also included as hazards (in addition to biological, chemical and physical hazards). Fourteen food allergens are defined in the FIC 'food information to consumers' legislation, i.e. gluten and gluten-containing cereals, fish, crustaceans, molluscs, milk, eggs, mustard, sesame, celery, lupine, sulphite (from 10 ppm on), soybeans, peanuts and other nuts (Regulation (EU) No 1169/2011).[8]

In cases of declared allergens, their presence is due to their use as a raw material or an ingredient in a given food product. In this case, labelling on pre-packed foods is legally required (Regulation (EC) No 1169/2011) or in the case of non–pre-packed foods, this information should be given to the consumers. The latter communication is possible using notices in the shop, webpage information, etc. (Regulation (EC) No 1169/2011).

The main issue is the presence of undeclared allergens mainly in raw materials or ingredients, and cross-contamination during storage, processing, distribution and between different products (Cucu et al., 2013). Cross-contamination with, for example, an allergenic ingredient can result in the presence of traces of allergens in the food. In most circumstances, the food producer is unaware of the presence of the allergen (Cucu et al., 2013), and preventive 'may contain' labelling is not always applied. An example of this scenario is the cross-contamination of shredded vegetables during industrial washing, when the same water is reused for other commodities (Kerkaert et al., 2012; Salomonsson et al., 2014). In order to prevent cross-contamination several practices can be introduced, such as cleaning activities after production or in between batches containing allergenic compounds, separate and protected storage of raw materials or intermediate products containing allergenic compounds, awareness training of food handlers in washing hands, avoiding the use of utensils for several products, etc. Cross-contamination can also be avoided by applying the principles of separation in time and/or place, i.e. products containing allergenic compounds are produced on dedicated days (time) or in different areas in the food plant.

Table 4: Classification of allergens based on their origin in the food chain

Type of allergens	Examples (non-exhaustive list)
Declared allergens: presence of a known allergen due to application as raw material in a certain food product	• Casein and lactose in milk or dairy products • Nuts such as almonds in cookies with almonds that are labelled on package
Undeclared allergens: presence of unknown allergens in raw materials or presence due to cross-contamination with an allergen ingredient, a recipient, hands of a member of the personnel during processing, storage or distribution	• Presence of traces of casein in a meat preparation due to application of pre-mixture with herbs and spices containing milk powder • Presence of traces of nuts in nut-free cookies due to previous production of cookies with nuts on same processing line

[8] 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 Text with EEA relevance. OJ L 304, 22.11.2011, p. 18–63.

1.3.3. Defining the prerequisite programme and hazard analysis and critical control point programmes/activities

To prevent or minimise contamination and/or cross-contamination of product(s) in food retail businesses, all aspects of the processes used must be properly controlled. This is achieved using a FSMS based on PRPs and HACCP. Food hygiene and safety is the result of the implementation of PRPs and procedures based on the HACCP principles. The PRPs provide the foundation for effective HACCP implementation and should be in place before any HACCP-based procedures are established (Commission Notice 2016/C 278/01).[9] Thus, HACCP is not a stand-alone programme and should be supported by PRPs (GHP and GMP), the pre-requisites for HACCP (Figure 1).

The objective of a FSMS is to control hazards in a food business and in their products. PRPs are defined by FAO/WHO as 'the conditions and measures necessary to ensure the safety and sustainability of food at all stages of the food chain' (FAO/WHO).[10] ISO 22000 uses a similar definition: 'the conditions that must be established throughout the food chain and the activities and practices that must be performed in order to establish and maintain a hygienic environment' (ISO, 2005).[11] PRPs includes GHPs and GMP among other good practices and, although food business specific, may be divided into 13 categories – 12 described in Commission Notice 2016/C 278/01 plus an additional PRP 'product information and customer awareness' proposed in this Opinion, as follows:

PRP 1: Infrastructure (building and equipment);
PRP 2: Cleaning and disinfection;
PRP 3: Pest control: focus on prevention;
PRP 4: Technical maintenance and calibration;
PRP 5: Physical and chemical contamination from production environment;
PRP 6: Allergens;
PRP 7: Waste management;
PRP 8: Water and air control;
PRP 9: Personnel (hygiene, health status);
PRP 10: Raw materials (supplier selection, specifications);
PRP 11: Temperature control of storage environment;
PRP 12: Working methodology;
PRP 13: Product information and customer awareness.

For more details on each of the first 12 PRPs, please see Commission Notice 2016/C 278/01 and Table 18 (Section 3.2.3). The proposed PRP 13 covers 'product information and consumer awareness'. All products at retail level should be accompanied by sufficient information to promote proper handling, storage and preparation by consumers. Moreover, consumers should have sufficient knowledge to enable them to understand the importance of product information, make informed choices appropriate to the individual, and to prevent contamination and growth or survival of foodborne pathogens. This information can be provided to the consumers using product labelling, other accompanying material (e.g. an information leaflet), or any other means including modern communication methods.

The 'product information and consumer awareness' could be based on WHO's 'Five keys for safer food'[12]:

1) *Keep clean:* Clean the food preparation area, chopping boards, utensils and refrigerators. Remember to wash your hands.
2) *Separate raw and cooked/RTE:* Use separate kitchenware and utensils in the storage, preparation and other handling of raw and cooked food. Knives and chopping boards should be washed with hot water and detergent after use. When placed in a refrigerator, foods should be properly packed and raw food should be placed below cooked food.
3) *Cook thoroughly:* Cook food thoroughly, especially meat, poultry, eggs and seafood. Bring foods like soups and stews to boiling to make sure that they have reached 70°C. For meat and poultry, make sure that juices are clear – not pink. Ideally use a thermometer. Reheat cooked food thoroughly – to a boil – or over 60°C.

[9] Commission Notice 2016/C 278/01 on the implementation of food safety management systems covering prerequisite programs (PRPs) and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses. OJ C 278, 30.7.2016, p. 1–32.
[10] http://www.fao.org/3/a-a0799e.pdf
[11] ISO 22000:2005—Food Safety Management Systems— Requirements for Any Organization in the Food Chain, ISO, 2005.
[12] http://www.who.int/foodsafety/consumer/5keys/en/

4) *Keep food at safe temperatures:* Do not leave cooked food at room temperature for more than 2 h. Refrigerate promptly all cooked and perishable foods (preferably below 5°C). Keep cooked food piping hot (more than 60°C) prior to serving.
5) *Use safe water and raw materials:* Use safe water or treat it to make it safe. Only use ice made with pure water. Select fresh and wholesome foods. Wash fruits and vegetables, especially if eaten raw. Peeling foods may reduce risk. Do not use food beyond its expiry date.

Further 'product information and consumer awareness' could include a warning of the potential presence of bones in meat or fish products, a warning of the potential presence of allergens or cross-contamination with allergens, the period of storage of non–pre-packed foods, the recommended storage conditions after opening a package, etc.

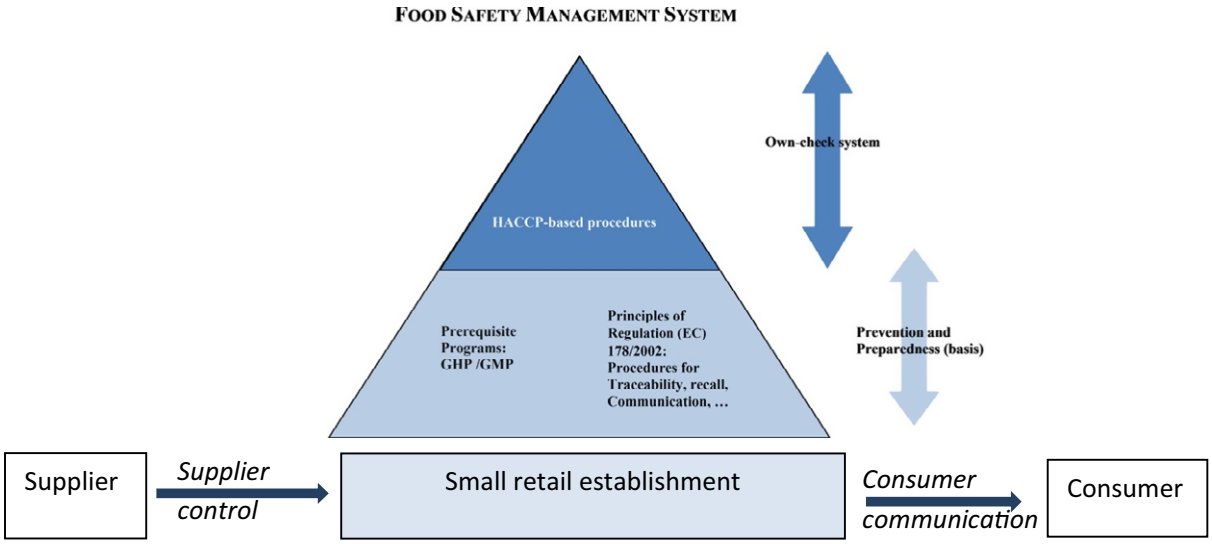


Figure 1: Prerequisite programmes (GHP and GMP) are the prerequisites for HACCP (modified from Commission notice 2016/C 278/01 on the implementation of food safety management systems)

GHP and GMP are described using standard operating procedures (SOP), established methods that are followed routinely for the performance of designated operations. Each SOP should address:

- the purpose and frequency of doing a task;
- who will do the task;
- a description of the procedure to be performed;
- corrective actions to be taken if the task is not properly performed.

A detailed PRP covering all the processes for each of the five target retail establishments covered by this Opinion is beyond the scope of this document and has been covered in the 'Commission Notice on the implementation of food safety management systems covering PRPs and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses'[13]. PRPs will be discussed in greater detail in Section 3.2.

While PRPs may prevent a food safety hazard from occurring, a HACCP system will implement CCPs, capable of controlling a food safety hazard that has been determined to be reasonably likely to occur. PRPs, unlike CCPs, are not hazard specific.

The CAC defines HACCP as 'a system which identifies, evaluates, and controls hazards which are significant for food safety'. There are seven principles or steps that must be applied when developing a HACCP plan as follows:

1) conducting a hazard analysis (including hazard identification of microbiological, chemical and physical hazards);

[13] Commission Notice 2016/C 278/01 on the implementation of food safety management systems covering prerequisite programs (PRPs) and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses. OJ C 278, 30.7.2016, p. 1–32.

2) determining CCPs (A CCP is defined as 'a step at which control can be applied and is essential to prevent or eliminate a hazard or reduce it to an acceptable level'.);
3) setting critical limits at each critical control (measurable and observable parameters);
4) establishing monitoring procedures to assess whether or not the critical limits are adhered by making direct observations and objective measurements of critical limits;
5) establishing corrective action(s) to be taken when a critical limit is breached;
6) establishing verification procedures to ensure the HACCP process is performing as planned by observing activities, calibrating equipment, reviewing records, etc.;
7) establishing documentation procedures (HACCP records including monitoring, corrective action, calibration, records, etc.).

FSMS, PRPs and HACCP in a butcher, a grocery, a bakery, a fish and an ice cream shop will be discussed in more detail in Section 3.2.

2. Data and methodologies

2.1. Literature search

A literature search was carried out as part of a review of existing methodologies for hazard identification and hazard evaluation (hazard ranking).

Search terms for hazard identification:

"hazard identification" and "food": 610 hits
"hazard identification" and "food" and "HACCP": 115 hits
"hazard identification" and "food" and "HACCP" and "method for hazard identification": 34 hits

Search terms for "hazard analysis":

"hazard analysis" and "food": 2,843 hits
"hazard analysis" and "food" and "HACCP": 724 hits
"hazard analysis" and "food" and "HACCP" and "methods for hazard analysis": 175 hits
"hazard analysis" and "food" and "HACCP" and "methods for hazard evaluation": 29 hits
"hazard analysis" and "food" and "decision tree": 19 hits
"hazard analysis" and "food" and "FMEA": 11 hits
"hazard analysis" and "food" and "probability" and "effect": 26 hits

Databases that were consulted included Web of Science Core Collection, BIOSIS Citation Index, CABI: CAB Abstracts, Chinese Science Citation Database, Data Citation Index, FSTA, KCI, Medline, SciElo Citation Index and Zoological record.

No filters were used to subset the time span in the literature search ('all years' was applied).

Those papers were extracted and abstracts screened. Key documents were selected based on working group discussion because a lot of repetition in the methodology hazard identification and hazard evaluation was found. The key methods of hazard identification and hazard evaluation are included in this opinion further.

2.2. EFSA opinions

The methodology for hazard ranking was based on the EFSA BIOHAZ Panel opinion on the development of a risk ranking toolbox (EFSA BIOHAZ Panel, 2015) that reviewed eight risk ranking tools for biological hazards in food.

2.3. Guidelines

Various guidelines on FSMS, including HACCP, were also used as a source of background information. These included information available from the Food and Agriculture Organisation of the World Health Organisation (FAO-WHO), specifically 'Hazard Analysis and Critical Control Point (HACCP) system and guidelines for its application (Annex to CAC/RCP 1-1969, Rev 3 (1997)).[14] Various guidance documents available from the European Commission Food Safety/Food/Biological Safety/Food Hygiene/Guidance website[15] were also used including 'Food Safety Management Systems', 'Prerequisite

[14] http://www.fao.org/docrep/005/Y1579E/y1579e03.htm
[15] http://ec.europa.eu/food/safety/biosafety/food_hygiene/guidance_en

Programs (Good Hygiene Practices)', 'Procedures Based on the HACCP Principles', 'Controls/Auditing' and 'Training/Teaching'.

2.4. Expert discussion

After a review of the scientific literature and available guidelines from international organisations and the previous risk ranking work of EFSA, discussions were held in the EFSA BIOHAZ Panel and its working group. Each step of this opinion was carefully developed with the target end users in mind.

The ultimate objective of this opinion was not to provide a scientific report as the outcome but, in compliance with the requested TORs, tools and methods applicable by small retailers were developed and presented. The use of the literature review was carried out based on the knowledge and expertise of the working group (WG) WG members. In these cases the experts in the WG selected relevant references starting from review papers, books chapters, non–peer-review papers known by the experts themselves until reaching coverage of the subject considered sufficient by the WG.

3. Assessment

3.1. Hazard analysis (TORs 1 and 2)

The current 'classical approach' (hereafter referred to as the 'classical approach') to hazard analysis and hazard ranking, which may still be relevant for large FBOs, is described; however, small retail businesses, such as those covered by this opinion, may have difficulty applying this approach due to a lack of expertise, costs, etc. (see Section 1.3 above). A simplified approach is also presented for the butcher, grocery, bakery, fish and ice cream shops.

There are a series of preliminary steps that must be undertaken when FBOs are developing their FSMS. These include: (1) assembling the FSMS team (often referred to as the HACCP team) that brings together as much available knowledge and expertise in the food business. In medium and large food companies this team should be multidisciplinary, representing all areas of the business such as engineering, production and quality assurance. In small food retail businesses, as described in this mandate, the team will probably include most, if not all, staff with the business owner serving as team coordinator, who has overall responsibility for the FSMS programme and therefore requires the necessary management skills and training in PRP and HACCP principles. The next step is to assemble product data, including a description of each product and the processes involved in preparation. In addition to the processes used, the product description should consider packaging, intended use, shelf life, labelling and distribution. A written list of ingredients for each product should also be prepared. When these have been achieved, the team is ready to prepare flow diagrams as described later in this document.

In the 'classical approach' to HACCP, the first of the seven principles is 'conduct a hazard analysis'. Hazard analysis is defined as 'the process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan' (CAC, 2009). It consists of a systematic evaluation of a specific food and its raw materials or ingredients to determine the risk from biological, chemical (including allergens) and physical hazards and is divided into hazard identification and hazard ranking (or hazard evaluation).

A 'hazard' is defined as 'A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect' (Codex, 2009) and a 'significant hazard' as hazards that are of such a nature that their elimination or reduction to an acceptable level is essential to the production of safe food (ILSI, 1999).

Using the 'classical approach' there are three stages in hazard analysis: (1) describe the processes used; (2) identify the hazards that may occur at each stage; and (3) rank the hazards as 'significant' or 'not significant'.

A similar but 'simplified approach' (this is the new approach developed in this Opinion and is hereafter referred to as the 'simplified approach' or 'Small Food Retailer Food Safety Management System 'SFR-FSMS') may be used for small food retail establishments. In the following sections of this document the 'simplified approach' (SFR-FSMS tables) will be developed and explained. It covers four activities including (1) identify the 'Stages' in the retail establishment; (2) 'Hazard identification' ('B' biological; 'C' chemical, 'P' physical and 'A' allergen); (3) 'Activities contributing to an increased/decreased occurrence of the hazard' and (4) 'Control activities'. For clarity an overview is provided at the outset (Table 5).

Table 5: An overview of the Small Food Retailer Food Safety Management System tables: a 'simplified approach' of hazard analysis for small retail establishments

Stage	Hazard identification[(a)]				Activities contributing to increased/decreased occurrence of the hazard	Control activities
	B	C	P	A		

(a): B: biological; C: chemical; P: physical; A: allergen.

Both (the 'classical' and 'simplified') approaches are now presented.

3.1.1. Step 1: Describe the processes used

In the 'classical approach', flow diagrams summarising the different stages used, from raw material to end product, are represented in a systematic way. Moreover, all incoming streams (raw materials, packaging material, water, air, etc.) and all outgoing streams (intermediate products, rework, returned goods, waste, etc.) are included. Each stage is accompanied by a short description of the activities undertaken. A floor plan is also included as knowledge of the infrastructure and layout is important for effective hygiene management. The floor plan includes facilities, sewage and water systems, as one of its primary functions is to identify potential routes for cross-contamination.

The 'simplified approach' also uses flow diagrams to provide an overview of the different stages/processes used in each of the retail establishments. These are provided for the butcher, grocery, bakery, fish and ice cream shops. In contrast to the 'classical approach', a detailed description of each activity and the floor plan are not required. The flow diagram may then be used to start developing the SFR-FSMS which, when complete, will provide the basis for food safety management in the five target retail establishments (see Table 6).

Table 6: Development of Small Food Retailer Food Safety Management System table with description of processing steps in the small food retail establishment

Stage	Hazard identification[(a)]				Activities contributing to increased/decreased occurrence of the hazard	Control activities
	B	C	P	A		
1 (e.g. receiving)						
2 (e.g. refrigerated storage)						
3 (e.g. cutting)						
etc.						

(a): B: biological; C: chemical; P: physical; A: allergen.

3.1.2. Step 2: Identify the hazards that may occur at each stage

In the 'classical approach' all relevant hazards (biological, chemical, physical) that may occur at each stage need to be identified. Codex 'General Principles on Food Hygiene' (CAC, 2003) states, for example, 'list all potential hazards associated with each step', and 'the HACCP-team should list all of the hazards that may be reasonably expected to occur at each step according to the scope from primary production, processing, manufacture, and distribution until the point of consumption. Hazard identification requires detailed knowledge of food safety and food technology that are often not present in small food retailers (see Section 1.3). For example, the butcher shop would have to know that *Salmonella* and *Campylobacter* may be present on poultry as biological hazards; veterinary drug residues above maximum residue levels (MRL) may be an issue as a chemical hazard and bone fragments may present a physical hazard in filleted products.

In the 'simplified approach' it is proposed that rather than specific hazards being identified, instead the hazards are simply grouped as 'biological', 'chemical', 'physical' or 'allergen'. There is no need for small food retailers to know detailed and hazard-specific information. Therefore, instead of, for

example, 'the presence of *Salmonella*, *Campylobacter* in poultry meat', it would be sufficient to know that 'biological hazards may be present'.

Thus in both the 'classical approach' and 'simplified approach' the hazards that may occur at each stage are identified. While FBOs, especially small food retailers, may find this challenging, information is available in the scientific and grey literature, surveillance reports and from the national food safety authorities in the various Member States. Moreover, while large FBOs should include details of which biological, chemical or physical hazards may occur at each stage, it is sufficient for small retailers to know the most relevant 'groups of hazards' and to be aware that these groups of hazards may occur at a particular stage. For example, it is sufficient for the butcher shop to know that a biological hazard may occur during receiving raw materials. This stage in the development of the SFR-FSMS is presented in Table 7. As previously described, allergens, which are an increasing issue for food businesses, have been separated from chemical hazards as they are a major issue requiring specific control activities.

Table 7: Development of Small Food Retailer Food Safety Management System table illustrating the 'simplified approach' where 'hazard grouping' is used instead of a detailed description of the hazards

Stage	Hazard identification[(a)]				Activities contributing to increased/decreased occurrence of the hazard	Control activities
	B	C	P	A		
1	**Y/N**	**Y/N**	**Y/N**	**Y/N**		
2	**Y/N**	**Y/N**	**Y/N**	**Y/N**		
3	**Y/N**	**Y/N**	**Y/N**	**Y/N**		
Etc.						

(a): B: biological; C: chemical; P: physical; A: allergen; Y: yes; N: no.

As part of step 2 (identifying the hazards that may occur at each stage) the 'simplified approach' also focuses on the activities (or lack thereof) that may contribute to the increased or decreased occurrence of a hazard. For example, a failure to chill properly will result in an increase in the concentration of pathogenic bacteria such as *Salmonella* spp. on meat. There are various tools available to identify the activities (or lack thereof) that will adversely affect food safety including using a 'structured questionnaire' (as illustrated in Table 8) and a fish bone or Ishikawa diagram (as illustrated in Figure 2).

Table 8: A structured questionnaire that can be applied at each step in the production process (follow the flow chart) to identify activities contributing to increased/decreased occurrence of the hazard (based on Jacxsens et al., 2009)

Question: can this stage contribute to the following hazards?	
Biological	
B1:	Poor microbiological quality of the incoming raw material (presence of pathogens)
B2:	Growth of microorganisms that are present (with or without the possibility of production of toxins)
B3:	Insufficient removal/killing of microorganisms
B4:	Contamination from the environment (e.g. air), personnel, equipment, etc.
Chemical	
C1:	Presence of (or too high quantities) chemical hazards in incoming raw materials
C2:	Insufficient removal of chemical hazards
C3:	Contamination with chemical hazards
C4:	Chemical reactions occurring during production process and leading to process contaminants
Physical	
P1:	Presence of foreign objects (intrinsic or extrinsic) in incoming raw materials
P2:	Insufficient removal of foreign objects (intrinsic or extrinsic)
P3:	Contamination with extrinsic foreign objects via environment, personnel, equipment, etc.

Question: can this stage contribute to the following hazards?	
Allergens	
A1:	Presence of allergens in raw materials or final products
A2:	Cross-contamination by allergens during storage/production

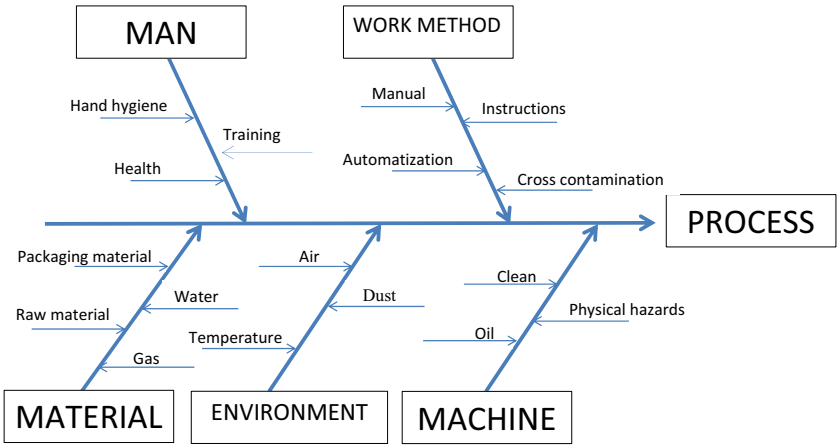


Figure 2: Example of fish bone or Ishikawa diagram to identify activities contributing to increased occurrence of the hazards along a production process

By applying the structured questionnaire (Table 8) and the Ishikawa diagram (Figure 2), factors contributing to an increased probability of occurrence of a hazard can be identified for each step in the production process. These have been added to the SFR-FSMS as shown in Table 9.

Table 9: Development of Small Food Retailer Food Safety Management System table with description of the stages, hazard identification and activities contributing to increased occurrence of the hazard at that stage

Stage	Hazard identification[(a)]				Activities contributing to increased/decreased occurrence of the hazard	Control activities
	B	C	P	A		
1	Y	–	–	–	**Growth due to a failure to chill properly Cross-contamination due to a failure to separate raw from cooked/ready-to-eat products**	
2	Y/N	Y/N	Y/N	Y/N	. . .	
3	Y/N	Y/N	Y/N	Y/N	. . .	
Etc.						

(a): B: biological; C: chemical; P: physical; A: allergen; Y: yes; N: no.

3.1.3. Step 3: Rank the hazards identified

In the 'classical approach', once the hazards have been identified, the significance of each in terms of the production of safe food should be assessed. According to Codex 'general principles on food hygiene': 'The HACCP team should conduct a hazard analysis to identify for the HACCP-plan, which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food. In conducting the hazard analysis, wherever possible the following should be considered' (CAC, 2003):

- the likely occurrence of hazards and severity of their adverse health effects;
- the qualitative and/or quantitative evaluation of the presence of hazards;
- survival or multiplication of micro-organisms of concern;
- production or persistence in foods of toxins, chemicals or physical agents;
- conditions leading to the above.

There are different methods used in the 'classical approach' for hazard ranking including qualitative, semi-quantitative and quantitative methods, an example of each of which will now be presented.

3.1.3.1. Hazard ranking in the 'classical approach' to food safety management

A qualitative method for hazard ranking in the 'classical approach' to food safety management

An example of a qualitative method for ranking the microbiological hazards is shown in Table 10. In this example the hazards have been identified and their 'likelihood of occurrence' and 'severity' determined from the scientific and grey literature. Most national food safety authorities and/or professional associations also provide this information.

Table 10: Ranking the biological hazards associated with beef products in a butcher shop based on the 'likelihood of occurrence' and 'severity' of illness in humans.

Hazard	Likelihood of occurrence	Severity	Overall ranking
Hazard 1	Low	Low	Low
Hazard 2	Low	High	Moderate
Hazard 3	High	Low	Moderate
Hazard 4	High	High	High

A semi-quantitative method for hazard ranking in the 'classical approach' to food safety management

Hazard evaluation may also use semi-quantitative methods, an example of which will now be described based on the attribution of 'probability of occurrence' and 'adverse effect' (Jacxsens et al., 2009). In this example the 'probability of occurrence' is assigned a value (1–4) as follows:

- 1 (very low): Theoretical chance – the hazard never occurred before OR there is a next step in the production process that will eliminate or reduce the hazard to an acceptable level OR the control measure(s) for the hazard are designed so that when the control measure is failing, no production is possible OR contamination is very limited.
- 2 (low): The probability that due to failing or absence of the general measures (GMP, PRP) the hazard that will occur in the end product is very limited OR the control measures for the hazard are general (GMP, PRP) and these are well implemented in practice.
- 3 (real): Failing or lack of the specific control measure does not result in the systematic presence of the hazard in the end product but the hazard can be present in a certain percentage of the end product in the associated batch.
- 4 (high): Failing or lack of the specific control measure will result in a systematic error and there is thus a high probability that the hazard is present in all end products of the associated batch.

The 'adverse effect' is also assigned a value (1–4) as follows:

- 1 (limited): There is no food hazard for the consumer (nature of hazard, e.g. paper, soft plastic, large size foreign materials) OR the hazard can never reach a dangerous concentration (e.g. colorants).
- 2 (moderate): No serious injuries and/or symptoms or only when exposed to an extremely high concentration during a long period of time OR a very short-term and mild illness.
- 3 (serious): Illness with short-term or long-term symptoms that may, but only rarely, result in mortality OR the hazard has a long-term effect.
- 4 (very serious): The consumer group belongs to a high-risk category and the hazard can result in mortality OR the hazard may cause serious illness that may result in mortality OR the hazard may cause permanent injury.

Each hazard can then be ranked as suggested in Table 11.

Hazards with a ranking of 1 to 2 are considered to be 'low' risk, those with a ranking of 3 to 4 to be 'moderate' risk and those ranking 5–7 to be 'high risk'.

Table 11: Semi-quantitative hazard ranking from 1 to 7 with ranking based on crossing lines of attribution of 'probability of occurrence' and 'adverse health effect' (based on Jacxsens et al., 2009)

Probability of occurrence					
	4	4	5	6	7
	3	3	4	5	6
	2	2	3	4	5
	1	1	2	3	4
		1	**2**	**3**	**4**
			Adverse health effect		

A quantitative method for hazard ranking in the 'classical approach' to food safety management

Both qualitative and semi-quantitative approaches use a simplified model to assess the occurrence of a hazard and its severity. The drawback of qualitative and quantitative approaches is related to the way in which occurrence and severity are combined. Quantitative methods for hazard ranking, or comparative risk assessment methods, are based on general principles of food safety risk assessment. They are generally designed to estimate risks associated with food–hazard pairs and to integrate data on the hazard and on the food supply system (from primary production, through manufacturing and processing, to retail distribution), on consumer food handling, on dose–response and on health effects, using inherent mathematical logic/equations and Monte Carlo simulations to account for variability and uncertainty. They also enable the evaluation of interventions applied throughout the food supply; therefore, quantitative methods can help find the processing steps at which hazards may be reduced for a more comprehensive, multistep approach to the control of hazard.

Quantitative methods, similar to the other previously presented methods, assess 'likelihood of occurrence' combined with 'severity'. The 'likelihood of occurrence' corresponds to the probability of observing an adverse effect specific to a particular hazard and associated with the consumption of a particular food product. To enable the comparisons of risks posed by different food–hazard pairs, disability-adjusted life years (DALYs) are generally used as a common metric (e.g. Murray et al., 2015). DALYs are indicators of the time lived with a disability and the time lost because of premature mortality associated with the adverse effect.

FDA-iRisk has been identified as the most advanced quantitative risk ranking tool (EFSA BIOHAZ Panel, 2015). In addition to its capacity to include different processing steps that impact the prevalence and the level of contamination, FDA-iRisk assesses risks quantitatively for both chemical and microbiological hazards, and subsequently facilitates risk ranking, including risks from different origins.

3.1.3.2. The 'simplified approach' to food safety management and hazard ranking

In the 'classical approach' to food safety management, hazard ranking is used to decide the control activities that should be applied. Thus, using the hazard ranking approaches (qualitative, semi-quantitative or quantitative) described above, the hazard associated with a given product or process step will be classified as 'low', 'moderate' or 'high' risk. This ranking is then used to determine the most appropriate 'control' actions (PRPs or CCPs).

Hazard analysis for the activities described for the five target small food retail establishments in this opinion suggested that the hazards that might occur could be most efficiently controlled using PRPs. Thus in the 'simplified approach' developed for these retailers, hazard ranking is not required.

3.2. Control measures (TOR3)

Control measures have been defined by the Codex as 'any action or activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level' (CAC, 2009). Thus, the objective of control measures is to keep product properties, production processes and human factors between certain acceptable tolerances of safety (Luning et al., 2009). Control measures also include further definitions of critical limits and tolerances, monitoring, corrective actions and record keeping.

3.2.1. Control measures in the 'classical approach'

In the 'classical approach' to food safety management, it is possible to distinguish between three different types of control measures (Table 12) (Jacxsens et al., 2009). The decision regarding which type of control measure is the most appropriate to control hazards at a certain step in the production process depends on the hazard ranking, as explained above (Section 3.1).

Table 12: Differentiation of the control measures in the 'classical approach' to food safety management (based on Jacxsens et al., 2009)

Type of control measure	Nature	Example
Once-only measures that are used to eliminate the hazard	The hazard is eliminated and the correct implementation of measures needs to be evaluated periodically	Presence of undeclared allergens in raw materials → selection of other raw materials where no undeclared allergens are present
Measures that are used to prevent the occurrence of the hazard ('preventive measures')	Include most of the general measures that are not process or product-specific. These usually correspond to general PRP measures	Establish cleaning between production batches to avoid cross-contamination with allergenic compounds
Measures to control the hazard by removing, eliminating or reducing to an acceptable level	Measures targeting the process and/or product. The hazards that can lead to a high risk are kept under control. These usually correspond to CCPs within the HACCP system	Include a pasteurisation process to eliminate specific pathogenic microorganisms

Once a hazard has been identified it is necessary to determine how it can be most effectively controlled. PRPs are the GHPs necessary to maintain a hygienic environment and are therefore the basic conditions required to produce safe food. Depending on the complexity and risk associated with the hazards and/or activities of the food business, PRPs may be all that is required. Thus if the hazards and/or activities are ranked as 'low risk', the FSMS may comprise PRPs only. In contrast, if the hazards/activities are ranked as 'high risk', HACCP-based interventions (CCPs) may be required.

A further distinction between PRP and HACCP activities is based on the specific target of these activities. In general, PRP activities target the environment in which the food is stored and prepared and not dedicated to controlling a specific hazard (e.g. microbiological contamination from the environment), while HACCP actions are targeted at the process and/or product and are designed to control a specific hazard (e.g. *L. monocytogenes*). The latter are usually focused on modifying the intrinsic characteristics of the food product (changes in the pH and a_w as well as by the use of additives such as antimicrobial agents) or the extrinsic characteristics, such as the temperature and/or the gas composition of the packages (Devlieghere et al., 2016).

Control measures focused on hazards have three main objectives including: (1) elimination or reduction of the hazard; (2) prevention of cross-contamination; and (3) in the case of biological hazards, prevention of growth and toxin production. Control measures aiming at inactivating or eliminating pathogens, for example, have been defined as intervention processes and include physical treatments (e.g. heating, freezing, drying, radiation), chemical processes (e.g. antimicrobial and disinfectant agents) and biological interventions (e.g. bacteriocins, polyphenols) (Devlieghere et al., 2016). Moreover, intervention CCPs are based on quantitative parameters, such as temperature, that can be directly measured, monitored and critical limits established (Devlieghere et al., 2016). The decision tree (Figure 3) has long been applied as the primary method for CCP attribution in HACCP.

Analysis of the hazards and activities of the target retail establishments (as summarised in the flow diagrams, Section 3.3) suggests that PRP activities are sufficient and the application of HACCP, including CCPs, is either not possible or would not enhance food safety. For example, in the butcher shop there is no practical intervention that would consistently achieve a specific reduction in bacterial pathogens on products to be sold as raw. However, PRP activities such as correct chilling, prevention of cross-contamination by separation of raw from cooked and effective cleaning and disinfection, etc. will minimise the risk associated with these hazards. Thus, as previously stated, in the proposed 'simplified approach' for small food retailers, hazard ranking can be omitted.

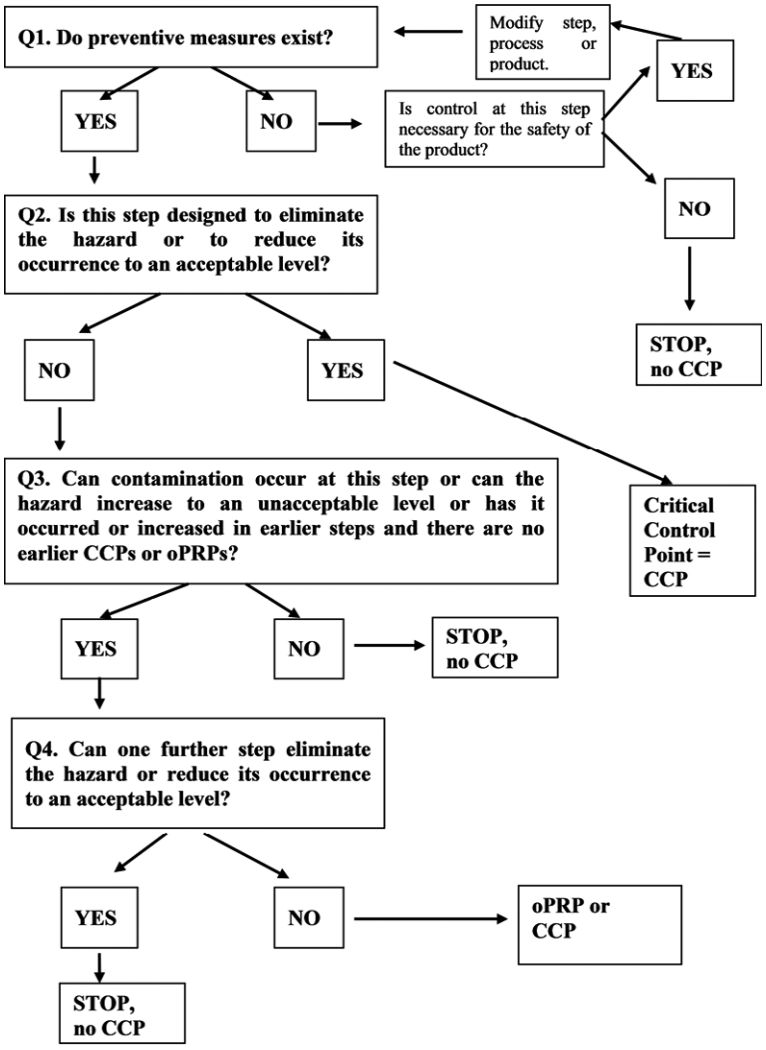


Figure 3: Example of a decision tree to identify critical control points (CCPs) (Commission notice on the implementation of food safety management systems (2016/C 278/01))

3.2.2. Control measures in the 'simplified approach'

In this section, biological hazards related to processes in small retail establishments and potential control options (PRPs) that will form part of the new 'simplified approach' to food safety management are presented in Table 13. Control activities for chemical and physical hazards are presented in Tables 14 and 15. Control activities for allergens are shown in Table 16.

Table 13: Potential control measures for biological hazards using prerequisite programmes (PRPs) in the Small Food Retailer Food Safety Management System

Stage	Activities contributing to increased/ decreased occurrence of the hazard	Control activities
Receiving of raw materials	Biological hazards in the raw material	PRP 10: Raw materials (supplier selection, specifications, etc.)
Storage of raw materials (cold storage)	Microbial growth: insufficiently low temperature and time control will result in microbial growth	PRP 4: Technical maintenance and calibration PRP 11: Temperature control of storage environment PRP 12: Working methodology
	Contamination with biological hazards during storage (includes cross-contamination	PRP 3: Pest control: focus on prevention PRP 12: Working methodology
Processing	Contamination via manual handling and personnel	PRP 9: Personnel (hygiene, health status)
	Contamination between raw and cooked/RTE products (includes cross-contamination	PRP 2: Cleaning and disinfection PRP 12: Working methodology
	Microbial growth: insufficient temperature and time control will result in microbial growth	PRP 11: Temperature control of storage environment PRP 12: Working methodology
Packaging	Contamination between raw and cooked/RTE products (includes cross-contamination)	PRP 2: Cleaning and disinfection PRP 12: Working methodology
	Microbial growth: insufficient temperature control will result in microbial growth	PRP 11: Temperature control of storage environment PRP 12: Working methodology
Selling	Contamination to food products via handling and personnel, e.g. due to money exchange (includes cross-contamination)	PRP 2: Cleaning and disinfection PRP 9: Personnel (hygiene, health status) PRP 12: Working methodology PRP 13: Product information and consumer awareness
Food waste disposal	Food stored beyond shelf life Improper collection and storage of waste	PRP 7: Waste management

Table 14: Potential control measures for chemical hazards using prerequisite programmes (PRPs) in the Small Food Retailer Food Safety Management System

Stage	Activities contributing to increased/decreased occurrence of the hazard	Control activities
Receiving of raw materials	Prohibited chemicals or chemicals at concentrations above the maximum level (ML)/maximum residue limit (MRL)/indicative value/specific migration limit (SML)/reference point for action (RPA) in the raw material/ingredient	PRP 10: Raw materials (supplier selection, specifications)
Storage of raw materials	Contamination from disinfectants and other non-food grade chemicals used in the shop, e.g. pest control products stored inappropriately	PRP 5: Physical and chemical contamination from production environment
	Other contamination with chemical hazards from outdoors, e.g. from traffic or neighbouring industries	PRP 5: Physical and chemical contamination from production environment PRP 8: Water and air control

Stage	Activities contributing to increased/decreased occurrence of the hazard	Control activities
Processing	Chemical contamination from residues of disinfectants used for cleaning knives and machines	PRP 2: Cleaning and disinfection
	Chemicals formed during processing, e.g. at high temperature	PRP 11: Temperature control of storage environment PRP 12: Working methodology
	Other contamination with chemical hazards	PRP 5: Physical and chemical contamination from production environment PRP 8: Water and air control
	Chemical contamination of water used in processing (e.g. ice making, washing and spraying)	PRP 8: Water and air control
Packaging	Chemicals released from food contact materials	PRP 10: Raw materials (supplier selection, specifications)
	Other contamination with chemical hazards	PRP 5: Physical and chemical contamination from production environment PRP 8: Water and air control
Food waste disposal	Food stored beyond shelf life allowing for mould growth and mycotoxin production	PRP 7: Waste management

Table 15: Potential control measures for physical hazards using prerequisite programmes (PRPs) in the Small Food Retailer Food Safety Management System

Stage	Activities contributing to increased/decreased occurrence of the hazard	Control activities
Receiving of raw materials	Damaged pre-packed raw materials	PRP 12: Working methodology
	Physical hazards in bulk raw materials (such as fruits and vegetables, fish covered with ice)	PRP 12: Working methodology
Storage of raw materials	Pests contaminating the raw materials	PRP 3: Pest control: focus on prevention
	Contamination from the storage area of the stored raw materials	PRP 4: Technical maintenance and calibration PRP 12: Working methodology
Processing	Contamination via manual handling and personnel intervention	PRP 9: Personnel (hygiene, health status)
	Contamination via production equipment, knives, etc.	PRP 1: Infrastructure (building and equipment) PRP 4: Technical maintenance and calibration
	Remains of intrinsic physical hazards during production	PRP 12: Working methodology
Packaging	Contamination via packaging materials	PRP 12: Working methodology

Both declared and undeclared allergens must be addressed. Control options for allergens will be on the basis of PRP 6 ('Allergens') in order to prevent cross-contamination between batches, or PRP 10 (Raw materials (supplier selection, specifications)). In small food retail establishments, it will also be important to be able to provide accurate consumer information. As requested in the frame of Food Information to Consumers (FIC) Regulation (EC) No 1169/2011, consumers must be informed of the presence of allergens. This also applies to non–pre-packed foods. Additionally 'may contain' labelling or information may be used if there is potential for cross-contamination.

When a small food retailer states 'free of…' or 'contains low', then additional control measures are required to justify these statements. For example, in EC Regulation 828/2014, limits on gluten are given for statements of 'gluten free' and 'very low gluten'. The additional control activities required include: strict contracts with suppliers and systematic control of the presence of allergens in raw materials, backed up by accredited testing; storage in separated rooms with restrictions on entrance; complete separation from allergen containing food production, e.g. via another building, other equipment, other staff, etc. or a focus on 'allergen free' foods. Separation in time is also possible. Final

product verification is necessary with appropriate analytical methods. Potential control options for allergens in small food retailers are presented in Table 16.

Table 16: Potential control measures for allergens using prerequisite programmes (PRPs) in the Small Food Retailer Food Safety Management System

Stage	Activities contributing to increased/decreased occurrence of the hazard	Control activities
Receiving of processed raw materials	Presence of undeclared allergens in purchased products	PRP 10: Raw materials (supplier selection, specifications)
Storage of raw materials	Contamination due to open packages (e.g. powdered materials) and/or other cross-contamination	PRP 12: Working methodology PRP 6: Allergens
Processing	Contamination via manual handling and personnel intervention (cross-contamination)	PRP 9: Personnel (hygiene)
	Contamination via production equipment, knives, etc. (cross-contamination)	PRP 2: Cleaning and disinfection
Packaging	Contamination during packaging (cross-contamination from other products that may also be packaged in the same area using the same equipment, packaging materials, etc.)	PRP 6: Allergens
Selling	Lack of or incomplete information related to potential cross-contamination or presence of allergens in products, both for declared and undeclared allergens	PRP 6: Allergens PRP 13: Product information and consumer awareness

Once the control option(s) have been determined, these are added to the SFR-FSMS as illustrated in Table 17. This 'simplified approach' has been applied to the five target small retail establishments in the next section.

In this section, the 'simplified approach' to food safety management in the five target small food retail establishments is applied. The flow diagrams are based on those provided by the European Commission, for the butcher, grocery, bakery, fish and ice cream shops and are provided in Figures 4–8, respectively. They do not cover all of the broad range of activities and products that may be encountered in these retail establishments (e.g. some butcher shop also sell fruit and vegetables) but the 'simplified approach' is sufficiently flexible to allow the FSMS developed to be tailored to the specific activities and products within a given shop. These flow diagrams are then used to identify the 'stages' that inform the first column of the SFR-FSMS tables. Information on the 'hazards', 'activity contributing to increased/decreased occurrence of the hazard' and 'control activity' are also included to complete the SFR-FSMS tables for the butcher shop (Table 19), fish shop (Table 20), grocery shop (Table 21), ice cream shop (Table 22) and bakery shop (Table 23).

Waste management, which may become a food safety issue, is not usually included in flow diagrams used for the development of FSMS and has not been included in the flow diagrams provided in this opinion. Waste management control activities are described in PRP 7 of Commission Notice 2016/C 278/01.

Table 17: Development of Small Food Retailer Food Safety Management System table with the control options added

Stage	Hazard identification				Activities contributing to increased/decreased occurrence of the hazard	Control activities
	B	C	P	A		
1	Y/N	Y/N	Y/N	Y/N	Growth of micro-organism due to failure to chill properly Cross-contamination due to failure to separate raw from cooked/ready-to-eat products	**PRP 11: Temperature control** **PRP 12: Working methodology**
2	Y/N	Y/N	Y/N	Y/N		
3	Y/N	Y/N	Y/N	Y/N		
Etc.						

(a): B: biological; C: chemical; P: physical; A: allergen; Y: yes; N: no.

3.2.3. Critical limits, monitoring, corrective actions, record keeping and documentation

PRP-based control activities are described in detail in Regulation (EC) No 852/2004 (Annex 2), EC Regulation 853/2004 for food of animal origin and/or EC Commission Notice 2016/C278/01. When control options are defined, the next step is setting critical limits, designing a monitoring system and corrective actions, record keeping and documentation.

In the classical HACCP approach, each defined CCP must have critical limits and tolerances, which are quantitative limits related to the safety of the products or processes. When these limits are breached, 'corrective actions' are required (Principle 3) targeting both the affected product and to ensure control of the process is regained and maintained. The parameters defined for each CCP must be monitored (Principle 4) and the description of monitoring procedures must clearly state what should be monitored, the frequency and who is responsible for these actions. Records of monitoring and corrective actions must also be maintained (Principle 7).

The 'simplified approach' developed in this Opinion for the five target retail establishments is based on PRP activities. As many PRPs are more general requirements of GHPs and GMPs and are not directly linked to a specific hazard, product or a process (as is the case with CCPs), it is often not possible to define quantitative critical limits or design a rigid monitoring plan (as in the classical HACCP approach). A more descriptive approach was therefore developed (Table 18).

Record keeping and documentation are resource-consuming activities in operating a FSMS. The classical approach' to food safety HACCP systems (Principle 7) requires 'establish documentation procedures' (HACCP records including monitoring, corrective actions, calibration, records, etc.). In many situations this is interpreted to mean continuous monitoring and recording of parameters such as temperature at CCPs, a record of any deviations from critical limits and a description of corrective actions, in addition to validation (demonstrating the CCP achieves the control, e.g. reduction in bacterial pathogens numbers, stated in the HACCP plan). It is proposed in the 'simplified approach' described in this Opinion that the requirement for record keeping should be reduced (Table 18). A record may be manually produced on a registration form, automatically generated (e.g. temperature monitoring devices), or can also be an invoice or communication with external contractors (e.g. in case of technical maintenance, calibration, periodic cleaning).

PRPs to control the hazards that may occur at each stage (as described in the Commission Notice 2016/C278/01, but with the inclusion of an additional PRP 'Product information and customer awareness' (PRP 13)) are usually based on qualitative and not quantitative parameters and thus are evaluated as being 'acceptable' or 'unacceptable'. Cleaning, for example, may be based on visual inspection. Other PRPs, e.g. cooking or chilling, are based on quantitative parameters (e.g. temperature) and their correct application may be assured by setting limits that must be achieved to ensure food safety. In the 'simplified approach' PRPs generally do not require record keeping except where there is a non-compliance or the control activity is such that quantifiable limits must be achieved to assure food safety, e.g. cooking. In the final section (Section 3.3) the 'simplified approach' was applied to the five target small food retail establishments.

Table 18: A summary of prerequisite programme (PRP) activities including the 12 defined PRPs from EC Commission Notice C278/2016 and an additional PRP 13 'product information and consumer awareness'

PRP	Control infrastructure/ activities	Monitoring	Record keeping required (yes/no)	Corrective action
PRP 1: Infrastructure (building and equipment)	Hygienic infrastructure and fit for purpose building and equipment	Monthly visual check based on checklist of infrastructure (hygiene and condition)	Yes, but only when there is remedial work required	Proper maintenance of premises and equipment
PRP 2: Cleaning and disinfection	Cleaning and disinfection schedule and/or 'clean as you go' policy	Spot visual checks Daily visual checks Monthly microbiological testing	Yes, when there is a non-compliance	Cleaning and disinfection of area/equipment affected Review and if necessary retrain staff and/or revise frequency and method of disinfection

PRP	Control infrastructure/ activities	Monitoring	Record keeping required (yes/no)	Corrective action
PRP 3: Pest control: focus on prevention	Pest control activities	Weekly check	No	Revise and/or renew pest control activities
PRP 4: technical maintenance and calibration	Maintain all equipment Calibrate measuring devices (e.g. thermometer, balance, etc.)	Ongoing monitoring of equipment Periodic (daily/weekly) calibration status with records	No Yes, status of calibration	Repair or replace equipment as necessary Review maintenance and calibration programme
PRP 5: Physical and chemical contamination from production environment	Ensure all materials are stored correctly Ensure all surfaces are properly rinsed after disinfection	Visual check during processing Monthly check based on checklist of infrastructure (hygiene and condition)	Yes, but only when there is remedial work required	Review storage, cleaning and disinfection procedures, etc.
PRP 6: Allergens	Ensure the absence of allergens in raw materials Keep an up-to-date inventory of potential allergens including sources (e.g. raw material, cross-contamination, etc.) Potential sources of cross-contamination identified and controlled	Raw material specifications from to suppliers Activities to prevent cross-contamination are implemented on a continuous basis	No	Stop using potentially 'contaminated' raw materials Review suppliers/supplier requirements Revise acceptance criteria Review and correct activities designed to prevent cross-contamination
PRP 7: Waste management	Complete separation of waste from raw materials or foods Specific requirements of legislation are in place in case of waste of foods of animal origin (animal by-products)	Routine visual check to ensure the food business's policy on waste management is being fully complied with	No	Remove waste directly Review and revise current waste management activities Retrain staff as required
PRP 8: Water and air control	Use of potable water, also for ice making Good condition of water distribution infrastructure with absence of toxic contact materials	If not a municipal supply, ongoing monitoring of water treatment Periodic microbiological testing	Yes, results of microbiological testing	Revise water treatment
PRP 9: Personnel (hygiene, health status)	Presence of hygiene rules and agreements with personnel adapted to the nature of the activities Health status of personnel	Daily visual check during processing Medical check and/or awareness training for all personnel	No Medical check and training record keeping	Address any personnel issues immediately Revise and inform personnel
PRP 10: Raw materials (supplier selection, specifications)	Raw materials are fulfilling legal requirements Retailers have acceptance criteria based on specifications	Presence of specifications from suppliers or presence of labels of packaged materials Acceptance criteria are checked upon each delivery	Yes, but only when there is a non-compliance, e.g. the raw materials were not delivered at the correct temperature	Do not use affected raw materials Review suppliers/supplier requirements Revise acceptance criteria

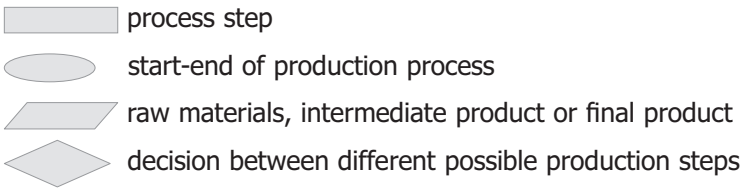
PRP	Control infrastructure/ activities	Monitoring	Record keeping required (yes/no)	Corrective action
PRP 11: Temperature control of storage environment	Temperature of storage environment (cooling or deep freezing) is adequate to reach product temperature requirements	Automatic monitoring with alarm and automated record keeping Manual monitoring/daily check or more checks of the temperature of storage facilities and product	Yes, where the control activity is based on quantifiable parameters such as temperature (e.g. chilling and cooking)	Replace/repair/reset chilling/ freezing equipment Based on the extent of the non-compliance consider disposal of the affected product For bakery products, high temperatures will promote acrylamide formation. Such 'over-cooked' product should be disposed of
PRP 12: Working methodology	Personnel following work descriptions, standard operating procedures (SOP)	Daily visual check	No	Retrain personnel
PRP 13: Product information and consumer awareness	All products at retail level should be accompanied by sufficient information to promote proper handling, storage and preparation by consumers Allergen and shelf life information should also be included if appropriate	Routine checks to ensure this information is provided	No	Review and revise the information as necessary

3.3. The application of these guidelines to hazard identification, ranking and control in five retail establishments including a butcher, grocery, bakery, fish and ice cream shops (TOR 4)

In this section, the 'simplified approach' to food safety management in the five target small food retail establishments is applied. The flow diagrams, based on those provided by the European Commission, for the butcher, grocery, bakery, fish and ice cream shops are provided in Figures 4–8, respectively. These flow diagrams are then used to identify the 'stages' that inform the first column of the SFR-FSMS tables. Information on the 'hazards', 'activity contributing to increased/decreased occurrence of the hazard' and 'control activity (PRP)' are also included to complete the SFR-FSMS tables for the butcher shop (Table 19), grocery shop (Table 20), bakery shop (Table 21), fish shop (Table 22) and ice cream shop (Table 23).

Waste management, which may be a food safety issue, is not usually included in flow diagrams used for the development of FSMS and has not been included in the flow diagrams provided in this opinion. Waste management control activities are described in PRP 7 of Commission Notice 2016/ C278/01 and summarised in Table 18 (Section 3.2.3). It is important to note that if side streams or waste streams are reprocessed (e.g. fruit products to marmalade, bread to bread pudding, meat to meat salads), it has to be included in the production stream and the side stream has to be considered as an ingredient.

Legend for flow charts:



3.3.1. Butcher shop

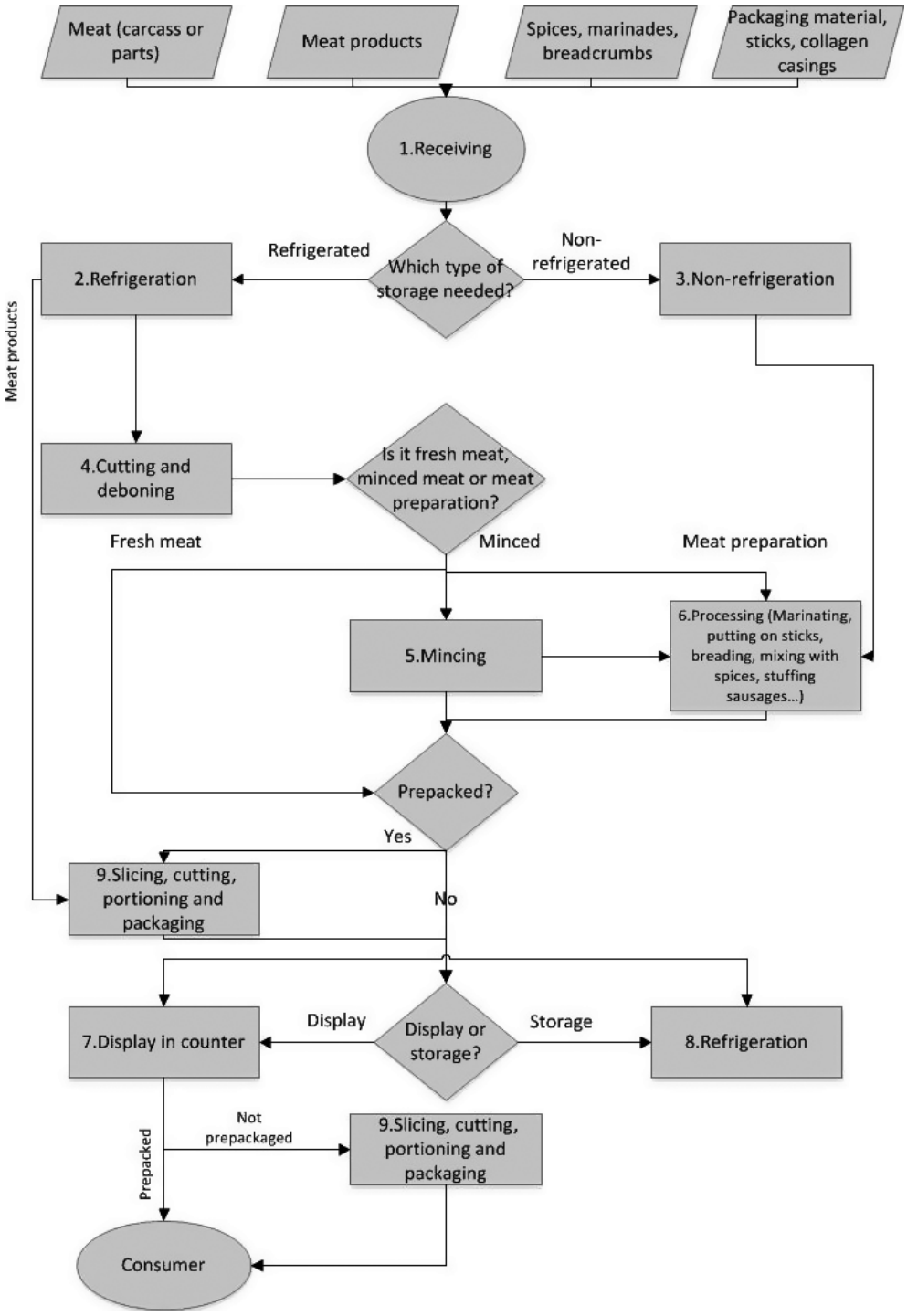


Figure 4: Flow diagram butcher shop

Table 19: Small Food Retailer Food Safety Management System for the butcher shop

Stage	Hazard identification[a]				Activities contributing to increased/ decreased occurrence of the hazard	Control activities
	B	C	P	A		
Receiving	Y	Y	Y	Y	Failure to ensure the microbiological quality of incoming raw materials Presence of chemical or physical hazards or allergens in incoming raw materials	PRP 10: Raw materials (supplier selection, specifications) PRP 11: Temperature control of storage environment PRP 12: Working methodology PRP 6: Allergens PRP 10: Raw materials (supplier selection, specifications) PRP 12: Working methodology
Refrigerated storage	Y	Y	Y	Y	Microbial growth due to failure to chill properly Cross-contamination due to a failure to separate raw from cooked/RTE products Contamination with chemical or physical hazards from the environment, personnel, etc. Contamination with allergens	PRP 4: Technical maintenance and calibration PRP 11: Temperature control of storage environment PRP 12: Working methodology PRP 3: Pest control: focus on prevention PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
Non-refrigerated (ambient) storage	Y	Y	Y	Y	Microbial growth due to failure to store in dry conditions Contamination with chemical or physical hazards from the environment, personnel, etc. Contamination with allergens	PRP 1: Infrastructure (building and equipment) PRP 2: Cleaning and disinfection PRP 1: Infrastructure (building and equipment) PRP 3: Pest control: focus on prevention PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
Cutting and portioning	Y	Y	Y	N	Contamination with biological, chemical or physical hazards due to a failure to clean and disinfect equipment properly, lack of personal hygiene, knives and equipment	PRP 2: Cleaning and disinfection PRP 4: Technical maintenance and calibration PRP 5: Physical and chemical contamination from production environment PRP 9: Personnel (hygiene, health status)
Mincing	Y	Y	N	Y	Cross-contamination with biological hazards due to a failure to clean and disinfect equipment properly or lack of personal hygiene Contamination with chemical hazards Contamination with allergens	PRP 2: Cleaning and disinfection PRP 9: Personnel (hygiene, health status) PRP 2: Cleaning and disinfection PRP 6: Allergens
Processing	Y	Y	Y	Y	Contamination with biological, chemical or physical hazards due to a failure to clean and disinfect equipment properly, lack of personal hygiene, environment, higher concentration of additives than allowed Contamination with allergens	PRP 2: Cleaning and disinfection PRP 5: Physical and chemical contamination from the production environment PRP 9: Personnel (hygiene, health status) PRP 12: Working methodology PRP 6: Allergens

Stage	Hazard identification[a]				Activities contributing to increased/ decreased occurrence of the hazard	Control activities
	B	C	P	A		
Display in counter	Y	Y	N	Y	Microbial growth due to failure to chill properly Cross-contamination with biological hazards due to a failure to separate raw from cooked/ RTE products Contamination with chemical hazards Contamination with allergens	PRP 4: Technical maintenance and calibration PRP 11: Temperature control of storage environment PRP 12: Working methodology PRP 2: Cleaning and disinfection PRP 5: Physical and chemical contamination from the production environment PRP 6: Allergens
Refrigerated storage	Y	Y	Y	Y	Microbial growth due to failure to chill properly Cross-contamination due to a failure to separate raw from cooked/RTE products Contamination with chemical or physical hazards from the environment, personnel, etc. Contamination with allergens	PRP 4: Technical maintenance and calibration PRP 11: Temperature control of storage environment PRP 12: Working methodology PRP 2: Cleaning and disinfection PRP 3: Pest control: focus on prevention PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
Slicing, serving and packing	Y	Y	Y	Y	Contamination with biological, chemical or physical hazards or allergens due to failure in working methodology and lack of personal hygiene Failure to inform the consumer of potential allergens and storage mode, time, etc.	PRP 2: Cleaning and disinfection PRP 5: Physical and chemical contamination from the production environment PRP 6: Allergens PRP 9: Personnel (hygiene, health status) PRP 12: Working methodology PRP 6: Allergens PRP 13: Product information and consumer awareness

(a): B: biological; C: chemical; P: physical; A: allergen; Y: yes; N: no.

3.3.2. Grocery shop

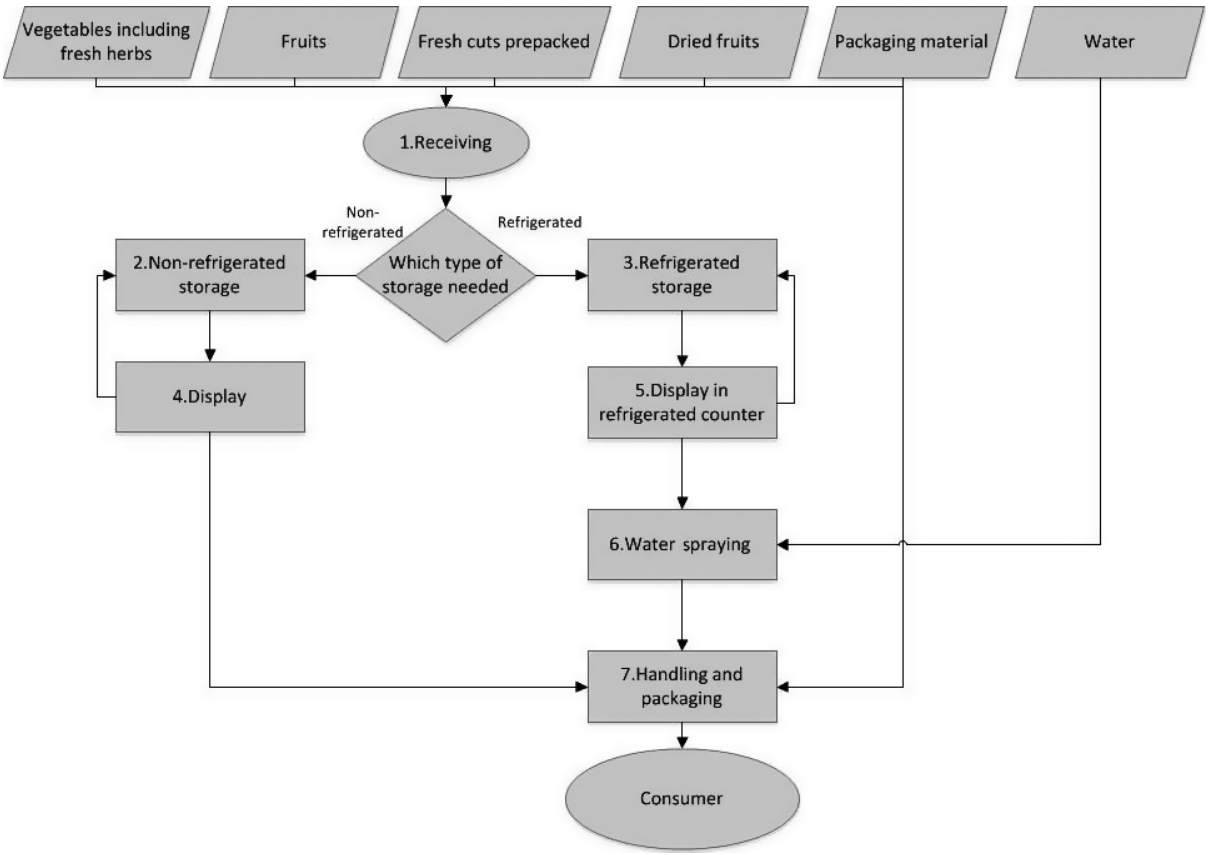


Figure 5: Flow diagram grocery shop

Table 20: Small Food Retailer Food Safety Management System for the grocery shop

Stage	Hazard identification[a]				Activities contributing to increased/ decreased occurrence of the hazard	Control activities
	B	C	P	A		
Receiving	Y	Y	Y	Y	Failure to ensure the microbiological quality of incoming raw materials Presence of chemical or physical hazards or allergens in incoming raw materials	PRP 10: Raw materials (supplier selection, specifications) PRP 11: Temperature control of storage environment PRP 12: Working methodology PRP 6: Allergens PRP 10: Raw materials (supplier selection, specifications) PRP 12: Working methodology
Non-refrigerated (ambient) storage	Y	Y	Y	Y	Contamination with biological, chemical or physical hazards from the environment, personnel, etc. Contamination with allergens	PRP 1: Infrastructure (building and equipment) PRP 3: Pest control: focus on prevention PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
Refrigerated storage	Y	Y	Y	Y	Microbial growth due to failure to chill properly Contamination with chemical or physical hazards from the environment, personnel, etc. Contamination with allergens	PRP 4: Technical maintenance and calibration PRP 11: Temperature control of storage environment PRP 3: Pest control: focus on prevention PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
Washing	Y	Y	Y	N	Contamination with biological, chemical and physical hazards from water, the environment, personnel, etc.	PRP 2: Cleaning and disinfection PRP 4: Technical maintenance and calibration PRP 5: Physical and chemical contamination from production environment PRP 8: Water and air control PRP 9: Personnel (hygiene, health status)
Display	Y	Y	Y	Y	Contamination with biological, chemical or physical hazards or allergens from the environment, personnel, etc.	PRP 1: Infrastructure (building and equipment) PRP 2: Cleaning and disinfection PRP 5: Physical and chemical contamination from the production environment PRP 6: Allergens PRP 7: Waste management

Stage	Hazard identification[a]				Activities contributing to increased/ decreased occurrence of the hazard	Control activities
	B	C	P	A		
Display in refrigerated counter	Y	Y	Y	Y	Microbial growth due to failure to chill properly Contamination with biological, chemical or physical hazards or allergens from the environment, personnel, etc.	PRP 4: Technical maintenance and calibration PRP 11: Temperature control of storage environment PRP 1: Infrastructure (building and equipment) PRP 2: Cleaning and disinfection PRP 5: Physical and chemical contamination from the production environment PRP 6: Allergens PRP 7: Waste management
Spraying	Y	Y	Y	N	Contamination with biological, chemical and physical hazards from water, the environment, personnel, etc.	PRP 2: Cleaning and disinfection PRP 4: Technical maintenance and calibration PRP 5: Physical and chemical contamination from production environment PRP 8: Water and air control PRP 9: Personnel (hygiene, health status)
Serving and packing	Y	Y	Y	Y	Contamination with biological, chemical or physical hazards or allergens from the environment, personnel, etc. Failure to inform the consumer of potential allergens and storage mode, time, etc.	PRP 2: Cleaning and disinfection PRP 5: Physical and chemical contamination from the production environment PRP 6: Allergens PRP 9: Personnel (hygiene, health status) PRP 12: Working methodology PRP 6: Allergens PRP 13: Product information and consumer awareness

(a): B: biological; C: chemical; P: physical; A: allergen; Y: yes; N: no.

3.3.3. Bakery shop

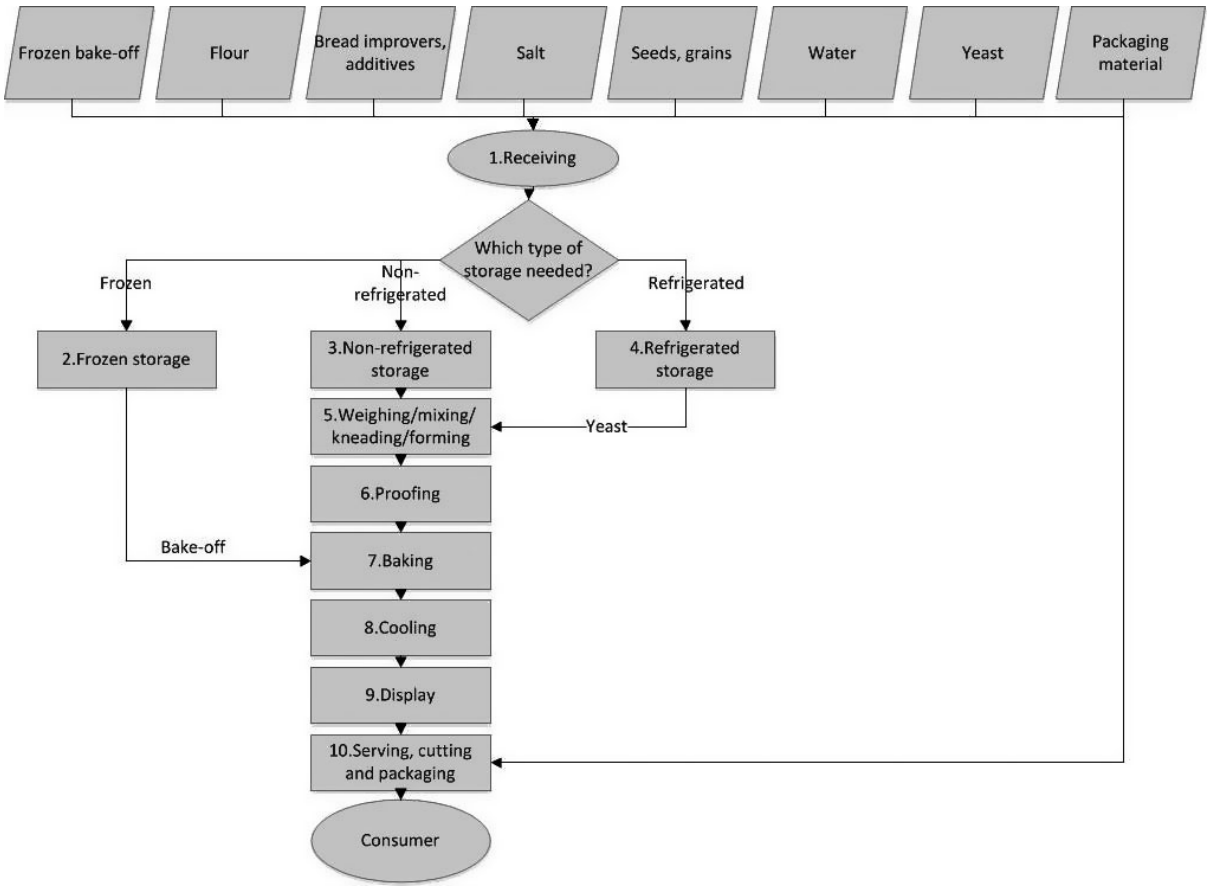


Figure 6: Flow diagram bakery shop

Table 21: Small Food Retailer Food Safety Management System for the bakery shop

Stage	Hazard identification[a]				Activities contributing to increased/ decreased occurrence of the hazard	Control activities
	B	C	P	A		
Receiving	Y	Y	Y	Y	Failure to ensure the microbiological quality of incoming raw materials Presence of chemical or physical hazards or allergens in incoming raw materials	PRP 10: Raw materials (supplier selection, specifications) PRP 11: Temperature control of storage environment PRP 12: Working methodology PRP 6: Allergens PRP 10: Raw materials (supplier selection, specifications) PRP 12: Working methodology
Non-refrigerated (ambient) storage	Y	Y	Y	Y	Microbial growth due to failure to store in dry conditions Contamination with chemical or physical hazards from the environment, personnel, etc. Contamination with allergens	PRP 1: Infrastructure (building and equipment) PRP 2: Cleaning and disinfection PRP 1: Infrastructure (building and equipment) PRP 3: Pest control: focus on prevention PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
Refrigerated storage	Y	Y	Y	Y	Microbial growth due to failure to chill properly Cross-contamination due to a failure to separate raw from cooked/RTE products Contamination with chemical or physical hazards from the environment, personnel, etc. Contamination with allergens	PRP 4: Technical maintenance and calibration PRP 11: Temperature control of storage environment PRP 12: Working methodology PRP 2: Cleaning and disinfection PRP 3: Pest control: focus on prevention PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
Weighing, mixing and kneading	N	Y	Y	Y	Contamination with chemical or physical hazards and allergens from the environment, personnel, higher levels of additives than allowed, etc.	PRP 4: Technical maintenance and calibration PRP 5: Physical and chemical contamination from the production environment PRP 6: Allergens PRP 12: Working methodology
Proofing	N	Y	Y	Y	Contamination with chemical or physical hazards from the environment, personnel, etc. Contamination with allergens	PRP 5: Physical and chemical contamination from the production environment PRP 12: Working methodology PRP 6: Allergens

Stage	Hazard identification[(a)]				Activities contributing to increased/ decreased occurrence of the hazard	Control activities
	B	C	P	A		
Baking	Y	Y	N	N	Failure to achieve sufficiently high temperatures to ensure that microbial hazards are killed Over-cooking resulting in the formation of acrylamide	PRP 4: Technical maintenance and calibration PRP 12: Working methodology PRP 12: Working methodology
Cooling	Y	Y	N	N	Failure to chill quickly Contamination with chemical hazards	PRP 4: Technical maintenance and calibration PRP 12: Working methodology PRP 5: Physical and chemical contamination from the production environment
Display	Y	Y	Y	Y	Contamination with biological, chemical or physical hazards or allergens from the environment, personnel, etc.	PRP 1: Infrastructure (building and equipment) PRP 2: Cleaning and disinfection PRP 5: Physical and chemical contamination from the production environment PRP 6: Allergens PRP 7: Waste management
Serving, cutting and packing	Y	Y	Y	Y	Contamination with biological, chemical or physical hazards or allergens due to a failure to clean and disinfect equipment properly Failure to inform the consumer of potential allergens and storage mode, time, etc.	PRP 2: Cleaning and disinfection PRP 5: Physical and chemical contamination from the production environment PRP 6: Allergens PRP 9: Personnel (hygiene, health status) PRP 12: Working methodology PRP 6: Allergens PRP 13: Product information and consumer awareness

(a): B: biological; C: chemical; P: physical; A: allergen; Y: yes; N: no.

3.3.4. Fish shop

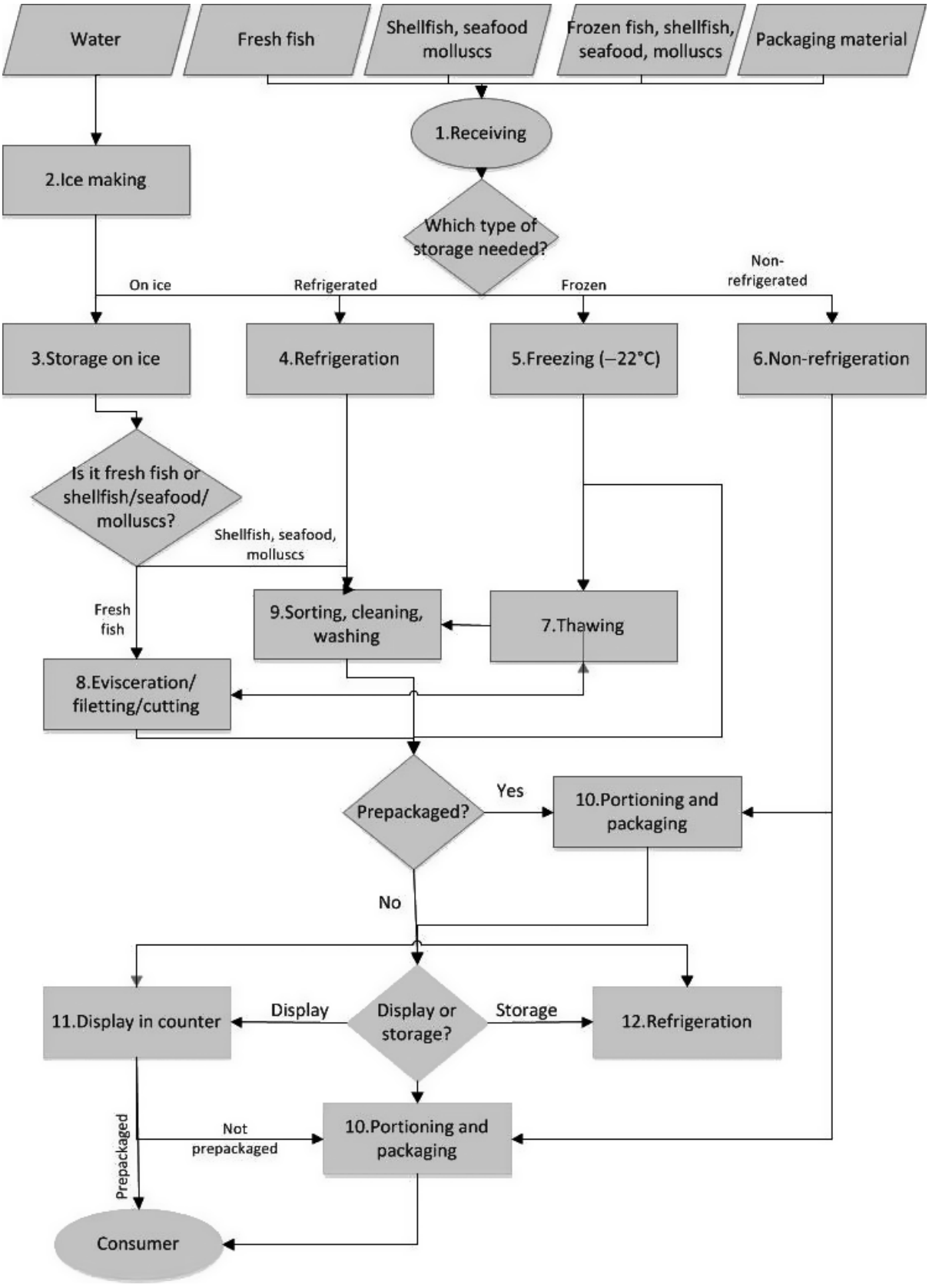


Figure 7: Flow diagram fish shop

Table 22: Small Food Retailer Food Safety Management System for the fish shop

Stage	Hazard identification[(a)]				Activities contributing to increased/ decreased occurrence of the hazard	Control activities
	B	C	P	A		
Receiving	Y	Y	Y	Y	Failure to ensure the microbiological quality of incoming raw materials Presence of chemical or physical hazards or allergens in incoming raw materials	PRP 10: Raw materials (supplier selection, specifications) PRP 11: Temperature control of storage environment PRP 12: Working methodology PRP 6: Allergens PRP 10: Raw materials (supplier selection, specifications) PRP 12: Working methodology
Ice making	Y	Y	Y	N	Failure to ensure the quality of the water used Failure to maintain, clean and disinfect equipment	PRP 5: Physical and chemical contamination from the production environment PRP 8: Water and air control PRP 2: Cleaning and disinfection PRP 4: Technical maintenance and calibration
Storage on ice	Y	Y	N	N	Microbial growth due to failure to chill properly Failure to prevent microbial growth and the production of histidine (time restriction) Contamination with chemical hazards	PRP 11: Temperature control of storage environment PRP 12: Working methodology PRP 12: Working methodology PRP 2: Cleaning and disinfection PRP 5: Physical and chemical contamination from the production environment PRP 8: Water and air control
Refrigerated storage	Y	Y	Y	Y	Microbial growth due to failure to chill properly Contamination with biological, chemical or physical hazards from the environment, personnel, etc. Contamination with allergens Failure to prevent microbial growth and the production of histidine (time restriction)	PRP 4: Technical maintenance and calibration PRP 11: Temperature control of storage environment PRP 2: Cleaning and disinfection PRP 3: Pest control: focus on prevention PRP 5: Physical and chemical contamination from production environment PRP 12: Working methodology PRP 6: Allergens PRP 12: Working methodology
Frozen storage	Y	Y	Y	N	Microbial growth due to failure in freezing temperature Contamination with chemical or physical hazards from the environment, etc.	PRP 4: Technical maintenance and calibration PRP 11: Temperature control of storage environment PRP 5: Physical and chemical contamination from production environment

Stage	Hazard identification[a]				Activities contributing to increased/ decreased occurrence of the hazard	Control activities
	B	C	P	A		
Non-refrigeration (ambient) storage	Y	Y	Y	Y	Microbial growth due to failure to store in dry conditions Contamination with chemical or physical hazards from the environment, personnel, etc. Contamination with allergens	PRP 1: Infrastructure (building and equipment) PRP 2: Cleaning and disinfection PRP 1: Infrastructure (building and equipment) PRP 3: Pest control: focus on prevention PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
Thawing	Y	Y	N	N	Microbial growth due to failure to maintain low temperatures Failure to prevent microbial growth and the production of histidine Contamination with chemical hazards	PRP 11: Temperature control of storage environment PRP 12: Working methodology PRP 2: Cleaning and disinfection PRP 5: Physical and chemical contamination from production environment
Evisceration	Y	Y	Y	N	Cross-contamination with biological hazards from the gut to the meat Contamination with biological, chemical and physical hazards from the environment, personnel, etc.	PRP 7: Waste management PRP 12: Working methodology PRP 2: Cleaning and disinfection PRP 5: Physical and chemical contamination from production environment PRP 9: Personnel (hygiene, health status)
Sorting, cleaning and washing	Y	Y	Y	N	Contamination with biological, chemical and physical hazards from water, the environment, personnel, working method, etc.	PRP 2: Cleaning and disinfection PRP 5: Physical and chemical contamination from production environment PRP 8: Water and air control PRP 9: Personnel (hygiene, health status) PRP 12: Working methodology
Cutting	Y	Y	Y	N	Contamination with biological, chemical or physical hazards due to a failure to clean and disinfect equipment properly, the environment, personnel, work method	PRP 2: Cleaning and disinfection PRP 5: Physical and chemical contamination from production environment PRP 9: Personnel (hygiene, health status) PRP 12: Working methodology
Refrigerated storage	Y	Y	Y	Y	Microbial growth due to failure to chill properly Contamination with biological, chemical or physical hazards from the environment, personnel, etc. Contamination with allergens Failure to prevent microbial growth and the production of histidine (time restriction)	PRP 4: Technical maintenance and calibration PRP 11: Temperature control of storage environment PRP 2: Cleaning and disinfection PRP 3: Pest control: focus on prevention PRP 5: Physical and chemical contamination from production environment PRP 12: Working methodology PRP 6: Allergens PRP 11: Temperature control of storage environment PRP 12: Working methodology

Stage	Hazard identification[(a)]				Activities contributing to increased/ decreased occurrence of the hazard	Control activities
	B	C	P	A		
Display in refrigerated counter	Y	Y	Y	Y	Microbial growth due to failure to chill properly Contamination with biological, chemical or physical hazards or allergens from the environment, personnel, etc. Contamination with allergens Failure to prevent microbial growth and the production of histidine (time restriction)	PRP 4: Technical maintenance and calibration PRP 11: Temperature control of storage environment PRP 1: Infrastructure (building and equipment) PRP 2: Cleaning and disinfection PRP 5: Physical and chemical contamination from the production environment PRP 6: Allergens PRP 7: Waste management PRP 6: Allergens PRP 11: Temperature control of storage environment PRP 12: Working methodology
Serving and packing	Y	Y	Y	Y	Contamination with biological, chemical or physical hazards or allergens from the environment, personnel, etc. Failure to inform the consumer of potential allergens and storage mode, time, etc.	PRP 2: Cleaning and disinfection PRP 5: Physical and chemical contamination from the production environment PRP 6: Allergens PRP 9: Personnel (hygiene, health status) PRP 12: Working methodology PRP 6: Allergens PRP 13: Product information and consumer awareness

(a): B: biological; C: chemical; P: physical; A: allergen; Y: yes; N: no.

3.3.5. Ice cream shop

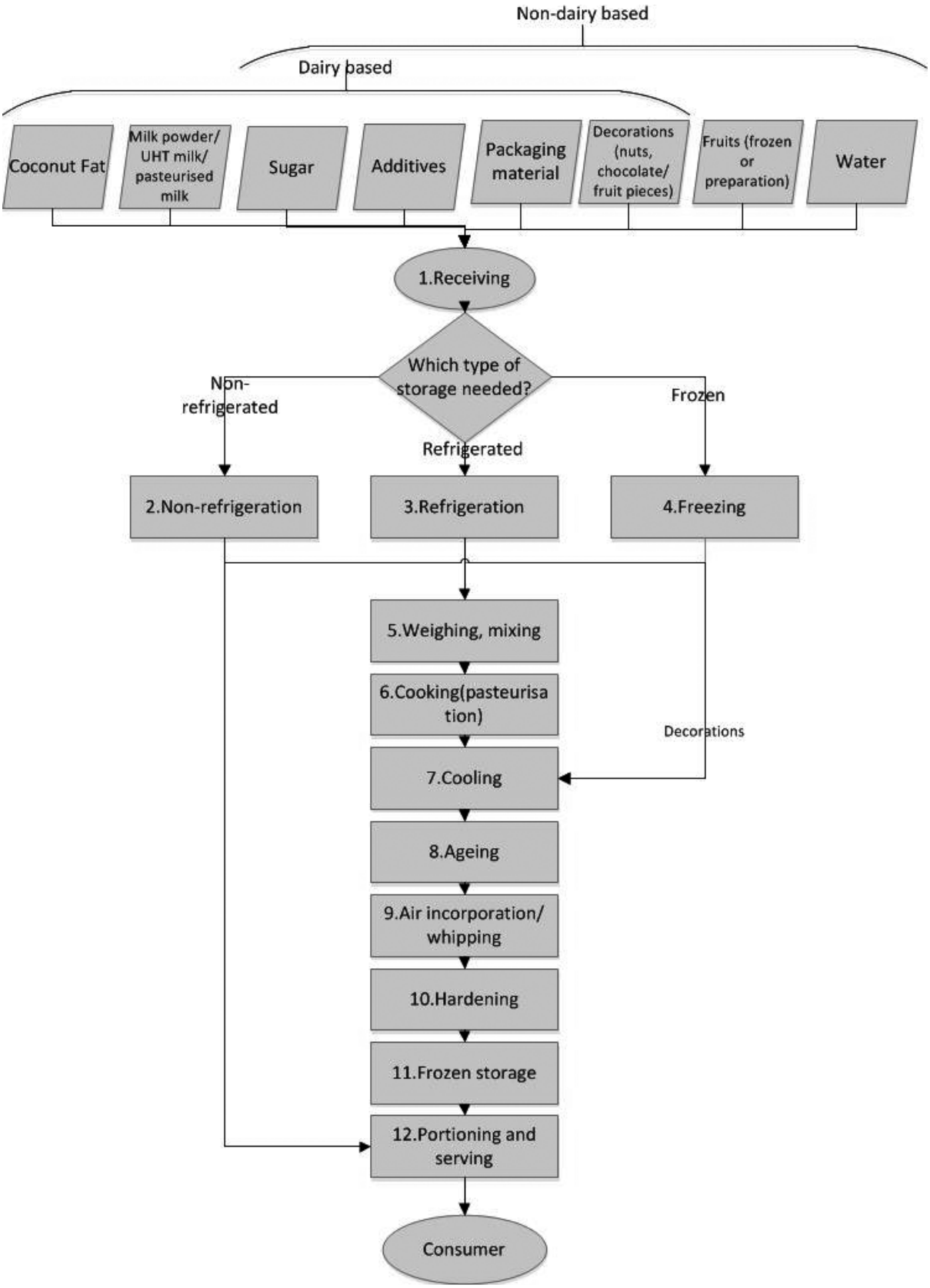


Figure 8: Flow diagram ice cream shop

Table 23: Small Food Retailer Food Safety Management System for the ice cream shop

Stage	Hazard identification[a]				Activities contributing to increased/ decreased occurrence of the hazard	Control activities
	B	C	P	A		
Receiving	Y	Y	Y	Y	Failure to ensure the microbiological quality of incoming raw materials Presence of chemical or physical hazards or allergens in incoming raw materials	PRP 10: Raw materials (supplier selection, specifications) PRP 11: Temperature control of storage environment PRP 12: Working methodology PRP 6: Allergens PRP 10: Raw materials (supplier selection, specifications) PRP 12: Working methodology
Ambient Storage	Y	Y	Y	Y	Microbial growth due to failure to store in dry conditions Contamination with chemical or physical hazards from the environment, personnel, etc. Contamination with allergens	PRP 1: Infrastructure (building and equipment) PRP 2: Cleaning and disinfection PRP 1: Infrastructure (building and equipment) PRP 3: Pest control: focus on prevention PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
Refrigerated storage	Y	Y	Y	Y	Microbial growth due to failure to chill properly Cross-contamination due to a failure to separate raw from cooked/RTE products Contamination with chemical or physical hazards from the environment, personnel, etc. Contamination with allergens	PRP 4: Technical maintenance and calibration PRP 11: Temperature control of storage environment PRP 12: Working methodology PRP 2: Cleaning and disinfection PRP 3: Pest control: focus on prevention PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
Frozen storage	Y	Y	Y	N	Microbial growth due to failure in freezing temperature Contamination with chemical or physical hazards from the environment, etc.	PRP 4: Technical maintenance and calibration PRP 11: Temperature control of storage environment PRP 5: Physical and chemical contamination from production environment
Weighing and mixing	Y	Y	Y	Y	Microbial growth due to long period of weighing and mixing Contamination with chemical or physical hazards and allergens from the environment, personnel, etc.	PRP 12: Working methodology PRP 2: Cleaning and disinfection PRP 5: Physical and chemical contamination from the production environment PRP 6: Allergens PRP 9: Personnel (hygiene, health status) PRP 12: Working methodology

Stage	Hazard identification[a]				Activities contributing to increased/ decreased occurrence of the hazard	Control activities
	B	C	P	A		
Cooking	Y	Y	N	N	Failure to achieve sufficiently high temperatures Contamination with chemical hazards	PRP 4: Technical maintenance and calibration PRP 12: Working methodology PRP 2: Cleaning and disinfection PRP 5: Physical and chemical contamination from the production environment
Cooling	Y	Y	N	N	Failure to chill quickly Contamination with chemical hazards	PRP 4: Technical maintenance and calibration PRP 12: Working methodology PRP 2: Cleaning and disinfection PRP 5: Physical and chemical contamination from the production environment
Ageing	Y	N	N	N	Microbial growth due to failure to chill properly	PRP 4: Technical maintenance and calibration PRP 11: Temperature control of storage environment
Air incorporation/ whipping	Y	Y	Y	N	Microbial growth due to failure to chill properly Contamination with chemical or physical hazards from the environment, personnel, etc.	PRP 4: Technical maintenance and calibration PRP 11: Temperature control of storage environment PRP 2: Cleaning and disinfection PRP 5: Physical and chemical contamination from the production environment PRP 8: Air and water control PRP 12: Working methodology
Packaging	Y	Y	Y	N	Contamination with microbial, chemical or physical hazards from the packaging materials, environment, personnel, etc.	PRP 2: Cleaning and disinfection PRP 5: Physical and chemical contamination from the production environment PRP 9: Personnel (hygiene, health status) PRP 12: Working methodology
Hardening	Y	Y	N	N	Microbial growth due to failure in freezing temperature Contamination with chemical hazards	PRP 4: Technical maintenance and calibration PRP 11: Temperature control of storage environment PRP 5: Physical and chemical contamination from the production environment
Frozen storage	Y	Y	N	N	Microbial growth due to failure in freezing temperature Contamination with chemical hazards	PRP 4: Technical maintenance and calibration PRP 11: Temperature control of storage environment PRP 5: Physical and chemical contamination from the production environment

Stage	Hazard identification[a]				Activities contributing to increased/ decreased occurrence of the hazard	Control activities
	B	C	P	A		
Portioning and serving	Y	Y	Y	Y	Contamination with biological, chemical or physical hazards or allergens due to a failure to clean and disinfect equipment properly	PRP 2: Cleaning and disinfection PRP 5: Physical and chemical contamination from the production environment PRP 6: Allergens PRP 9: Personnel (hygiene, health status) PRP 12: Working methodology
					Failure to inform the consumer of potential allergens and storage mode, time, etc.	PRP 6: Allergens PRP 13: Product information and consumer awareness

(a): B: biological; C: chemical; P: physical; A: allergen; Y: yes; N: no.

4. Conclusions

A 'simplified approach' was proposed for the development of FSMS for the five small retail establishments (butcher, grocery, bakery, fish and ice cream shops). This 'simplified approach' formulated guidelines for small retail establishments on how to identify the most relevant biological hazards as well as relevant chemical (including allergens) and physical hazards along the production stages of these small food retail establishments. Moreover, in this approach, the retailer does not require specific knowledge of the hazard but should be aware that 'biological', 'chemical', 'physical' or 'allergen' hazards may be present and also of activities that contribute to increased or decreased occurrence of the hazard (TOR1).

It was concluded that, based on an analysis of the hazards which may occur in the five target retail establishments, PRPs were sufficient to assure food safety. The 'classical approach' of hazard ranking and prioritisation, which usually informs that most effective control activities, was therefore not necessary in the 'simplified approach' (TOR2).

The 'simplified approach', which overcomes many of the resource and other limitations characteristic of small businesses when investing in food safety management infrastructure and activities, was based on a fundamental understanding of the food processes used, whether or not biological, chemical or physical hazards may occur at each stage in these processes and activities (or lack thereof, e.g. chilled storage) that may contribute to an increased or decreased occurrence of the hazards. Controls were based on PRPs as described in EC Notice 2016/C278 and an additional PRP 'product information and consumer awareness' developed in this Opinion, some of which required monitoring and limited record keeping (when there was a non-compliance or the control activity was based on quantifiable parameters such as temperature in cooking or chilling) (TOR3).

The developed 'simplified approach' thus developed was applied to the five target small food retail establishments (TOR4).

5. Recommendations

It is recommended that the butcher, grocery, bakery, fish and ice cream shops apply the 'simplified approach' to food safety management as described in this Opinion. While this general approach may be used, it is important that individual retail establishments tailor their SFR-FSMS in a clear and user-friendly way based on the specific processes (stages) and products relevant to their business.

The 'simplified approach' would also overcome many of the issues encountered by other small food businesses when developing and attempting to implement effective FSMS. It should therefore be considered for wider application within the food industry.

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Glossary

Critical control point (CCP)	A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.[16] Most typical CCPs to control microbiological hazards are temperature requirements, e.g. the temperature for storage or transport, the time/temperature conditions to reduce or eliminate a hazard (e.g. pasteurisation). Other CCPs may be checking that packages are clean and non-damaged, checking for physical hazards by sieving or metal detection or checking time/temperature of frying oil to avoid chemical process contaminants.
Critical limit	A criterion which separates acceptability from unacceptability. In the CCP examples above, they refer respectively to the maximum temperature (storage and transport), the minimum temperature (hazard reduction/elimination) and the presence of contamination or damages.
Food Safety Management (or control) system (FSMS)	The combination of PRPs as preventive control measures; traceability, recall and communication as preparedness and HACCP plan defining CCPs and/or PRPs as control measures linked to the production process (see Figure 1). The FSMS is also the combination of control measures and assurance activities. The latter aims at providing evidence that control measures, such as validation and verification, documentation and record keeping, are working properly.
GHP (good hygiene practices), GMP (good manufacturing practices)	Package of preventive practices and conditions to ensure the safety of the food produced. GHP underline more the need for hygiene, GMP stress correct work methodologies. Most PRPs (all those mentioned in Annex I of Commission Notice 2016/C278/01) are GHP or GMP. Sometimes no differentiation is made between GHP and GMP, calling all preventive measures 'GMP'.
HACCP-based procedures or 'HACCP'	Procedures based on the hazard analysis and critical control point (HACCP) principles, i.e. an auto-control system which identifies, evaluates and controls hazards which are significant for food safety consistent with the HACCP principles.
HACCP plan	A document, possibly electronic, fully describing the HACCP-based procedures. The initial HACCP plan shall be updated if there are changes in the production and must be supplemented with records from outcomes of monitoring and verification, and from corrective actions taken.

[16] CAC/RCP 1-1969, Rev. 2003.

Hazard	a biological (e.g. *Salmonella* spp.), chemical (e.g. dioxin, allergens) or physical (e.g. hard, sharp foreign bodies as pieces of glass, metal) agent in, or condition of food with the potential to cause an adverse health effect.[17]
Monitor	The act of conducting in real time a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.[16] As regards the examples, this is the regular (or continuous if automatic) measuring of the temperatures and the observation of contamination and damages.
Prerequisite program(s) (PRP(s)	Preventive practices and conditions needed prior to and during the implementation of HACCP and which are essential for food safety. The PRPs needed depend on the segment of the food chain in which the sector operates and the type of sector. Examples of equivalent terms are good agriculture practice (GAP), good veterinarian practice (GVP), GMP, GHP, good production practice (GPP), good distribution practice (GDP) and good trading practice (GTP). Sometimes, procedures to ensure traceability of food and recall in case of non-compliance are considered part of the PRPs. In Codex Alimentarius standards, PRPs are referred to as 'Codes of Good Practice'.
Risk	A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard.[18]
Validation	Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome. Revalidation may be required in case of changes. Detailed examples can be found in CAC/GL 69-2008.
Verification	The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP-based procedures.[16] Verification is conducted periodically to demonstrate that the HACCP system is working as planned

Abbreviations

A	allergen
B	biological
C	chemical
CAC	Codex Alimentarius Commission
CCP	critical control point
DALY	disability-adjusted life years
FAO	Food and Agriculture Organization of the United Nations
FBO	food business operator
FIC	Food Information to Consumers
FSMS	food safety management system
FVO	Food and Veterinary Office
GAP	good agricultural practices
GHP	good hygiene practices
GMP	good management practices
HACCP	hazard analysis and critical control point
ML	maximum level
MRL	maximum residue limit
N	no
P	physical
PRP	prerequisite programme
RPA	reference point for action
RTE	ready-to-eat
SFR-FSMS	food safety management system for small food retailers

[17] Article 3(14) of Regulation (EC) No 178/2002.
[18] Article 3(9) of Regulation (EC) No 178/2002.

SML	specific migration limit
SOP	standard operating procedure
TOR	Term of reference
US-FDA	United States Food and Drug Administration
WG	working group
WHO	World Health Organization
Y	yes