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Hazard analysis approaches for certain small retail establishments and food donations: second scientific opinion

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Abstract

In 2017, EFSA published a 'simplified' food safety management system (FSMS) for certain small retail establishments (butcher, grocer, baker, fish and ice cream shop) based on the application of prerequisite programme (PRP) criteria. The aim of this opinion was to develop similar FSMSs for other small retail enterprises including retail distribution centres, supermarkets, restaurants (including pubs and other catering activities) and food donation. The latter presents several novel food safety challenges because donated food may be nearing the end of its shelf-life and several actors are involved in the food donation chain, each reliant on each other to assure food safety. In this opinion, the simplified approach to food safety management is presented based on a fundamental understanding of processing stages and the activities contributing to increased occurrence of the hazards (biological, chemical (including allergens) or physical) that may occur. Control is achieved using PRP activities as previously described but with a modified 'temperature control' PRP and the addition of PRPs covering shelf-life control, handling returned foods, shelf-life evaluation for food donation, allocation of remaining shelf-life, and freezing food intended for donation. Examples of the simplified approach are presented for retail distribution centres, supermarkets, restaurants and food donation.

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Keywords: food safety management, small food retail distribution centre, supermarkets, restaurants, catering, food donation, prerequisite programme

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Summary

The European Commission requested that the European Food Safety Authority (EFSA) provides a scientific opinion that identified and, if appropriate, ranked the hazards in small retail distribution centres, supermarkets, restaurants (including pubs and catering) and in food donation for 'regular consumers' (i.e. excluding those that are immune compromised due to illness, pregnancy, drug treatment, age, etc.). Under current European hygiene legislation, all food businesses are obliged to develop and implement food safety management systems (FSMS), usually based on prerequisite programme (PRP) activities and hazard analysis and critical control point (HACCP) principles. However, this can be particularly challenging for small food retail establishments, where a lack of expertise and other resources may limit the development and implementation of effective FSMS. Thus, EFSA were requested to and provided a previous Opinion that developed and presented a 'simplified' FSMS for certain small retail establishments (butcher, grocer, baker, fish and ice cream shops) based on the application of PRP activities. In this Opinion, a similar approach was used to develop a FSMS for small retail distribution centres, supermarkets, restaurants (including pubs and catering) and in food donation.

While this work builds on the previous small retail FSMS Opinion (EFSA, 2017), other sources of information and data were used and the Opinion was developed based on a review of the relevant scientific and grey literature 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 the European Commission, *Codex Alimentarius*, Food and Agriculture Organization of the United Nations (FAO), etc. Biological, chemical, physical and allergen hazards were investigated and relevant control activities identified. Food donation presented a special challenge as these foods may be close to their 'use by' or 'best before' dates and there are multiples activities required, undertaken by many different actors often on a voluntary basis with very limited resources. This necessitated the development of four new PRPs: 'shelf-life control', 'handling returned foods', 'evaluation for food donation and allocation of remaining shelf-life' and 'freezing food intended for donation'.

As there is considerable overlap between the different target establishments, a single table was developed summarising the hazards and control activities (PRPs) that comprise the 'simplified' FSMS. These PRPs were based on those described in the Commission Notice 2016/C 278/01, but with the modification of PRP 11 to include all 'temperature control' activities and the inclusion of an additional PRP 'product information and customer awareness' (PRP 13) (EFSA, 2017) and the four PRPs mentioned above. The activities in each target establishment (retail distribution centre, supermarket, restaurant and food donation) were also briefly described in the text and using a flow diagram, and the proposed FSMS summarised in table format. It was considered sufficient for the relevant personnel 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. Moreover, a failure to undertake key control activities, such as correct chilled storage or separation of raw from ready-to-eat (RTE)/cooked products, etc., was considered as these could contribute to increased risk of illness for the consumer.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

In accordance with Regulation (EC) No 852/2004 on hygiene of foodstuffs, all food business operators (FBOs), including those carrying out retail activities, must comply with general hygiene requirements (prerequisite programmes, PRPs). In addition, FBOs, 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).

On 18 January 2017, the EFSA Panel on Biological Hazards adopted an Opinion on 'Hazard analysis approaches for certain small retail establishments in view of the application of their food safety management systems (FSMS)'. In this opinion, a simplified approach to food safety management is developed and presented based on a fundamental understanding of processing stages and the activities contributing to increased occurrence of the hazards (biological, chemical or physical) that may occur in a butcher, grocery, bakery, fish and ice cream shop.

The opinion was very much appreciated by competent authorities and relevant stakeholders' organisations in the EU. It provides a tool for a better understanding and harmonised application of hazard analysis approaches within the EU. It is in line with the Commission objective to support small and medium size enterprises in the implementation of EU requirements.

Other food retailers are often also small enterprises (restaurants, pubs, supermarkets, caterers, distribution centres...) and specific attention might be needed for potential additional hazards that may emerge within the frame of food donations at retail level. These activities may benefit from recommendations on hazard analysis approaches within their FSMS.

Facilitating food donation is an EU priority within the frame of meeting the sustainable Development Goals, adopted in 2015, but might be challenging from a food safety point of view given the involvement of additional actors (e.g. food banks and other charity organisations) and as food which is redistributed may be approaching the end of its shelf-life when considered for food donations.

Even though redistribution of food surplus is a growing phenomenon and food manufacturers, retailers and restaurants/contract caterers would be willing to donate their surplus to food banks and charities, the amount of food redistributed still represents a small fraction of the overall edible surplus food available in the EU. For instance, in 2015, members of the European Federation of Food Banks (FEBA) distributed 532,000 tons of food to 5.7 million people,¹ which represents only a small fraction of the estimated volume of food waste generated annually in the EU (88 million tonnes²).

Member States (MS) and stakeholders have identified legal and operational barriers, for donors and recipients, to the redistribution of safe, edible food in the EU.³ The Action Plan proposed by the Commission to promote a Circular Economy⁴ therefore requires the Commission inter alia to clarify EU legislation related to food in order to facilitate food donation.

The Commission has published EU guidelines on food donation,⁵ which clarify relevant provisions in EU legislation in order to facilitate compliance of providers and recipients of surplus food with the requirements laid down in the EU regulatory framework (e.g. food safety, food hygiene, traceability, liability etc.). In the area of food hygiene, for instance, the guidelines outline the need for food business operators (including food banks and other charities) to apply good hygiene practices and have an auto-control system in place related to food redistribution activities.

Terms of Reference

EFSA is asked to provide a scientific opinion on hazard analysis approaches for certain small retail establishments, including consideration of possible additional hazards that may emerge within the

¹ European Federation of Food Banks (FEBA) <http://www.eurofoodbank.eu/>. In addition, the Tafel (German 'food banks' which are not member of FEBA), distribute some 220.000T of food annually to approximately 1.5 million people.

² Estimates of European food waste levels, FUSIONS (March 2016) <http://www.eu-fusions.org/phocadownload/Publications/Estimates%20of%20European%20food%20waste%20levels.pdf>

³ Documented for instance in *Comparative study on EU Member States' legislation and practices on food donations (EESC, 2014)*; *Counting the Cost of Food Waste: EU food waste prevention (UK House of Lords, 2013-14)*; *Review of EU legislation and policies with implications on food waste (FUSIONS, 2015)*; *Food redistribution in the Nordic Region (Nordic Council of Ministers, Temalord 2014-2016)*; as well as Commission meetings with and individual contributions received from national competent authorities and stakeholders (see https://ec.europa.eu/food/safety/food_waste/eu_actions_en).

⁴ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions. Closing the loop - an EU action plan for the Circular Economy. COM(2015) 614 final <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52015DC0614>

⁵ Commission notice C/2017/6872 EU guidelines on food donation, OJ C 361, 25.10.2017, p. 1–29.

frame of food donation. In particular, starting from generic flow diagrams with processing steps for respectively a restaurant, pub, caterer, supermarket and distribution centres (including food banks) in Appendix A, EFSA is requested:

- 1) To identify and, if appropriate, rank the hazards in a restaurant, pub, caterer, supermarket and distribution centre and to describe appropriate control activities for the hazards identified including PRPs, CPs and CCPs and, where required, indicate critical limits and monitoring systems. The opinion might be limited to the consideration of regular consumers, not for specific more sensitive consumer groups (e.g. catering for hospitals).
- 2) To provide recommendations on additional hazards to be included in a FSMS within the frame of food donations at retail level. Such recommendations should cover all stages of food donations at retail starting from donations in relevant retail shops (including those covered by the first EFSA opinion and left-overs from restaurants or caterers), transportation, storage (at ambient temperature, chilled or frozen), distribution centres (e.g. food banks), processing and preparation for the final consumer (e.g. social restaurants).

When carrying out the analysis and making recommendations, EFSA should consider that mostly these small retailers are limited with regards 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 have been interpreted to include 'small retail establishments' for Terms of Reference (ToR) 1. The term 'small retail establishment' is interpreted, for the purposes of this Opinion, to be a restaurant, pub or catering business or supermarket that has less than 50 employees and an annual turnover or balance sheet total of €10 million or less (EC 2003/361) and includes 'micro businesses' (less than 10 employees with an annual turnover or balance sheet total of €2 million or less). These 'small retail establishments' require the 'simplified' HACCP approach developed in 'Hazard analysis approaches for certain small retail establishments in view of the application of their food safety management systems' (EFSA BIOHAZ Panel, 2017) as they usually lack the resources required to implement a full HACCP programme. Although the hazards encountered in small and larger retail establishments may be similar, fewer people are potentially affected since small businesses supply a small and often local population. Thus, the 'simplified' approach is restricted to small retail establishments. Moreover, the ToR was interpreted such that small retailers supplying susceptible populations (e.g. hospitals) were not included and should have full HACCP systems.

For ToR 2, 'food donations at retail level' is interpreted to mean all food donations from retailers, i.e. restaurants, caterers and supermarkets, including those covered in the previous Opinion (butcher, grocery, bakery, fish and ice cream shops), regardless of the size of the retailer. Thus, it includes food donations from 'small' catering establishments (restaurant, pub and/or caterer), and 'small' supermarkets as well as the food donation part of the chain for all retail establishments (regardless of their size). This Opinion will develop a FSMS, based on the simplified approach used in 'Hazard analysis approaches for certain small retail establishments in view of the application of their FSMS' (EFSA BIOHAZ Panel, 2017) that will: (1) identify the food safety hazards that may occur; (2) rank (if required) these hazards to inform the most suitable control action (PRP or critical control point (CCP)) and (3) develop control activities (PRP or CCP) to control these hazards (to include critical limits and monitoring systems for CCPs). A clear distinction is made between distribution centres that form part of the conventional retail chain (i.e. centres that act as a warehouse and supplier to supermarkets and referred to as 'retail distribution centres' in this Opinion) and distribution centres concerned entirely with food donation (serve as a collection point, storage and distributor of donated foods) and referred to 'food donation distribution centres' in this Opinion.

In this opinion, broad categories of chemical hazards (i.e. veterinary drug residues, pesticide residues, cleaning chemical residues and additives) will be identified but information on specific chemicals/compounds will not be provided. Allergens are discussed as a separate category of hazards.

Broad categories of physical hazards, including those intrinsically present in the product (e.g. bones) and those that may contaminate from the external environment (metal, glass, wooden splinters, etc.) will also be presented, including identifying the steps in the catering, retail and distribution centre/food donation chains where they occur and the associated control activities.

1.3. Additional information

FSMS are designed to prevent, reduce or eliminate hazards along the food chain, which includes primary production (farms), processors, retail distribution centres, supermarkets, restaurant, pub and other catering as well as food donation distribution centres, as shown in Figure 1. All participants in the food chain must have fully operational FSMSs in place. Food safety control at primary production is achieved using PRP activities including Good Agricultural Practices (GAP), Good Farming Practices (GFP), biosecurity and Good Hygiene Practices (GHP), and Good Veterinarian Practices (GVP). Current FSMS in the food processing plant, in catering and retail distribution centres and supermarkets are also based on PRPs (Good Manufacturing Practices (GMP), Good Hygiene Practices (GHP), Good Production Practices (GPP) and Good Distribution Practices (GDP)) but HACCP principles need also to be applied. The latter is used to control hazards, which cannot be controlled under the PRP and are of significant risk to consumers, for example thermal treatment of beef to eliminate bacterial pathogens. Although not covered by any legislative framework, consumers also have a role in food safety and should ensure the food is stored, handled and prepared in a manner that ensures it is safe for consumption. To facilitate this process, in addition to information which is mandatory in accordance with Regulation (EU) No 1169/2011⁶ on food information to consumers, all products at retail level should be accompanied by sufficient information to promote proper handling, storage and preparation by consumers. This information should be provided, preferably on the label but may also be communicated verbally or using leaflets, and will be covered under PRP 13 ('product information and customer awareness') later in this Opinion.

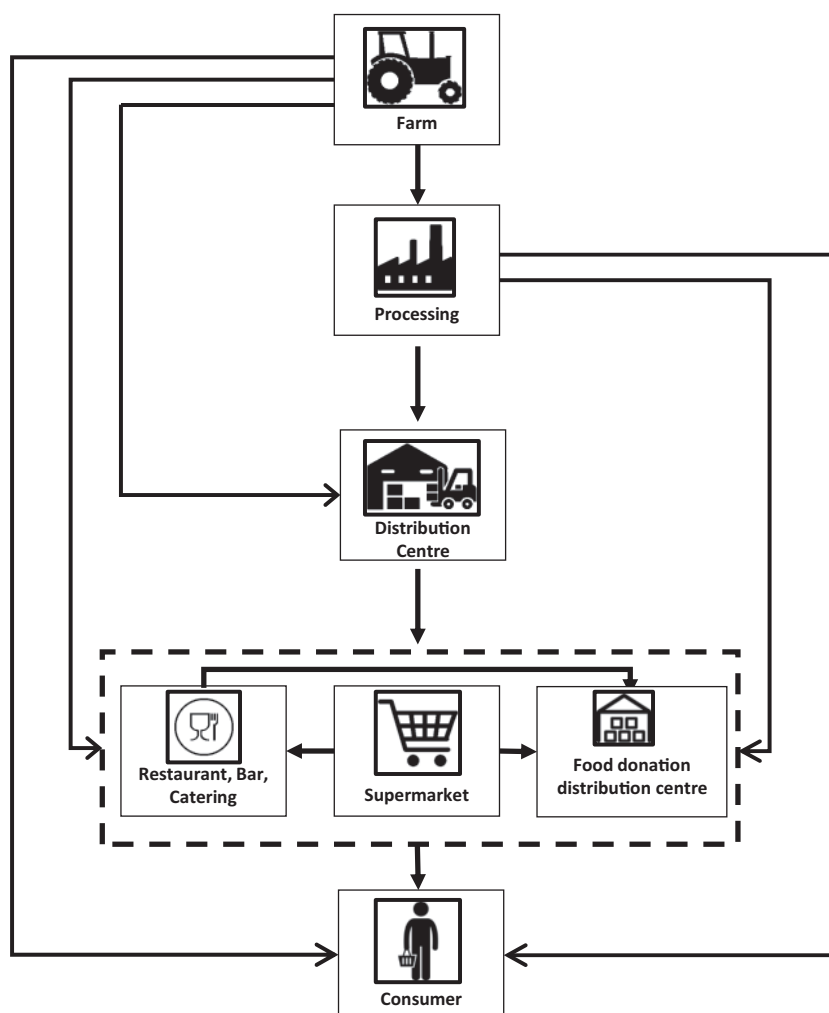


Figure 1: The food chain relationship between farms, food processors, distribution centres, supermarkets, catering (including restaurants and pubs) and food donation distribution centres

⁶ 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. OJ L 304, 22.11.2011, p. 18–63.

FSMSs are not static but require continuous review and updating. For example, specific hazards may change over time or with the inclusion of a new food, novel process, ingredient or suppliers. Their implementation also requires monitoring to verify that the actions required are being undertaken and that these are having the desired outcome in terms of food safety. 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, the effectiveness of the PRP and HACCP plan is dependent on a strong business food safety culture (Wallace et al., 2012, 2014).

The history and legislation covering HACCP and PRPs, the various challenges in implementing these systems in retail establishments and the different types of hazards (biological, chemical, physical and allergens) have been covered in the previous EFSA HACCP Opinion (EFSA BIOHAZ Panel, 2017). The target establishments in this Opinion include supermarkets, catering (restaurant, pub and other catering) and both retail and food donation distribution centres. Supermarkets provide a range of different products and/or activities including fruit and vegetable (grocery), meat (butcher and fish counter activities), dairy, other non-meat perishables, bread and cakes (bakery), and the FSMSs for these were partly covered in the previous EFSA HACCP Opinion (EFSA BIOHAZ Panel, 2017). This document will therefore focus on the new areas/activities and, where relevant, reference the previous Opinion. These areas include, for example, the handling and storage of dairy and other non-meat perishables in chilled cabinets, food products sold at the deli counter and using self-service salad bars.

Prerequisite programmes and critical control points

Food safety hazards are controlled using PRP activities and CCP activities. 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, 2006). 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).⁷ PRPs may be divided into 13 categories: PRP 1 to PRP 12 are provided in Commission Notice 2016/C 278/01 and, with the exception of PRP 11, are applied as described. In Commission Notice 2016/C 278/01 PRP 11 'Temperature control of the storage environment' has been modified to include all temperature control activities. Thus the title has been changed to 'Temperature control' and this covers the application of heat during cooking, removing heat during the chilling process as well as the temperature of the food during storage (e.g. chilled storage, frozen storage, hot holding in a bain-marie, etc.). An additional PRP 'product information and customer awareness' was developed by EFSA (EFSA BIOHAZ Panel, 2017), 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;
- PRP 12: Working methodology;
- PRP 13: Product information and customer awareness.

These are summarised in terms of the control infrastructure and activities required, monitoring, the requirement for record keeping and corrective action(s) in Table 1.

⁷ ISO 22000:2005—Food Safety Management Systems— Requirements for Any Organization in the Food Chain, ISO, 2005.

Table 1: 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' as defined by EFSA BIOHAZ Panel (2017)

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, results of microbiological testing. Also 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 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	Control infrastructure/ activities	Monitoring	Record keeping required (yes/no)	Corrective action
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 Based on the extent of the non-compliance consider disposal of the affected product
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 packed 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 (non-compliant) raw materials Review suppliers/ supplier requirements Revise acceptance criteria
PRP 11: Temperature control	Temperatures required during cooking or chilling are achieved for the required times. The temperature of the 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 cooking/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	Relevant information (storage conditions, shelf-life, allergens, etc.) should be provided, consistent with the general principles, requirements and responsibilities governing food information, and in particular food labelling as set out in Regulation (EU) No 1169/2011	Routine checks to ensure this information is provided	No	Review and revise the information as necessary

The PRPs provide the foundation for effective food safety management and should be in place as part of a HACCP programme. Indeed, FSMSs may be composed entirely of PRP activities and may not require additional CCPs. The latter is required when there are specific hazards that are not controlled by PRPs.

The Codex Alimentarius Commission defines HACCP as 'a system which identifies, evaluates, and controls hazards which are significant for food safety'.⁸

There are seven principles or steps that must be applied when developing a HACCP plan as follows:

- conducting a hazard analysis (including hazard identification of microbiological, chemical and physical hazards);
- determining critical control points (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');
- setting critical limits at each critical control (measurable and observable parameters);
- establishing monitoring procedures to assess whether or not the critical limits are adhered by making direct observations and objective measurements of critical limits;
- establishing corrective action(s) to be taken when a critical limit is breached;
- establishing verification procedures to ensure the HACCP process is performing as planned by observing activities, calibrating equipment, reviewing records, etc.;
- establishing documentation procedures (HACCP records including monitoring, corrective action, calibration, records, etc.

FSMSs for restaurant, pub, caterer, supermarket and distribution centres will now be developed and presented including hazard identification (biological, chemical, physical or allergen) and control activities.

2. Data and methodologies

2.1. Literature search

A literature search was used to gather scientific publications, reports and official documents relevant for this opinion. In general, the qualitative evaluation by means of literature review was carried out based on the knowledge and expertise of the Working Group (WG) members. The experts in the WG selected relevant references starting with review papers, book chapters and peer-reviewed papers retrieved through searches, broadening this out using 'footnote chasing' (White et al., 1992) until reaching a coverage of the subject considered sufficient by the WG. Considerable use was made of on-going citation input by WG members and information about relevant publications provided by members of the EFSA Biological Hazards (BIOHAZ) Panel.

2.2. EFSA opinions

The EFSA BIOHAZ Panel opinion on hazard analysis approach for certain small retail establishments (EFSA BIOHAZ Panel, 2017) was used as a basis for the development of a similar simplified foods safety management systems for the small food retail establishments and food donations discussed in this Opinion.

2.3. Guidelines

Various guidelines on FSMSs, including HACCP, were also used as a source of background information. These included information available from the Food and Agriculture Organization (FAO) and the World Health Organization (WHO), specifically 'Hazard Analysis and Critical Control Point (HACCP) system and guidelines for its application' (Annex to CAC/RCP 1-1969, Rev 3 (1997)).⁹ Various guidance documents available from the European Commission Food Safety/Food/Biological Safety/Food Hygiene/Guidance website¹⁰ were also used including 'Food Safety Management Systems', 'Prerequisite Programs (Good Hygiene Practices)', 'Procedures Based on the HACCP Principles', 'Controls/Auditing' and 'Training/Teaching' and the EU guidelines on food donation (2017/C 361/01).¹¹

⁸ CAC/RCP 1-1969, Rev. 2003, http://www.fao.org/input/download/standards/23/CXP_001e.pdf

⁹ <http://www.fao.org/docrep/005/Y1579E/y1579e03.htm>

¹⁰ http://ec.europa.eu/food/safety/biosafety/food_hygiene/guidance_en

¹¹ Commission notice — EU guidelines on food donation (C/2017/6872) OJ C 361, 25.10.2017, p. 1–29.

2.4. Expert discussion

After a review of the scientific literature and available guidelines from international organisations and the previous HACCP opinion, 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.

3. Assessment

3.1. Development of a simplified food safety management system

The simplified FSMS was previously developed for butcher, bakery, fishmonger, grocery (fruit and vegetable) and ice cream shops and is described in the Opinion 'Hazard analysis approaches for certain small retail establishments in view of the application of their food safety management systems' (EFSA BIOHAZ Panel, 2017). The rationale for the development and implementation of the 'simplified' approach is described in detail in that document. The 'simplified' approach thus developed differs to the 'classical' approach to food safety as follows: (1) the target establishment need only to be aware that a hazard (biological, chemical, physical or allergen) may occur at a particular stage, without having an in-depth knowledge of that hazard (e.g. knowing there may be a biological hazard associated with raw meat without knowing it is *Salmonella*); (2) the target establishment must understand that failure to perform certain activities, such as separating raw and ready-to-eat (RTE) foods, constitutes a risk; (3) there is no requirement to understand or apply risk ranking; (4) allergens are treated as a separate hazard, as opposed to a chemical hazard; and (5) control is based on PRP activities. Moreover, 13 PRPs were described, 12 of which were based on those described in the Commission Notice 2016/C278/01, with the inclusion on an additional PRP 'product information and customer awareness' (PRP 13). For the purpose of this mandate, four additional PRPs have been developed. While they may overlap with the 13 PRPs mentioned above, these 4 PRPs are required to provide control for specific activities within the supermarket, restaurants, food distribution but especially food donation which presents unique challenges in relation to shelf-life, handling returned foods and freezing to preserve food intended for food donation.

PRP 14: Shelf-life Control

Shelf-life is the period of time during which a food maintains its acceptable or desirable characteristics under specified storage and handling conditions. These acceptable or desirable characteristics may be related to the safety or quality of the product and can be microbiological, chemical or physical in nature. Regulation (EU) No 1169/2011 requires that the shelf-life of a foodstuff be indicated by either a date of minimum durability ('best before') or by a 'use by' date. The date of minimum durability, or 'best before' date, is the date until which a foodstuff retains its specific properties, e.g. taste, aroma, appearance, any specific qualities which relate to the product, vitamin content, oxidative status, etc., when the product has been stored appropriately and the package unopened. Typically, a 'best before' date is used for food products such as canned, dried, ambient, frozen foods, etc.¹² By law (EC 1169/2011, Annex III, Point 6), frozen meat, frozen meat preparations and frozen unprocessed products must include a date of freezing (or first freezing where the product has been frozen more than once). Many foods that are past their 'best before' date may still be safe to eat, but their quality may have deteriorated. In contrast, perishable foods may constitute a food safety hazard after a relatively short period of time and shelf-life is indicated using a 'use by' date, the date up until which the food may be consumed safely, assuming correct storage. After the 'use by' date, a food is deemed unsafe in accordance with Articles 14(1) and 14(2) of Regulation (EC) No 178/2002¹³ and cannot be sold and should not be consumed. Typically, a 'use by' date is used for fresh meat, fresh fish and chilled RTE foods. An exception to this is raw, shell eggs which require a 'best before' date as set out in Regulation (EC) No 589/2008¹⁴ as regards the marketing standards for eggs, set 28-days from laying. Furthermore, uncut fresh fruit and vegetables, except sprouting seeds and similar products such as legume sprouts, do not require a 'best before' date. The FBO (usually the manufacturer or producer)

¹² https://www.fsai.ie/faq/shelf_life/best_before_and_use_by.html

¹³ 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.

¹⁴ Commission Regulation (EC) No 589/2008 of 23 June 2008 laying down detailed rules for implementing Council Regulation (EC) No 1234/2007 as regards marketing standards for eggs. OJ L 163, 24.6.2008, p. 6–23.

is responsible for deciding whether a 'best before' or 'use by' date is required as well as the length of shelf-life. FBOs who receive bulk food products and subsequently break it down and repack it are responsible for ensuring that the information provided relating to this product, including its shelf-life, is correct, as part of their obligations under Article 8 of Regulation (EU) No 1169/2011. If changes are made to the information provided, if allowed by EU and national rules, these may only be made provided such modifications do not mislead the final consumer or otherwise reduce the level of consumer protection or the opportunity for the final consumer to make informed choices. The FBOs are responsible for any changes they make to the food information accompanying a food.

Based on Regulation (EU) No 1169/2011, a 'best before' or 'use by' date does not have to be declared on non-prepacked foods. Non-prepacked foods are foods offered for sale to the final consumer or to mass caterers without prepacking. It also includes foods that are packed on the sales premises at the consumer's request (e.g. sandwiches at a deli counter) or foods prepared on the premises and prepacked for sale from that premises (e.g. lasagne made on the premises, packed and available for sale). Furthermore, Annex X, 1(d) states that "an indication of the date of minimum durability shall not be required for:

- Fresh fruit and vegetables which have not been peeled, cut or similarly treated (this does not apply to sprouting seeds and similar products such as legume sprouts which do require a date of minimum durability)
- Wines, liqueur wines, sparkling wines, aromatised wines and similar products obtained from fruit other than grapes, and beverages falling within CN code 2206 00 obtained from grapes or grape musts
- Beverages containing 10% or more alcohol by volume
- Bakers' or pastry cooks' wares (bakery products) which, given the nature of their content, are normally consumed within 24 h of their manufacture
- Vinegar
- Cooking salt
- Solid sugar
- Confectionery products consisting almost solely of flavoured and/or coloured sugars
- Chewing gums and similar chewing products."

The FBO should routinely check foods to assure the removal of foods after expiry of the 'use by' date. It is not possible to place products on the market past the 'use by' date. In case of freezing foods prior to the 'use by' date, in view of their further redistribution, guidelines in some MS recommend relabelling the frozen food with a 'best before' date. This procedure can be supported by traceability systems through the tracking and online visibility of inventory shelf-life and associated expiration dates. This system enables FBOs to proactively move these products before their expiration and send them for disposal, further processing or donation.

PRP 15: Handling Returned Foods

A FBO must ensure that food returns are held and kept separate until they are: (1) ascertained to be safe and suitable for consumption; (2) destroyed or otherwise used or disposed of in line with applicable EU legislation, such as Regulation (EC) No 1069/2009¹⁵ on animal by-products not intended for human consumption; (3) (a) returned to its supplier or (b) sent for donation if the product is fit for human consumption; and (4) further processed. It is important that there is full traceability of returned products as part of the overall traceability system imposed by Regulation (EC) No 178/2002. Therefore, the traceability system should keep track of food that is returned by customers and food that is disposed of by the FBO. It is suggested that the traceability system should record a basic description of the returned food, the name and contact details of the customer returning the food, the date of return and the reasons for return as well as actions taken. Returned food that does not comply with retailer's specifications may be suitable for donation if fit for human consumption. For example, foods may be returned for reasons other than food safety, e.g. quality issues, size of product, insufficient shelf-life according to retailer Minimum Life on Receipt requirements, packaging issues, etc. If the food is to be donated, it should be in proper condition and if there are any indications of damaged packing materials, temperature abuse, quality deterioration, etc.; these foods should be

¹⁵ Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation). OJ L 300, 14.11.2009, p. 1–33.

disposed of. Moreover, there should be sufficient shelf-life remaining (as indicated by the 'use by' or 'best before' dates (see PRP 16)) to enable transportation, processing and/or delivery to consumers.

PRP 16: Evaluation for food donation and allocation of remaining shelf-life

The following types of foods can be considered for food donation:

- A) Prepacked foods which carry date marking;
- B) Prepacked foods which do not need a 'best before' date, e.g. packed fruits and vegetables, which have not been peeled, cut or similarly treated, bakery products or other foods as listed in PRP 14 (as per Regulation (EU) 1169/2011);
- C) Non-prepacked foods which may need to be wrapped or packed before donation can occur, e.g. fresh fruits and vegetables, fresh meat, fresh fish, bakery products, surplus food from catering/restaurants (food which was prepared by the catering/restaurant but never served to the consume as long as they have been handled, stored and are distributed appropriately).

In this Opinion, a strict interpretation is applied regarding the 'use by' date. Foods placed on the market (including those intended for food donation) must not exceed the 'use by' date, during distribution nor before intended consumption. However, in the case of a 'best before' date, as food safety is not directly impacted, products exceeding this date could still be distributed for food donation purposes if the following conditions apply: (1) the integrity of packing material (no damage, no opening, no condensation, etc.) is not compromised; (2) proper storage of the food according to the required temperature and other conditions (e.g. deep freezing at -18°C or dried storage); (3) in the case of frozen food, checking the freezing date (if provided); (4) the food is still organoleptically acceptable (still acceptable for consumption, e.g. absence of moulds, rancidity, etc.); and (5) no exposure to any other significant food safety or other health risk, e.g. radioactivity. The amount of available product life remaining should also be assessed both upon sending and receipt of the product made available for food donation.

Tasks of donors in relation to shelf-life of foods:

A) For foods with a 'best before' date, if donation takes place earlier than the labelled date, no further action is needed by the donor, except for maintaining package integrity and assuring the prescribed storage conditions are achieved. In cases where donation occurs after the 'best before' date, according to EU rules, it is permitted to redistribute these products, provided that they are still safe and there is no ambiguity in the information provided to consumers. Some MS have established indicative guidelines for food redistribution past the 'best before' date and the donors should consult these when assessing suitability of the food for donation. Such products may be marketed separately with labelling indicating that the 'best before' date has been exceeded and where relevant, recommending immediate consumption.

For foods labelled with a 'use by' date, food donors should ensure that there is sufficient shelf-life available upon the delivery of such products to food banks and other charity organisations to allow for their safe redistribution and use by the final consumer prior to the indicated 'use by' date. Some MS have specific rules regarding the minimum amount of shelf-life which should be available when foods are provided for donation. For example, in France, there is a requirement that there should be a minimum of 48 h of available shelf-life remaining at the time when the product is delivered to the food bank or other charity.

Under no circumstance can the 'use by' dates be exceeded as the food cannot be considered safe for human consumption beyond this date.

B) Prepacked foods which do not need a shelf-life date as listed in PRP 14, e.g. packed fruits and vegetables, pastries, etc., need to be handled and stored appropriately and checked to ensure they are acceptable for consumption.

C) In case non-prepacked foods are donated (e.g. fresh fruits and vegetables, fresh meat, fish, pastries with whipped cream or surplus food from catering), wrapping or repackaging may be required by the donor to allow redistribution to the recipients.

Donated fresh meat, fresh fish, surplus food from restaurant/catering, etc., may be frozen by the donor and transported in this state. If not frozen by the donor, this should be done immediately upon receipt at the donation centre.

Donors and recipients should ensure timely transportation of foods to the recipients, under proper and documented conditions of temperature and storage, so that the products retain the remaining shelf-life.

Tasks of recipients in relation to the shelf-life of foods:

In addition to the donors, recipients should inspect the food to assess, to the possible extent, the hygiene, safety and quality status of all foods received including packing. This may be done with destructive (e.g. opening of the package, sensory evaluation, etc.) or non-destructive methods (e.g. temperature records, visual inspection for overall appearance, drip loss, softening, browning and package integrity, etc.). In general, although this will depend on the intended use of the food, recipients should inspect the completeness and readability of the labels and ensure compliance with the requirements of Regulation (EU) 1169/2011 and the existence of clear food handling instructions. If refrigerated foods are to be frozen, then the aforementioned practices and those detailed in PRP 17 should be applied.

For foods labelled with a 'use by' date, recipients should make sure that food is received in a refrigerated state (e.g. the surface and core temperature of food upon reception is at the chilled temperature as defined by the competent authorities in the relevant member state) or in the frozen state and be able to assess that the correct storage temperatures were maintained throughout the chill chain.

Although a 'use by' date does not have to be declared on non-prepacked foods (EC 1169/2011), this does not preclude the donation of non-prepacked, highly perishable foods such as fresh meat, fish or surplus foods from restaurants/catering provided that, for food of animal origin, national measures are in place to authorise such practice (see PRP 17 below). As a general rule, these foods should be consumed immediately but may be stored at the required temperature, or frozen, if there is written information accompanying the food which shows its history, including conforming to required storage time and conditions.

PRP 17: Freezing food intended for donation

Freezing of foods before their expiration date in order to extend shelf-life and facilitate safe redistribution would facilitate donation as food received by redistribution organisations and charities cannot always be delivered to the customer before the 'use by' or 'best before' (in the case of chilled foods) date. However, for hygienic reasons, Regulation (EC) No 853/2004¹⁶ prescribes that food of animal origin intended for freezing must be frozen without undue delay after production. This requirement applies to retailers, including those supplying other food business operators such as food banks and freezing such food at retail is therefore not allowed. There are exceptions to this and some member states are allowed to freeze food of animal origin for redistribution purposes, provided that such retail activity is marginal, localised and restricted in accordance with its Article 1(5)(b)(ii). National measures should be adopted accordingly and notified to the Commission and other Member States.

Freezing of perishable foods that carry a 'use by' date or chilled foods that have a 'best before' date (if permissible), should be done as early as possible before, but definitely no later than the end of the 'use by' date indicated on the label and to a temperature of -18°C or lower. This temperature must be maintained throughout distribution.

In the case of non-prepacked foods which are donated such as non-prepacked fresh meat, fresh fish, surplus food from restaurant/catering, which do not contain a 'use by' date, the recipient should be informed of the storage time and conditions of these foods to allow an assessment of the suitability for freezing or consumption (Table 2).

Freezing of food can be done both by food donors or recipients, if permissible by the MS and national provisions are respected. In doing so, the 'use-by' or 'best before' date can be extended. In some member states (e.g. Ireland), it is recommended that the frozen food be used within 1 month of freezing. In other member states (e.g. Belgium) this may be up to 2 months. In addition, the packages should indicate the original 'use by' or 'best before' date (if provided) of the products and the date it was frozen and provide instructions for proper thawing practices. Labelling should be done by the freezing operator, who is also responsible for the repacking of the frozen food. Depending on the type of food, there may be a requirement to consume immediately after thawing. In the UK, for example, it is recommended that food should be consumed within 24 h of thawing (Jones et al., 2017). Such information should be conveyed to the consumers, for example, using information on the label (PRP 13).

¹⁶ 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.

Table 2: Descriptive summary and associated monitoring, record-keeping and corrective activities with the newly introduced PRPs 14 (shelf-life control), 15 (handling returned foods), 16 (shelf-life – time that can still be allocated for prepacked and non-prepacked food and evaluation for food donation) and 17 (freezing food intended for donation)

PRP	Control infrastructure/ activities conducted by both donors and recipients	Monitoring	Record keeping	Corrective action
14: Shelf-life control	<p>Compliance with Regulation (EU) 1169/2011 for food labelling regarding date marking ('use by' vs 'best-before' dates)</p> <p>Proper storage of foods according to the conditions of temperature, light and moisture conditions, recommended by the manufacturer</p>	<p>Foods should be routinely checked to ensure the removal of products after expiry of the 'use by' date. FBOs may also take this opportunity to check the integrity of the packaging, proper storage conditions, etc.</p>	No*	<p>Disposal, or refuse or return of foods in the following cases:</p> <ol style="list-style-type: none"> 1) insufficient remaining product life available 2) reception after expiration of 'use by' date 3) if damaged packing is detected 4) improper or inadequate (unclear or invisible) labelling
15: Handling returned foods	<p>Proper warehouse facilities for different types of storage (chilled, frozen, ambient) with segregation from non-returned products</p> <p>Logistics and traceability systems using first in-first out approach</p>	<p>Batch inspection of package integrity and other visual defects, no visible signs of spoilage</p> <p>Temperature monitoring at receiving. Decision on acceptability for donation</p>	Yes, record of the basic description of the returned food, date of return and its destination	<p>Disposal of foods deemed inappropriate for human consumption or that were not timely placed in proper storage</p> <p>Reprocessing of foods to be rendered safe</p>
16: Evaluation for food donation and allocation of remaining shelf-life	<p>Products with the shortest remaining shelf-life-first out logistics for chilled and ambient delivery</p> <p>Facilities and working methodology for sensory evaluation</p> <p>Traceability systems</p>	<p>Evaluation if a 'best before' or 'use by' date is present on prepacked foods and decide which time still can be allocated</p> <p>In case of prepacked foods without a legally required shelf-life date (e.g. packed fruits and vegetables, bakery wares, wine, etc. – see list PRP 14) a sensorial evaluation and decision if still fit for consumption</p> <p>In the case of food with a 'best before' date, foods exceeding this date may be considered for food donation but this food should be routinely checked to ensure: (1) integrity of packing material (no damage, no opening, no condensation, etc.), (2) proper storage of the food according to required temperature and other conditions (e.g. deep freezing at –18°C or dried storage), (3) in case of frozen food, checking</p>	Yes, logging of initial labelling/ information upon reception	<p>Disposal, or recall of foods in case of after expiration of 'use by' date</p> <p>Foods that require but do not have a shelf-life date: disposal</p>

PRP	Control infrastructure/ activities conducted by both donors and recipients	Monitoring	Record keeping	Corrective action
		the freezing date, (4) evaluate sensory property (still acceptable for consumption (absence of moulds, rancidity, etc.), and (5) no exposure to any other significant food safety hazard or other health risk		
17: Freezing for food donations	<p>Rapid freezing and frozen storage infrastructure</p> <p>Logistics</p> <p>Compliance with Regulation (EU) 1169/2011 for food labelling regarding the expiration date ('use by' vs 'best-before' dates)</p> <p>Compliance with Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin</p>	<p>Temperature monitoring</p> <p>Inspection of package integrity</p> <p>Labelling inspection</p> <p>Indication of freezing date and allocating new 'best before' or 'use by' date</p>	No	<p>Disposal of foods in the following cases:</p> <ol style="list-style-type: none"> 1) reception after expiration of 'use by' date 2) if packing damages are detected 3) improper or inadequate (unclear or invisible) labelling 4) foods not timely placed in proper storage

*: Whilst there is no need to keep records in relation to shelf-life, traceability requirements apply to food donation.

3.2. Application of a simplified food safety management system in distribution centres, supermarkets, restaurants, pubs, caterers and food donations

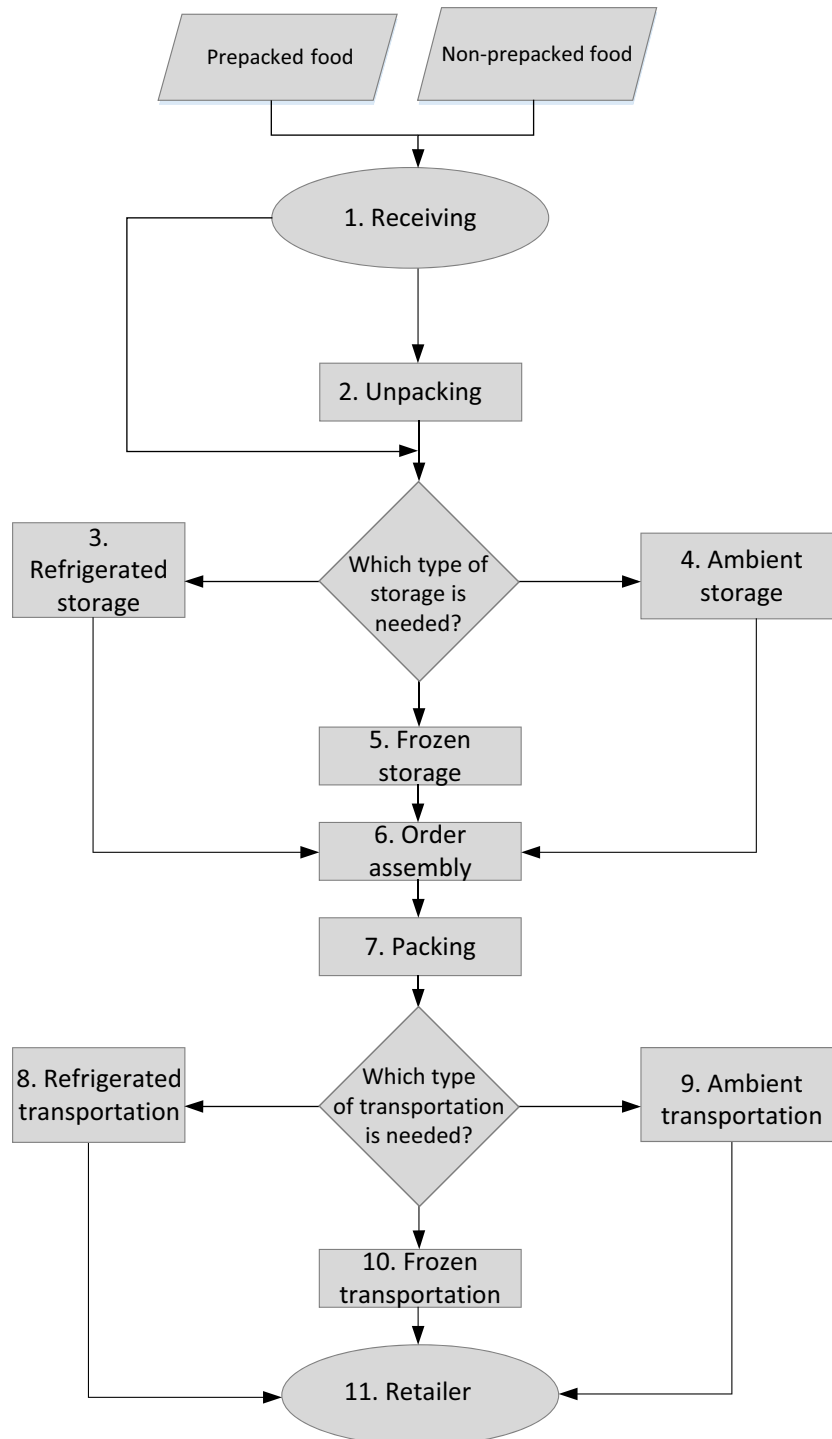
In this section, the stages involved in distribution centres, supermarkets, restaurants (including pubs and catering) and food donations are summarised, including a flow diagram for each.

3.2.1. Distribution centres

Distribution centres are typically warehouses with conditioned temperatures and have activities associated to the collection of (big) volumes of foods from vendors/producers (typically on pallets, boxes or shipping containers), storing it (for a short period of time), repalletising the products and distributing them (often including transportation). Their customers can be retailers, other wholesalers or they may sell directly to individual consumers but this is a minor activity. Distribution centres are also referred to as wholesalers, order fulfilment centres, cross-dock facilities, bulk break centres, and package handling centres. The name by which the distribution centre is known is commonly based on the purpose of the operation. For example, a 'retail distribution centre' normally distributes goods to retail stores, an 'order fulfilment centre' commonly distributes goods directly to consumers. This type of distribution centre is mainly used by e-commerce and others that need to outsource the logistics of order processing and delivery, and a 'cross-dock facility' stores little or no product but distributes goods from a truck or railroad to other destinations with little or no storage in between.

In the food donation chain, food banks are typical food donation distribution centres, which are collecting foods from multiple donors, are storing them and redistributing towards various charity organisations. One of the major issues for food banks is the flexibility in their work, as a food donation chain is heavily dependent on charity; it is not always clear which foods will be delivered and when these deliveries will take place. This is completely different from the well organised just-in-time principle in conventional (retail) food distribution, where an optimisation of the request-offer policy minimises food waste. Thus, food banks need more flexibility in their organisation (e.g. more space to store, more people to manage the work, etc.) and need a management plan focused on shelf-life and food safety.

The stages in distribution centres are summarised in the flow diagram (Figure 2) below. The hazards and control PRPs are presented in Table 5 (covers all target establishments) in Section 3.3 and Table A.1 (specific for food distribution centres) in Appendix A.1.



- Legend for flow charts:
- process step
 - start-end of production process
 - raw materials, intermediate product or final product
 - decision between different possible production steps

Figure 2: Flow diagram for food distribution centre

3.2.2. Supermarket

Supermarkets are usually self-service shops offering a wide range of food and household products. The food products include fruit, vegetables, meat, fish, seafood, dairy, eggs, baking ingredients, canned foods, dried cereals, bakery, alcoholic and non-alcoholic drinks, juices, beverages, delicatessen foods, RTE foods, diet foods, dressings, sauces, frozen foods, tea, coffee and snack foods. Many of these come in individually wrapped packages and are offered in the aisles of the main floor. However, they may also be non-prepacked and/or available through butcher, seafood, bakery and delicatessen counters as well as through the salad bar.

Supermarkets are usually chain stores supplied by retail distribution centres that are part of the same retail company. Large multinational supermarket chains purchase food from around the world, which is often transported to a central distribution centre(s) that supplies stores in several different countries. Thus, the range of food ingredients, products, sources and transportation distances has increased substantially in recent years. However, supermarkets may also be small companies with one or two retail outlets where the goods are purchased from wholesale stores or warehouses that are 'trade only'. Perishable or short shelf-life foods such as pasteurised milk, meat and bread are usually supplied directly by the processor. Some supermarkets also include a café or other catering facility.

In recent years, mobile supermarkets have also emerged to provide a direct connection between producers and consumers as well as opportunities to acquire and retain new customers. Mobile supermarkets are considered to be 'temporary premises' in EC 852/2004 and may sell a range of foods from mobile sales vehicles. However, they still represent a very small segment of the food retail market but may be higher risk in terms of food safety.

The stages in supermarkets are summarised in the flow diagram (Figure 3) below. The hazards and control PRPs are presented in Table 5 (covers all target establishments) in Section 3.3 and Table A.2 (specific for supermarkets) in Appendix A.2.

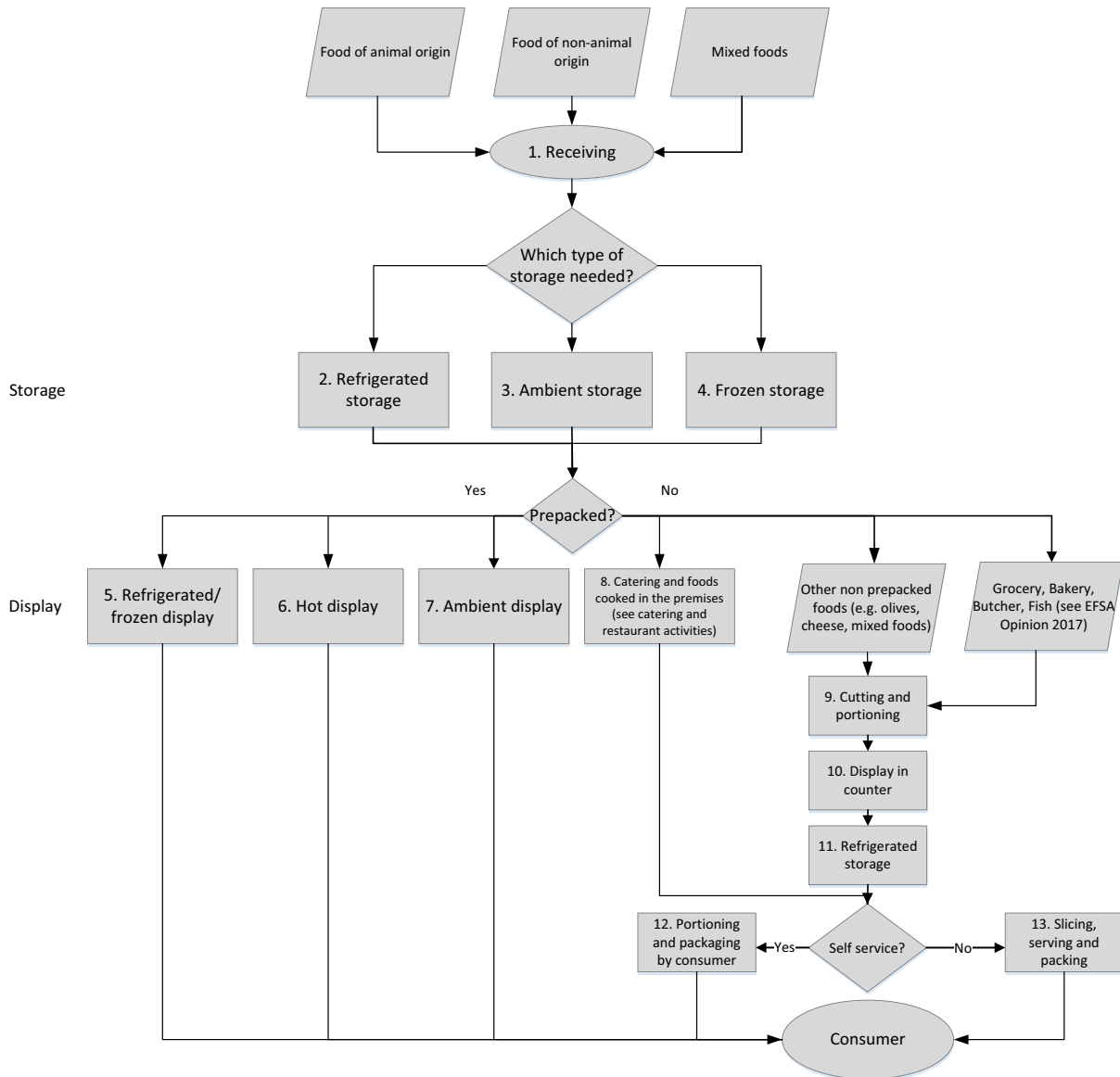


Figure 3: Flow diagram for supermarkets

3.2.3. Restaurants (pubs and other catering)

Catering covers a range of food and drink related activities. While restaurants focus on food preparation, the main business of pubs is serving alcoholic and non-alcoholic drinks and beverages such as tea and coffee. Food may also be provided. Catering differs to both the restaurant and the pub as the food is often prepared offsite and transported to the venue where it is to be served. Food safety is reliant on good hygiene as well as proper food handling, preparation and storage. Perishable foods such as meat and dairy products and cooked foods that are not for immediate consumption must be stored at chilled temperatures (in a fridge, cold room or other chilling device). Chilling units must not be over stacking and the air in the chilling unit should circulate freely around the foods being stored. Perishable foods may also be stored frozen at temperatures of -18°C or below. Exceptions to this include ice cream, which should be stored at -12°C or lower. Frozen foods should be thawed in the chiller or if necessary using the defrost cycle in a microwave oven but never at room temperature as this would allow bacterial pathogens on the surface of the food an opportunity to grow, multiply and/or produce toxins. In addition, care should be taken to ensure that the core of the food is fully thawed as a frozen centre may not receive sufficient heat in any subsequent cooking process to ensure the destruction of pathogens.

Cooking is a reliable method of eliminating most food-borne pathogens. It is generally accepted that cooking to a core temperature of at least 70°C for at least 2 min or achieving at least 75°C in the

centre of the food are sufficient to destroy most vegetative bacteria, and some viruses and parasites. However, pork products, for example may require higher temperatures and/or longer times to eliminate pathogens such as hepatitis E virus. Lower cooking temperatures are applied for some dishes. To assure food safety, the cooking time–temperature conditions used should be validated to ensure the elimination of pathogens and these dishes should be consumed shortly after cooking, e.g. within 30 min of cooking, unless maintained at temperatures above 65°C (where they can be consumed up to 4 h after cooking).

In restaurants, pubs and catering establishments, additional thermal treatments, (other than conventional cooking) may also be applied (see Table 3) for culinary purposes, without necessarily targeting (or achieving) pathogen inactivation. These pathogens, which are primarily bacterial, are included in the 'biological hazards' referred to elsewhere in this document. While all bacteria exist as vegetative cells some are also capable of forming spores, a mechanism to facilitate survival under adverse conditions. Both vegetative cells and spores need to be controlled (destroyed by cooking or growth prevented by correct storage conditions) if the safety of the food is to be assured. Heating food, regardless of the primary purpose may also affect the chemical safety of the product, due to the formation of processing contaminants, thus precautions should be applied. Typical examples are shown in Table 4.

Hot holding is a temporary measure often applied in catering. For example, food should be placed in the bain-marie or other hot holding device and held at 63°C or higher thus preventing the growth and/or toxin production by bacteria such as *Staphylococcus aureus*, *Clostridium perfringens* and *Bacillus cereus*.

In catering, foods are often precooked, chilled, transported and reheated. Precooked foods that are not served at chilled temperatures must be heated immediately after removal from the chiller/chilled transportation, to a core temperature of, e.g. not less than 70°C, must be served shortly after heating, e.g. within 30 min, and must not be reheated more than once. While reheating will destroy most bacterial cells, preformed toxins may remain. Thus, this activity should be used in conjunction with chilling and/or hot holding.

Temperature monitoring may assist in better temperature control throughout the above processes. Serving of chilled, cooked or reheated products that have been exposed to a temperature-abuse zone (typically between 5 and 60°C) should follow national safety guides (or other relevant document). Beyond this specified tolerable duration of temperature abuse, products should be immediately chilled or disposed of (e.g. if already reheated once, or the duration of temperature abuse is greater than the maximum allowable).

Some dishes containing ingredients of animal origin may be served raw or semi-raw. It has been reported that these dishes represent a higher risk of food-borne infection for consumers. Indeed several *Salmonella* and Shiga toxin-producing *Escherichia coli* (STEC) outbreaks in Europe have been associated with these products (Haeghebaert et al., 2001; Isakbaeva et al., 2005; Doorduyn et al., 2006; Greenland et al., 2009; Whelan et al., 2010; Soborg et al., 2013). In France, where the consumption of undercooked minced beef is more common than in other European countries, case control studies have identified eating undercooked minced beef as a major risk factor for STEC-associated haemolytic uraemic syndrome (HUS) and *Salmonella* infection in children (Haeghebaert et al., 2001; Valliant, 2005). In order to minimise the risk of food-borne infection, strict controls should be in operation throughout the food chain operated as PRP 10 (raw materials) with stringent requirements for hygienic handling (PRP 2, 5 and 9). To avoid cross-contamination of other foods, there should be strict segregation of preparation areas for these particular products (PRP 1) from the other products served by the same restaurant, pub and/or catering service.

In the USA, the FDA Food Code includes the following: (1) undercooked ground meat should not be offered for sale on a children's menu; (2) consumers should be informed of the significantly increased risk of consuming such foods by way of a prescribed disclosure and reminder; and (3) these products should not be offered for sale in food establishments that serve a highly susceptible population. Similar recommendations are found in EU member states. For example, the Food Safety Authority of Ireland (FSAI) 'strongly advise' that undercooked or raw minced beef or beef burgers should not be consumed by children under 5 years of age, pregnant women, people older than 65 years old and people undergoing treatments or who have medical conditions which impair their immune system (FSAI, 2013).¹⁷ In the UK, restaurants serving undercooked beef products need

¹⁷ <https://www.fsai.ie/microbiologicalsafetyofrawmincedbeefandbeefburgersonretailsaleinireland.html>

specific approval and the Food Standards Agency (FSA)¹⁸ requires: (1) 'steps throughout the supply chain to minimise and/or reduce the risk of contamination of meat used to make burgers the following for beef burgers that are served less than thoroughly cooked'; (2) 'a process or processes which achieve a minimum reduction of bacteria of 4-log (equivalent to killing 99.99% bacteria)'; and (3) 'messages that inform consumers regarding the potential risks from burgers that are not thoroughly cooked'. Indeed, the latter activity is required or suggested in many EU member states and a similar approach could be applied in the target establishments in this Opinion (PRP 13). However, it should be noted that the FBO is always responsible for the safety of the food they provide even when the customer has been informed of a potential higher risk from raw or semi-cooked products.

The stages in restaurants, pubs and catering are summarised in the flow diagram (Figure 4) below. The hazards and control PRPs are presented in Table 5 (covers all target establishments) in Section 3.3 and Table A.3 (specific for restaurants, pubs and catering) in Appendix A.3.

Table 3: Summary of the most commonly used culinary practices where heat is applied and its impact on microbiological safety

Culinary practice	Heat type	Effect on vegetative pathogens or spores?
Grilling, barbeque	Dry heat	Only vegetative pathogens at the surface will be affected
Oven baking/roasting	Dry heat	In oven baking, dry air is used and the surface of the food will obtain high temperatures. The core temperature will depend on the time that the food is in the oven and on the starting temperature of the food. Care has to be taken for baking/roasting frozen food to ensure a sufficiently high core temperature is achieved. Vegetative pathogens will be killed where sufficient heat is applied; spores may also be inactivated if the temperature is sufficiently high for sufficiently long
Microwaving (heating or reheating)	Electromagnetic waves	As in oven, but mainly effective in foods with high moisture content or in aqueous spots within bulk food pieces
Frying	Frying oil	Frying has a direct impact on the surface pathogens as high temperatures are applied; however, the core temperature will depend on the time of frying. Vegetative cells and spores will be inactivated, where sufficient heat is applied
Hot smoking	Steam and smoke	Hot smoke will have a direct impact on the vegetative pathogens on the surface; the core temperature will depend on the time of application
Steaming	Steam	Only vegetative pathogens are affected; the core temperature will depend on the time of application
Vacuum cooking (sous-vide), slow cooking	Steam	In this culinary practice, the food temperature will stay relatively low (typically 40–50°C) and any bactericidal effect will be limited
Blanching, poaching,	Hot water or steam (usually 70–110°C) (blanching), or in the required amount of liquid at just below boiling point (poaching)	Blanching is performed to destroy enzymes in vegetables and to make produce more soft. A reduction in vegetative pathogens may be achieved
Stewing	Long, slow cooking method where food is cut into pieces and cooked in the minimum amount of liquid, water, stock or sauce	Mainly targeting vegetative bacterial cells but spores may also be affected
Sterilisation/retort cooking	Hot water applied, often in a pressurised system	Elimination of spore forming pathogens if the time–temperature combination is sufficiently high, e.g. 121°C for 3 min

¹⁸ <https://www.food.gov.uk/sites/default/files/media/document/beef-burger-advice-industry.pdf>

Table 4: Overview of most commonly used culinary practices and their impact on chemical food safety

Process	Food	Processing contaminants	What can be done to avoid contaminant
Grilling/ barbecuing	Meat, meat products, fish and fish products	Polycyclic aromatic hydrocarbons (PAHs) Maillard reaction products, e.g. heterocyclic amines Nitrosamines	Avoid overcooking (black and 'coaled meat or fish') Avoid fat from the meat dripping on the coals resulting in flames Use of wood giving low contamination If nitrite/nitrate salted: low concentrations of nitrite/nitrate
Frying	Meat and meat products	Maillard reaction products, e.g. heterocyclic amines Nitrosamines (nitrite/nitrate salted)	Avoid overcooking (black and 'coaled meat') Use proper fats for frying Low concentrations of nitrite/nitrate ^(a)
	Fish and fish products	Maillard reaction products Nitrosamines	See meat and meat products Time and temperature If nitrite/nitrate salted: low concentrations of nitrite/nitrate
Oven preparation	Potatoes	Acrylamide	See 'Methods of Reduction for finished French Fries' in acrylamide toolbox ^(b) ; Commission Regulation (EU) 2017/2158 ^(c)
Deep frying	Potatoes	Acrylamide	See 'Methods of Reduction for finished French Fries' in acrylamide toolbox ¹³ ; Commission Regulation (EU) 2017/2158
	Other foods	Hydrolysis and oxidation products in oil	Use of good quality of oil; changing oil regularly
Baking	Bread and bakery products	Acrylamide	See 'Methods of Reduction for Bread Products' ^(d) and 'Methods of Reduction for Biscuits, Crackers and Crisp-bread' ^(e) in acrylamide toolbox; Commission Regulation (EU) 2017/2158
Toasting	Bread	Acrylamide Furan	Temperature and time control; not browning too much
Smoking	Meat and meat products as well as Fish and fish products	PAH Nitrosamines	Use of wood resulting in lower contamination Time and temperature If nitrite/nitrate salted: low concentrations of nitrite/nitrate

(a): Nitrites are used to inhibit the germination of *Clostridium botulinum* spores and the concentrations used should be sufficient to achieve this if the food is to be stored anaerobically at temperatures above 3°C. Reformulation using other food additives and/or reducing the holding time may also be applied.

(b): https://ec.europa.eu/food/sites/food/files/safety/docs/cs_contaminants_catalogue_acrylamide_frenchfries-final_en.pdf

(c): Commission Regulation (EU) 2017/2158 of 20 November 2017 establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food. OJ L 304, 21.11.2017, p. 24–44.

(d): At https://ec.europa.eu/food/sites/food/files/safety/docs/cs_contaminants_catalogue_acrylamide_bread-final_en.pdf

(e): https://ec.europa.eu/food/sites/food/files/safety/docs/cs_contaminants_catalogue_acrylamide_biscuits-final_en.pdf

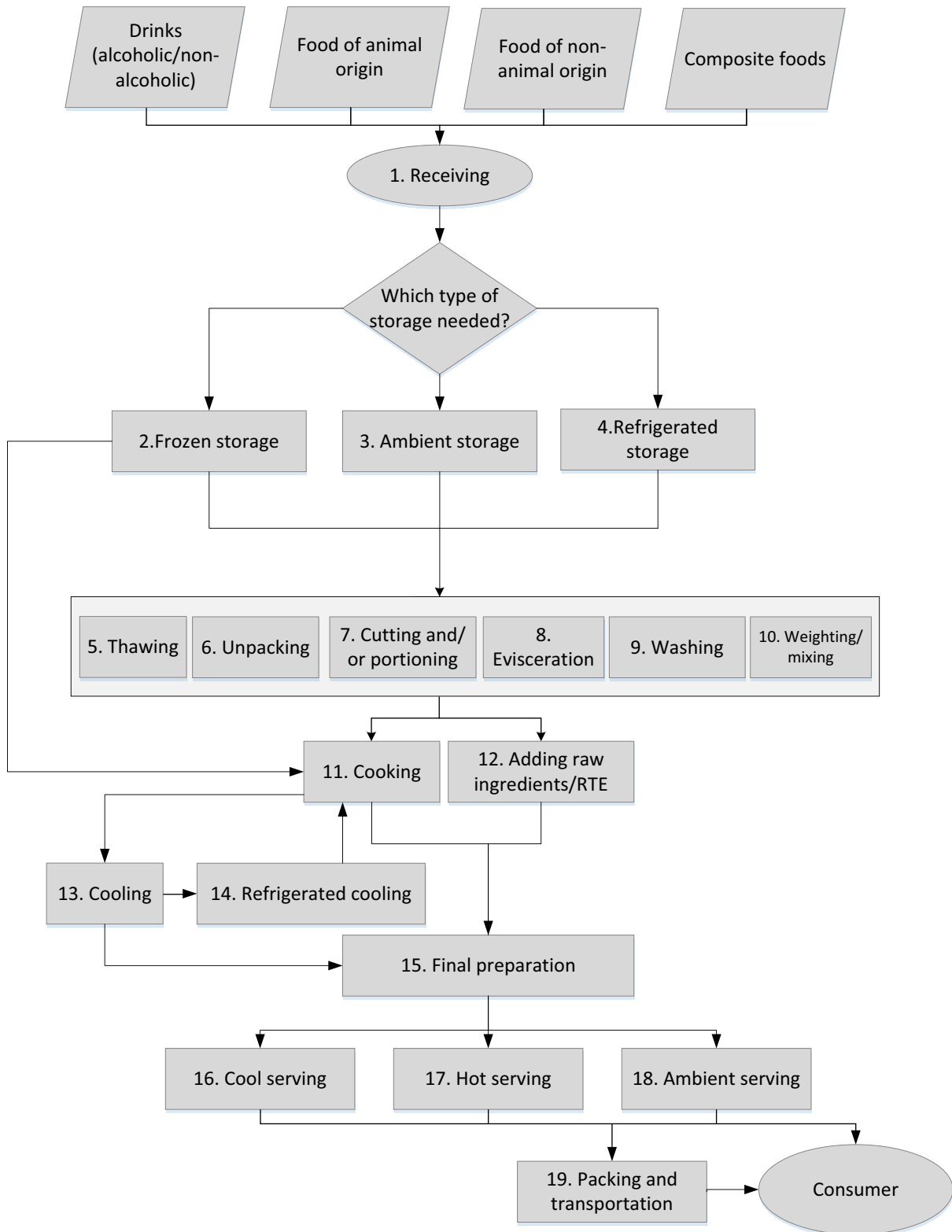


Figure 4: Flow diagram restaurant, catering services and pubs

3.2.4. Food donations

Food processors and food retailers including distribution centres, supermarkets, restaurants, etc., may provide some of their unsold food for food donation. A food donation chain can typically be divided into food donors (i.e. FBOs at any stage of the food chain such as retailers, food processors)

and food recipients (i.e. FBOs as redistribution organisations and charity organisations). Non-profit redistribution organisations and charity organisations are involved in redistributing these foods to the final consumer. The donors and recipients are considered to be food business operators and a FSMS has to be in operation. The European Commission has developed a Commission Notice on guidelines for food donations,⁵ to clarify relevant legal provisions applying to food redistribution (e.g. food hygiene, food information to consumers, VAT, etc.)

The food donation chain can be complex and fragmented. De Boeck et al. (2017) reported that it typically consists of 'donors' (allocating prepacked or non-prepacked foods for donations) and 'recipients' (receiving the food and redistributing this to those in need). In the same study, it was reported that products from redistribution organisations (such as a food banks) are further distributed to more than 620 charity organisations spread over the 10 different provinces in Belgium. All food products obtained from recipients are distributed for free to persons in need of this support. Redistribution is mainly (73%) organised through composite food parcels distributed through food charity organisations and social groceries and restaurants accounting for 24% of food aid. These three types of food aid can be publicly or privately organised. Recipients in government run organisations also receive food from the food banks. The remaining 3% of food aid consists of smaller local initiatives such as packages of multiple food distributed by social assistance centres, to be used at dedicated shops and other food donation initiatives (Vandevoort, 2013). For these other types of local community initiatives, local social assistance centres are often consulted in order to reach the target population. In other EU member states the situation is similar. A recent study in UK by Filimonau and Gherbin (2017) also reported that fragmentation is a major issue for charity organisations. A study from the European Economic and Social Committee (EESC) in 2014 found that food donation is organised differently in EU member states in terms of legislation, initiatives taken, type of organisations, VAT status, etc. (BIO by Deloitte, 2014).

In 2017, the European Commission issued guidance on food donation (Commission notice (2017)/C 361/01) in order to clarify relevant provisions in EU legislation and help lift barriers to food redistribution within the current regulatory framework. These guidelines complement those which may be established by national authorities in order to set out for all actors the rules and operating procedures existing at national level including the respective responsibilities of key players. Furthermore, the European Commission launched an 'EU Platform on Food Losses and Food Waste'¹⁹ which brings together public entities (e.g. MS, EU bodies, international organisations) and several stakeholders in the food chain including consumer and non-governmental organisations. The major goal of the platform is to achieve the United Nations Sustainable Development Goals (SDG)²⁰ concerning food loss and waste reduction targets without compromising food and feed safety and/or animal health. Part of the agenda is 'facilitation of food redistribution' with a subgroup of the Platform dedicated to this issue.

At retail level, individual supermarkets have their own policies and strategies for food donation. The standard procedure for donation of products in Belgium, for example, varied from donation of prepacked food 4 days before the 'use by' date up to donation in the late afternoon of the day itself. This has major implications for the recipients (redistribution organisations or local charity organisations), as it determines the time they have left to redistribute the food. The latter (donation at the 'use by' date itself) requires immediate redistribution, which is not always possible due to the voluntary nature of this activity. National food redistribution organisations (such as food banks) usually receive food stuffs directly from the retailer's central warehouses (distribution centres), food manufacturers and primary producers. Food banks may also receive food purchased through the Fund for European Aid to the Most Deprived. Smaller, local food charity organisations usually receive donations directly from local shops. The latter have to comply with certain requirements, which vary depending on the local retailer. For example, donated foods must be distributed for free and the distance between the donating shop and the food donation distributor may be restricted.

Donation of fresh meat and fish is very limited, as these products are susceptible to immediate microbiological deterioration, and require strict management of the chill chain to maintain quality and safety. There are several issues that may compromise the safety of food donations including complex logistics, a lack of suitable food storage capacity and a lack of food safety knowledge amongst volunteers. Moreover, these problems discourage food companies and retailers from donating for fear that incorrect handling and/or storage could lead to a well-publicised outbreak associated with a

¹⁹ EU Platform on Food Losses and Food Waste. http://ec.europa.eu/food/safety/food_waste/eu_actions/eu-platform/index_en.htm

²⁰ <https://sustainabledevelopment.un.org/sdgs>

particular food brand or retail outlet/chain. This would damage sales and adversely affect the corporate image of the company even though the food safety issues arose in a part of the food chain that was not under their control. With this in mind, some donating FBOs invest in training of charities so as to help ensure food safety or formal redistribution partnership agreements are established (based on De Boeck et al., 2017 and Filimonau and Gherbin (2017)).

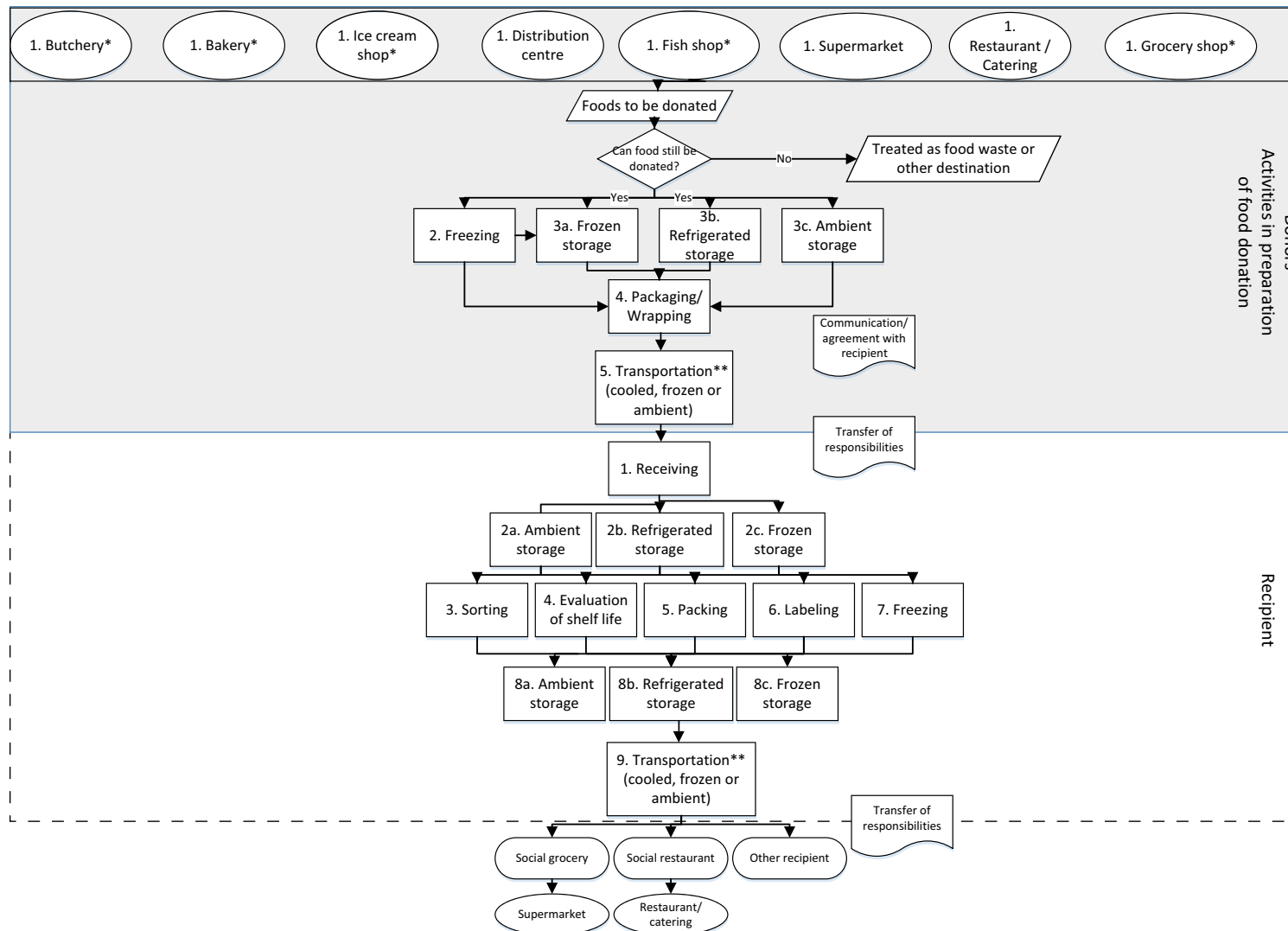
The interviews of De Boeck et al. (2017) further revealed that due to the fact that these non-profit organisations are reliant on volunteers, who have limitations in terms of time allocation to the food charity work, difficulties in the organisation and planning of pick-up and transportation of donated food are recurring issues for the recipients. Furthermore, transportation and logistics cost must be borne by the recipient and an efficient collection system may be hampered by a lack of funds.

In these interviews, the recipients also highlighted several issues including the fact that donating FBOs sometimes use the food donation to redistribute food that cannot be made available for sale through the usual commercial channels (e.g. food with labelling errors, food not meeting retailer specifications, etc.). This issue was also identified in other similar studies (Winne, 2008; Garrone et al., 2014). Moreover, the donated foods reflect sales or lack of sales in the supermarket and the foods donated may not match the need of those relying on food donation.

There are also issues in judging 'acceptability' of a product for food consumption. Therefore, it is important for both donors and recipients to agree on what is 'acceptable' and under which 'conditions' the food is acceptable to donate/receive, so that donated foods are still fit for consumption. In some EU MS, this issue has been addressed by the competent national authority in consultation with relevant stakeholders and taking into account the European Commission 'Guidance on Food Donation'. Furthermore, FEBA, FoodDrinkEurope and Eurocommerce recently launched the guide 'Every meal matters'²¹ with the goal to facilitate the donation/acceptation process. General information on food loss (and prevention) is provided as well as information on what foods can be donated and to whom. However, this guide does not cover food hygiene and food safety issues, as only traceability is covered.

The stages in food donation are summarised in the flow diagram (Figure 5) below. The hazards and control PRPs are presented in Table 5 (covers all target establishments) in Section 3.3 and Table A.4 (donors) and A.5 (recipients) (specific for food donation) in Appendix A.4.

²¹ https://www.fooddrinkurope.eu/uploads/publications_documents/Every_Meal_Matters_Food_Donation_Guidelines.pdf



* EFSA BIOHAZ Panel, 2017

** Transport can be done by donor or pick up by recipient (mutual agreement)

Figure 5: Flow diagram for food donation

3.3. The different stages in the target establishments and control PRPs

In this section, all the stages (activities) in the target establishments (distribution centre, supermarket, restaurant and food donation) have been combined and presented alphabetically in Table 5. This table also includes an indication whether or not a biological, chemical, physical or allergen hazard may occur at each stage, a short description of the hazard or mitigation action and the associated control PRPs. This 'simplified' approach is based on PRP activities and some of these, specifically 1 (infrastructure), 2 (cleaning and disinfection), 3 (pest control), 9 (personnel) and 12 (working methodology) are applicable at all stages in the target establishments. Thus, for clarity in the presentation, they have been excluded from repetitive mention at every stage, but included at the start of each summary table.

It should be noted that within a given establishment there may be several of these activities. For example, a food bank may be represented by the 'food donation' model but if they are preparing food for consumption they may also include the catering activities. Social supermarkets include most of the activities of a supermarket but will also have some of the operations associated with food donation. Thus it is the responsibility of each organisation to select the activities which best represent their role, develop their own flow chart(s) and tailor the FSMS to their specific food safety needs.

Table 5: Summary table showing the different activities (in alphabetical order) that may occur in the distribution centre, supermarket, restaurant and food donation, associated hazards (biological, chemical, physical and allergens), description of the hazard and the specific PRPs that may be applied to control these hazards. As PRPs 1, 2, 3, 9 and 12 apply to all stages, they have not been included at each stage in the table

Stage	Hazard identification B = biological C = chemical P = physical A = allergen				Description of the hazard	PRPs to control the hazards at each stage (in addition to PRPs 1, 2, 3, 9 and 1, which apply to all stages)
	B	C	P	A		
Stages common to all four target establishments (distribution centre, supermarket, restaurant and food donation)						
Receiving	Y	Y	Y	Y	Failure to ensure the microbiological quality of incoming raw materials	10, 11, 14
					Presence of chemical/physical hazards or allergens in incoming raw materials	6, 10
					Incomplete shelf-life data	14
					Mixing returns with other products	15
					Failure to clearly communicate with recipients on donated foods, e.g. shelf life, temperature control, transport conditions, freezing conditions, etc. There may be communications requirements also for the end beneficiary, i.e. consumer)	13, 16, 17
Storage and/or transportation (ambient)	Y	Y	Y	Y	Microbial growth due to failure to store in dry conditions	8, 11, 14
					Contamination with microbial/chemical/physical hazards or allergens from the environment, personnel, etc.	5, 6
					Contamination with allergens due to failure in segregation between allergen-containing and non-allergen-containing products (e.g. dust, aerosols, etc.)	6
Storage and/or transportation (refrigerated)	Y	Y	Y	Y	Microbial growth due to failure to chill properly (i.e. correct temperature and time) or due to storage for too long period	4, 11, 14
					Cross-contamination due to a failure to separate raw from cooked/RTE products	5, 6
					Contamination with biological/chemical/physical hazards or allergens from the environment, personnel, etc.	5, 6
Storage and/or transportation (frozen)	Y	Y	Y	Y	Microbial growth due to failure in freezing temperature	4, 11, 14
					Contamination with biological/chemical/physical hazards or allergens from the environment, personnel, etc.	5, 6
Storage and/or transportation (hot)	Y	Y	Y	Y	Microbial growth due to failure to reach by heating and maintain high temperatures that prevent microbial proliferation	11
					Contamination with chemical and physical hazards from the transportation environment, personnel, etc., or due to packaging damage	5, 6

Stage	Hazard identification B = biological C = chemical P = physical A = allergen				Description of the hazard	PRPs to control the hazards at each stage (in addition to PRPs 1, 2, 3, 9 and 1, which apply to all stages)
	B	C	P	A		
Stages common to three target establishments (supermarket, restaurant and food donation)						
Final preparation Adding raw materials/RTE ingredients	Y	Y	Y	Y	Contamination with biological, chemical or physical hazards or allergens from the environment, personnel, etc., due to a failure to clean and disinfect equipment properly and lack of personal hygiene	5, 6
					Cross-contamination with microbial hazards due to a failure to separate raw from cooked/RTE products	4
					Cross-contamination via contaminated surfaces that are used in common for raw and RTE foods	7
					Contamination with chemical hazards due to the packing material	10
					Failure of attribution of shelf-life for prepacked food	16
					Failure to inform the consumer of potential allergens and storage mode, time, etc.	13
Washing	Y	Y	Y	Y	Contamination with biological, chemical or physical hazards or allergens from the environment, personnel, etc.	5, 6
					Accumulation of microbial and chemical hazards in washing water. Inadequate removal of microbial and chemical hazards from the washed tissue. Misuse of sanitising solutions and accumulation of chemical residues	7, 8, 10
Weighing and mixing	Y	Y	Y	Y	Contamination with biological, chemical or physical hazards or allergens from the environment, personnel, etc.	5, 6
					Cross-contamination with microbial hazards due to a failure to separate raw from cooked/RTE products	4, 5
Stages common to supermarkets and restaurants						
Cooking	Y	Y	N	Y	Failure to achieve sufficient temperatures/time to eliminate pathogens, and to control potential growth and toxin formation	4, 11
					Low heat transfer due to improper cleaning of heated containers	4, 11
					Formation of process contaminants, e.g. acrylamide or PAHs	5
					Contamination with chemical hazards and allergens by improperly cleaned cooking tools, or reused oil and water	5, 6
Cooling	Y	Y	N	Y	Microbial growth due to failure to achieve low temperatures within a certain time	4, 11
					Cross-contamination with chemical hazards and allergens	5, 6
Cutting and/or portioning	Y	Y	Y	Y	Contamination with biological, chemical or physical hazards and allergens due to a failure to clean and disinfect equipment properly, lack of personal hygiene	4, 5, 6

Stage	Hazard identification B = biological C = chemical P = physical A = allergen				Description of the hazard	PRPs to control the hazards at each stage (in addition to PRPs 1, 2, 3, 9 and 1, which apply to all stages)
	B	C	P	A		
Evisceration (fish)	Y	Y	Y	Y	Cross-contamination with microbial hazards from the gut to the meat	7
					Contamination with biological, chemical or physical hazards or allergens from the environment, personnel, etc.	5, 6
Serving (ambient)	Y	Y	Y	Y	Contamination with biological/chemical/physical hazards or allergens via contaminated serving utensils and/or improper handling	4, 5
					Contamination with allergens due to failure in segregation between allergen-containing and non-allergen-containing products or ingredients	6, 13
Serving (cold and/or hot)	Y	Y	Y	Y	Microbial growth due to failure to chill properly and temperature abuse of products for longer than the specified period	4, 11
					Microbial growth due to failure to reach by heating and maintain high temperatures that prevent microbial proliferation	4, 11
					Contamination with microbial/chemical/physical hazards or allergens via contaminated serving utensils and/or improper handling	5, 6, 13
					Contamination with allergens due to failure in segregation between allergen-containing and non-allergen-containing products or ingredients	6, 13
Thawing	Y	N	N	N	Microbial growth due to failure to maintain low temperatures and appropriate time	11
Stages common to supermarkets and food donation						
Self-service by consumer: portioning and packing by consumer	Y	Y	Y	Y	Contamination with biological, chemical or physical hazards or allergens due to customer behaviour	10, 13
Slicing, serving and/or packing	Y	Y	Y	Y	Contamination with biological, chemical or physical hazards or allergens	5, 6
					Contamination with chemical hazards due to the packing material	10
					Contamination with biological hazards and allergens due to a failure to separate products	6
					Failure of attribution of shelf-life for prepacked food	16
				Failure to inform the consumer of potential allergens and storage mode, time, etc.	13	

Stage	Hazard identification B = biological C = chemical P = physical A = allergen				Description of the hazard	PRPs to control the hazards at each stage (in addition to PRPs 1, 2, 3, 9 and 1, which apply to all stages)
	B	C	P	A		
Stages common to distribution centres and restaurants						
Unpacking	Y	Y	Y	Y	Contamination with biological, chemical or physical hazards or allergens from the environment, personnel, etc.	5, 6
					Cross-contamination with microbial hazards due to a failure to separate raw from cooked/RTE products	4
					Chemicals released from food contact materials	10
					Presence of incomplete/wrong label information	13, 14
					Contamination with chemical hazards and allergens	5, 6
Stages common to distribution centres and food donations						
Order assembly	Y	Y	Y	Y	Contamination with biological/chemical/physical hazards or allergens from the environment, personnel, etc.	5, 6
Packing (including wrapping/repacking)	Y	Y	Y	Y	Contamination with biological, chemical or physical hazards or allergens from the environment, personnel, etc.	5, 6
					Cross-contamination with microbial hazards due to a failure to separate raw from cooked/RTE products	4
					Chemicals released from food contact materials	10
					Presence of incomplete/wrong label information	13, 14
Stages for supermarkets only						
Display in counter (ambient, refrigerated or hot)	Y	Y	Y	Y	Microbial growth due to failure to store at the required temperature	4
					Contamination with biological, chemical or physical hazards or allergens from the environment, personnel, etc.	5, 6
Stages for food donation only						
Decision on the acceptability of food to be donated	Y	Y	Y	Y	A critical review has to be undertaken by the donating and the receiving organisations to establish if foods are still suitable for donation based on shelf-life evaluation, status of packing material, label information, etc.	16
Evaluation of shelf-life	Y	N	N	N	Before products are entering the food donation organisation, the attributed shelf life has to be evaluated if products still can be donated, stored, frozen, relabelled, etc. (and receiving organisation also checks if remaining shelf-life is acceptable)	16, 17

Stage	Hazard identification B = biological C = chemical P = physical A = allergen				Description of the hazard	PRPs to control the hazards at each stage (in addition to PRPs 1, 2, 3, 9 and 1, which apply to all stages)
	B	C	P	A		
Freezing	Y	N	N	N	Decision if prepacked foods still can be frozen including ensuring there is sufficient shelf-life remaining	17
					Failure to ensure the microbiological quality of food products to be frozen (quick frozen)	11
					Re-attributing a date of freezing – labelling	17
Sorting	Y	Y	Y	Y	Microbial contamination of food products sorted out (e.g. mould growth on fruits)	No additional PRPs
					Contamination with biological/chemical/physical hazards or allergens from the environment, personnel, etc.	5, 6

For non-prepacked foods in display counter (foods in the butcher counter, fish counter, bakery counter and/or fruit & vegetables), see EFSA (2017) Scientific opinion on hazard analysis approaches for certain small retail establishments in view of the application of their food safety management systems. EFSA Journal 2017;15(3):4697, 52 pp. <https://doi.org/10.2903/j.efsa.2017.4697>

4. Conclusions

The 'simplified' approach developed in a previous EFSA Opinion was applied for the development of FSMS for small retail distribution centres, supermarkets, restaurants (including pubs and catering) [ToR 1] and food distribution [ToR 2]. Biological, chemical, physical or allergen hazards may be identified without knowledge of each specific hazard and ranking of the hazards was not required [ToR 1]. Based on analysis of the hazards which may occur in the target establishments and the fact that more sensitive consumer groups were not considered, PRPs were sufficient to assure food safety [ToR 1]. However, in addition to the PRPs described in EC Notice 2016/C278 and the additional PRP 'product information and consumer awareness' developed in the previous EFSA Opinion, this necessitated the development of four new PRPs including 'shelf-life control', 'handling returned foods', 'Evaluation for food donation and allocation of remaining shelf-life' and 'freezing food intended for donation'.

High risk foods, such as semi-cooked or raw meat products (e.g. steak tartar) are of particular concern. The elimination of pathogenic organisms along food chain is often reliant on a single step, the application of heat during cooking. If for organoleptic, perceived nutritional value or other reasons this activity is removed or reduced, pathogenic organisms may survive and cause human illness. The FBO is legally required to provide safe food and measures such as the application of PRP 10 (raw materials), stringent requirements for hygiene handling (PRPs 2, 5 and 9) and segregation of preparation areas for these particular products (PRP 1) from the other products served by the same restaurant, pub and/or catering service may be undertaken to ensure an appropriate level of consumer protection. Regardless, the FBO should inform consumers of the increased risks associated with the consumption of these high risk foods (PRP 13) with a clear understanding that this activity does not pass responsibility for food safety to the customer but always remains with the FBO.

5. Recommendations

Given that small food retail establishments have specific difficulties developing and implementing HACCP, it is recommended that small retail distribution centres, supermarkets, restaurants (including pubs and other catering) and food donation activities apply the 'simplified approach' to food safety management as described in this Opinion. While a general approach was used in this document, it is important that individual establishments carefully identify the specific stages/activities used in their establishment and tailor the FSMS to control all the hazards that may occur at each stage. Furthermore, it is recommended that the competent authorities in each member state monitor the implementation of the 'simplified' FSMS thus developed and provide feedback to the European Commission on how this approach may work in practice.

Finally, as this 'simplified approach' overcomes many of the issues encountered by food businesses when developing effective food safety management systems, a broader application within the food industry may be considered in the future.

References

- Bio by Deloitte. 2014. Comparative Study on EU Member States' legislation and practices on food donation: executive Summary. European Economic and Social Committee, Brussels, Belgium.
- De Boeck E, Jacxsens L, Goubert H and Uyttendaele M, 2017. Ensuring food safety in food donations: case study of the Belgian donation/acceptation chain. *Food Research International*, 100, 137–149.
- Doorduyn Y, de Jager CM, van der Zwaluw WK, Friesema IHM, Heuvelink AE, de Boer E, Wannet WJB and van Duynhoven YTHP, 2006. Shiga toxin-producing *Escherichia coli* (STEC) O157 outbreak, The Netherlands, September-October 2005. *Eurosurveillance*, 11, 636.
- EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Ricci A, Chemaly M, Davies R, Fernández Escámez PS, Girones R, Herman L, Lindqvist R, Nørrung B, Robertson L, Ru G, Simmons M, Skandamis P, Snary E, Speybroeck N, Ter Kuile B, Threlfall J, Wahlström H, Allende A, Barregård L, Jacxsens L, Koutsoumanis K, Sanaa M, Varzakas T, Baert K, Hempen M, Rizzi V, Van der Stede Y and Bolton D, 2017. Scientific opinion on hazard analysis approaches for certain small retail establishments in view of the application of their food safety management systems. *EFSA Journal* 2017;15(3):4697, 52 pp. <https://doi.org/10.2903/j.efsa.2017.4697>
- FAO/WHO (Food and Agriculture Organization/World Health Organization), 2006. FAO/WHO guidance to governments on the application of HACCP in small and/or less-developed food businesses. FAO Food and Nutrition paper No. 86. Available online: <http://www.fao.org/3/a-a0799e.pdf> [Accessed: 29 November 2017].

- Filimonau V and Gherbin A, 2017. An exploratory study of food waste management practices in the UK grocery retail sector. *Journal of Cleaner Production*, 167, 1184–1194.
- FSAI (Food and Safety Authority of Ireland), 2013. Microbiological safety of raw minced beef and beef burgers on retail sale in Ireland (11NS1). Available online: <https://www.fsai.ie/microbiologicalsafetyofrawmincedbeefandbeefburgersonretailsaleinireland.html>
- FUSIONS, 2016. Estimates of European food waste levels. In. Swedish Environmental Research Institute, Stockholm, Sweden.
- Garrone P, Melacini M and Perego A, 2014. Surplus food recovery and donation in Italy: the upstream process. *British Food Journal*, 116, 1460–1477.
- Greenland K, de Jager C, Heuvelink A, van der Zwaluw K, Heck M, Notermans D, van Pelt W and Friesema I, 2009. Nationwide outbreak of STEC O157 infection in the Netherlands, December 2008-January 2009: continuous risk of consuming raw beef products. *Eurosurveillance*, 14, 19129.
- Griffith CJ, Livesey KM and Clayton DA, 2010. Food safety culture: the evolution of an emerging risk factor? *British Food Journal*, 112, 426–438.
- Haeghebaert S, Duché L, Gilles C, Masini B, Dubreuil M, Minet JC, Bouvet P, Grimont F, Delarocque Astagneau E and Vaillant V, 2001. Minced beef and human salmonellosis: review of the investigation of three outbreaks in France. *Eurosurveillance*, 6, 223.
- Isakbaeva E, Lindstedt BA, Schimmer B, Vardund T, Stavnes TL, Hauge K, Gondrosen B, Blystad H, Kløvstad H, Aavitsland P, Nygård K and Kapperud G, 2005. *Salmonella* Typhimurium DT104 outbreak linked to imported minced beef, Norway, October - November 2005. *Eurosurveillance*, 10, 2829.
- Jones AK, Cross P, Burton M, Millman C, O'Brien SJ and Rigby D, 2017. Estimating the prevalence of food risk increasing behaviours in UK kitchens. *PLoS ONE*, 12, e0175816.
- Soborg B, Lassen SG, Müller L, Jensen T, Ethelberg S, Mølbak K and Scheutz F, 2013. A verocytotoxin-producing *E. coli* outbreak with a surprisingly high risk of haemolytic uraemic syndrome, Denmark, September-October 2012. *Eurosurveillance*, 18, 20350.
- Valliant V, 2005. Outbreak of *E. coli* O157: H7 infections associated with a brand of beefburgers in France. *Eurosurveillance*, 10, 2–4.
- Vandevoort L, 2013. Sociaal aan de slag met voedseloverschotten. Departement Welzijn Volksgezondheid en Gezin: Afdeling Welzijn En Samenleving. Available online: <https://www.vlaanderen.be/nl/publicaties/detail/sociaal-aan-de-slag-met-voedseloverschotten> [Accessed: 29 November 2017]
- Wallace C, Holyoak L, Powell S and Dykes F, 2012. Re-thinking the HACCP team: an investigation into HACCP team knowledge and decision-making for successful HACCP development. *Food Research International*, 47, 236–245.
- Wallace CA, Holyoak L, Powell SC and Dykes FC, 2014. HACCP – the difficulty with hazard analysis. *Food Control*, 35, 233–240.
- Whelan J, Noel H, Friesema I, Hofhuis A, de Jager CM, Heck M, Heuvelink A and van Pelt W, 2010. National outbreak of *Salmonella* Typhimurium (Dutch) phage-type 132 in the Netherlands, October to December 2009. *Eurosurveillance*, 15, 19705.
- White HD, Bates MJ and Wilson P, 1992. For Information Specialists: Interpretations of Reference and Bibliographic Work. Ablex Publishing Corporation, Norwood, New Jersey, USA. 320 pp.
- Winne M, 2008. Closing the Food Gap. Resetting the table in the land of the plenty. Beacon Press, Boston, MA.

Glossary

Food business	any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food. ¹⁹
Food business operator	the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control. ¹⁹
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.

Hazard	a biological (e.g. <i>Salmonella</i> 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. ²²
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'.
Prerequisite programme(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), Good Manufacturing Practice (GMP), Good Hygiene Practice (GHP), Good Production Practice (GPP), Good Distribution.
Auto-control system	the self-checking system or food safety management system based on PRPs and HACCP principles.
Retail	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. ¹⁹
Risk	means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard. ¹⁹

Abbreviations

BIOHAZ	EFSA Panel on Biological Hazards
CCP	critical control point
EESC	European Economic and Social Committee
FAO	Food and Agriculture Organization of the United Nations
FEBA	European Federation of Food Banks
FSA	Food Standards Agency
FSAI	Food Safety Authority of Ireland
GAP	Good Agricultural Practices
GDP	Good Distribution Practices
GFP	Good Farming Practices
GHP	Good Hygiene Practices
GMP	Good Manufacturing Practices
GPP	Good Production Practices
GVP	Good Veterinarian Practices
HACCP	hazard analysis and critical control point
HUS	haemolytic uraemic syndrome
MS	Member States
PAH	polycyclic aromatic hydrocarbon
RTE	ready to eat
SDG	United Nations Sustainable Development Goals
SOP	standard operating procedure
STEC	Shiga toxin-producing <i>Escherichia coli</i>
WG	Working Group
WHO	World Health Organization

²² Regulation (EC) No 178/2002.

Appendix A – Simplified food safety management system for specific small retail establishments

A.1. Simplified food safety management system for food distribution centre

Table A.1: Simplified food safety management system for food distribution centre

Stage	Hazard identification ^(a)				Activities contributing to increased/decreased occurrence of the hazard	Control activities
	B	C	P	A		
All stages						PRPs 1, 2, 3, 9, 12
Receiving	Y	Y	Y	Y	Failure to ensure the microbiological quality of incoming raw materials	PRP 10: Raw materials (supplier selection, specifications) PRP 11: Temperature control PRP 14: Expiration date control
					Presence of chemical/physical hazards or allergens in incoming raw materials	PRP 6: Allergens PRP 10: Raw materials (supplier selection, specifications)
					Incomplete shelf-life data	PRP 14: Expiration date control
					Mixing returns with other products	PRP 15: Returns Management
Unpacking	Y	Y	Y	Y	Contamination with biological, chemical or physical hazards or allergens from the environment, personnel, etc.	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
					Cross-contamination with microbial hazards due to a failure to separate raw from cooked/RTE products	PRP 4: Technical maintenance and calibration
					Chemicals released from food contact materials	PRP 10: Raw materials (supplier selection, specifications)
					Presence of incomplete/wrong label information	PRP 13: Product information and consumer awareness PRP 14: Expiration date control
					Contamination with chemical hazards and allergens	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
					Microbial growth due to failure to chill properly (i.e. correct temperature and time), or due to storage for too long period	PRP 4: Technical maintenance and calibration PRP 11: Temperature control PRP 14: Expiration date control
Refrigerated storage	Y	Y	Y	Y	Cross-contamination due to a failure to separate raw from cooked/RTE products	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens

Stage	Hazard identification ^(a)				Activities contributing to increased/decreased occurrence of the hazard	Control activities
	B	C	P	A		
All stages						PRPs 1, 2, 3, 9, 12
Ambient storage	Y	Y	Y	Y	Contamination with biological/chemical/physical hazards or allergens from the environment, personnel, etc.	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
					Microbial growth due to failure to store in dry conditions	PRP 8: Water and air control PRP 11: Temperature control PRP 14: Expiration date control PRP 16: Evaluation for food donation and allocation of remaining shelf-life
					Contamination with microbial/chemical/physical hazards or allergens from the environment, personnel, etc.	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
					Contamination with allergens due to failure in segregation between allergen-containing and non-allergen-containing products (e.g. dust, aerosols, etc.)	PRP 6: Allergens
Frozen storage	Y	Y	Y	Y	Microbial growth due to failure in freezing temperature	PRP 4: Technical maintenance and calibration PRP 11: Temperature control PRP 14: Expiration date control
					Contamination with microbial/chemical/physical hazards due to environment	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
Order Assembly	Y	Y	Y	Y	Contamination with biological/chemical/physical hazards or allergens from the environment, personnel, etc.	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
Packing	Y	Y	Y	Y	Contamination with biological/chemical/physical hazards or allergens from the environment, personnel, etc.	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
					Cross-contamination with microbial hazards due to a failure to separate raw from cooked/RTE products	PRP 4: Technical maintenance and calibration
					Chemicals released from food contact materials	PRP 10: Raw materials (supplier selection, specifications)
					Presence of incomplete/wrong label information	PRP 13: Product information and consumer awareness PRP 14: Expiration date control

Stage	Hazard identification ^(a)				Activities contributing to increased/decreased occurrence of the hazard	Control activities
	B	C	P	A		
All stages						PRPs 1, 2, 3, 9, 12
Ambient transportation	Y	Y	Y	Y	Microbial growth due to failure to store in dry conditions	PRP 8: Water and air control PRP 11: Temperature control PRP 14: Expiration date control PRP 16: Evaluation for food donation and allocation of remaining shelf-life
					Contamination with microbial/chemical/physical hazards or allergens from the environment, personnel, etc.	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
					Contamination with allergens due to failure in segregation between allergen-containing and non-allergen-containing products (e.g. dust, aerosols, etc.)	PRP 6: Allergens
Refrigerated transportation	Y	Y	Y	Y	Microbial growth due to failure to chill properly (i.e. correct temperature and time) or due to storage for too long period	PRP 4: Technical maintenance and calibration PRP 11: Temperature control PRP 14: Expiration date control
					Cross-contamination due to a failure to separate raw from cooked/RTE products	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
					Contamination with biological/chemical/physical hazards or allergens from the environment, personnel, etc.	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
Frozen transportation	Y	Y	Y	Y	Microbial growth due to failure in freezing temperature	PRP 4: Technical maintenance and calibration PRP 11: Temperature control PRP 14: Expiration date control
					Contamination with microbial/chemical/physical hazards due to environment	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens

PRP: prerequisite programme; RTE: ready-to-eat.

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

A.2. Simplified food safety management system for the supermarket

Table A.2: Simplified food safety management system for the supermarket

Stage	Hazard identification ^(a)				Activities contributing to increased/decreased occurrence of the hazard	Control measures
	B	C	P	A		
All stages						PRPs 1, 2, 3, 9, 12
Receiving	Y	Y	Y	Y	Failure to ensure the microbiological quality of incoming raw materials	PRP 10: Raw materials (supplier selection, specifications) PRP 11: Temperature control PRP 14: Expiration date control
					Presence of chemical/physical hazards or allergens in incoming raw materials	PRP 6: Allergens PRP 10: Raw materials (supplier selection, specifications)
					Incomplete shelf-life data	PRP 14: Expiration date control
					Mixing returns with other products	PRP 15: Returns Management
Storage (not yet in display)						
Ambient storage	Y	Y	Y	Y	Contamination with biological/chemical/physical hazards or allergens via contaminated serving utensils and/or improper handling	PRP 8: Water and air control PRP 11: Temperature control PRP 14: Expiration date control PRP 16: Evaluation for food donation and allocation of remaining shelf-life
					Contamination with microbial/chemical/physical hazards or allergens from the environment, personnel, etc.	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
					Contamination with allergens due to failure in segregation between allergen-containing and non-allergen-containing products (e.g. dust, aerosols, etc.)	PRP 6: Allergens
Refrigerated storage	Y	Y	Y	Y	Microbial growth due to failure to chill properly (i.e. correct temperature and time) or due to storage for too long period	PRP 4: Technical maintenance and calibration PRP 11: Temperature control PRP 14: Expiration date control
					Cross-contamination due to a failure to separate raw from cooked/RTE products	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
					Contamination with biological/chemical/physical hazards or allergens from the environment, personnel, etc.	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens

Stage	Hazard identification ^(a)				Activities contributing to increased/decreased occurrence of the hazard	Control measures
	B	C	P	A		
All stages						PRPs 1, 2, 3, 9, 12
Frozen storage	Y	Y	Y	Y	Microbial growth due to failure in freezing temperature	PRP 4: Technical maintenance and calibration PRP 11: Temperature control PRP 14: Expiration date control
					Contamination with biological/chemical/physical hazards or allergens from the environment, personnel, etc.	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
Packed foods in display counter (display and self-service by customer)						
Ambient storage	Y	Y	Y	Y	As above	As above
Refrigerated storage	Y	Y	Y	Y	As above	As above
Frozen storage	Y	Y	Y	Y	As above	As above
Non-packed in display counter						
Foods in the butcher counter, fish counter, bakery counter and/or fruit & vegetables					See EFSA (2017) Scientific opinion on hazard analysis approaches for certain small retail establishments in view of the application of their food safety management systems. EFSA Journal 2017;15(3):4697, 52 pp. https://doi.org/10.2903/j.efsa.2017.4697	
Other non-packed foods in display counter						
1. Deli counter foods (e.g. Cheese, olives, mixed foods)						
Cutting and/or portioning	Y	Y	Y	Y	Contamination with biological, chemical or physical hazards and allergens due to a failure to clean and disinfect equipment properly, lack of personal hygiene	PRP 4: Technical maintenance and calibration PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
					Microbial growth due to failure to store at the required temperature	PRP 4: Technical maintenance and calibration
Display in counter (ambient, refrigerated or hot)	Y	Y	Y	Y	Contamination with biological, chemical or physical hazards or allergens from the environment, personnel, etc.	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens

Stage	Hazard identification ^(a)				Activities contributing to increased/decreased occurrence of the hazard	Control measures
	B	C	P	A		
All stages						PRPs 1, 2, 3, 9, 12
Display in counter (frozen)	Y	Y	Y	Y	Microbial growth due to failure in freezing temperature	PRP 4: Technical maintenance and calibration PRP 11: Temperature control PRP 14: Expiration date control
					Contamination with biological/chemical/physical hazards or allergens from the environment, personnel, etc.	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
Refrigerated storage	Y	Y	Y	Y	As above	As above
Self-service by consumer: portioning and packaging by consumer	Y	Y	Y	Y	Contamination with microbial, chemical or physical hazards or allergens due to failure in working methodology and lack of personal hygiene by consumers. Although the hygiene of self-service is dependent on the customer, retailers can facilitate this by providing supervision, guidance as well as clean utensils, gloves, etc., and proper packaging material	PRP 10: Raw materials (supplier selection, specifications) PRP 13: Product information and consumer awareness
2. Catering and foods cooked on the premises (e.g. roast chicken, sausages, pizzas, etc.)						
Cooking	Y	Y	N	Y	Failure to achieve sufficient temperatures/time to eliminate pathogens, and to control potential growth and toxin formation	PRP 4: Technical maintenance and calibration PRP 11: Temperature control
					Low heat transfer due to improper cleaning of heated containers	PRP 4: Technical maintenance and calibration PRP 11: Temperature control
					Formation of process contaminants, e.g. acrylamide or PAHs	PRP 5: Physical and chemical contamination from the production environment
					Contamination with chemical hazards and allergens by improperly cleaned cooking tools, or reused oil and water	PRP 5: Physical and chemical contamination from the production environment PRP 6: Allergens
Cooling	Y	Y	N	Y	Microbial growth due to failure to achieve low temperatures within a certain time	PRP 4: Technical maintenance and calibration PRP 11: Temperature control
					Contamination with chemical hazards and allergens	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens

PRP: prerequisite programme; RTE: ready-to-eat; PAH: polycyclic aromatic hydrocarbon.

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

A.3. Simplified food safety management system for restaurants, catering services and pubs

Table A.3: Simplified food safety management system for restaurants, catering services and pubs

Stage	Hazard identification ^(a)				Activities contributing to increased/decreased occurrence of the hazard	Control measures
	B	C	P	A		
All stages						PRPs 1, 2, 3, 9, 12
Receiving	Y	Y	Y	Y	Failure to ensure the microbiological quality of incoming raw materials	PRP 10: Raw materials (supplier selection, specifications) PRP 11: Temperature control PRP 14: Expiration date control
					Presence of chemical/physical hazards or allergens in incoming raw materials	PRP 6: Allergens PRP 10: Raw materials (supplier selection, specifications)
					Incomplete shelf-life data	PRP 14: Expiration date control
					Mixing returns with other products	PRP 15: Returns management
Ambient storage	Y	Y	Y	Y	Contamination with biological/chemical/physical hazards or allergens via contaminated serving utensils and/or improper handling	PRP 8: Water and air control PRP 11: Temperature control PRP 14: Expiration date control PRP 16: Evaluation for food donation and allocation of remaining shelf-life
					Contamination with microbial/chemical/physical hazards or allergens from the environment, personnel, etc.	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
					Contamination with allergens due to failure in segregation between allergen-containing and non-allergen-containing products (e.g. dust, aerosols, etc.)	PRP 6: Allergens
Refrigerated storage	Y	Y	Y	Y	Microbial growth due to failure to chill properly (i.e. correct temperature and time) or due to storage for too long period	PRP 4: Technical maintenance and calibration PRP 11: Temperature control PRP 14: Expiration date control
					Cross-contamination due to a failure to separate raw from cooked/RTE products	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
					Contamination with biological/chemical/physical hazards or allergens from the environment, personnel, etc.	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens

Stage	Hazard identification ^(a)				Activities contributing to increased/decreased occurrence of the hazard	Control measures
	B	C	P	A		
All stages						PRPs 1, 2, 3, 9, 12
Frozen storage	Y	Y	Y	Y	Microbial growth due to failure in freezing temperature	PRP 4: Technical maintenance and calibration PRP 11: Temperature control PRP 14: Expiration date control
					Contamination with biological/chemical/physical hazards or allergens from the environment, personnel, etc.	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
Preparation handling/processing						
Thawing	Y	N	N	N	Microbial growth due to failure to maintain low temperatures and appropriate time	PRP 11: Temperature control
Cutting and/or portioning	Y	Y	Y	Y	Contamination with biological, chemical or physical hazards and allergens due to a failure to clean and disinfect equipment properly, lack of personal hygiene	PRP 4: Technical maintenance and calibration PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
					Evisceration (fish)	Y
Washing	Y	Y	Y	Y	Contamination with biological, chemical or physical hazards or allergens from the environment, personnel, etc.	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
					Accumulation of microbial and chemical hazards in washing water. Inadequate removal of microbial and chemical hazards from the washed tissue. Misuse of sanitising solutions and accumulation of chemical residues	PRP 7: Waste management PRP 8: Water and air control PRP 10: Raw materials (supplier selection, specifications, etc.)
Weighting/mixing	Y	Y	Y	Y	Contamination with biological, chemical or physical hazards or allergens from the environment, personnel, etc.	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
					Cross-contamination with microbial hazards due to a failure to separate raw from cooked/RTE products	PRP 4: Technical maintenance and calibration PRP 5: Physical and chemical contamination from production environment

Stage	Hazard identification ^(a)				Activities contributing to increased/decreased occurrence of the hazard	Control measures
	B	C	P	A		
All stages						PRPs 1, 2, 3, 9, 12
Unpacking	Y	Y	Y	Y	Contamination with biological, chemical or physical hazards or allergens from the environment, personnel, etc.	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
					Cross-contamination with microbial hazards due to a failure to separate raw from cooked/RTE products	PRP 4: Technical maintenance and calibration
					Chemicals released from food contact materials	PRP 10: Raw materials (supplier selection, specifications)
					Presence of incomplete/wrong label information	PRP 13: Product information and consumer awareness PRP 14: Expiration date control
					Contamination with chemical hazards and allergens	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
Cooking	Y	Y	N	Y	Failure to achieve sufficient temperatures/time to eliminate pathogens and to control potential growth and toxin formation	PRP 4: Technical maintenance and calibration PRP 11: Temperature control
					Low heat transfer due to improper cleaning of heated containers	PRP 4: Technical maintenance and calibration PRP 11: Temperature control
					Formation of process contaminants, e.g. acrylamide or PAHs	PRP 5: Physical and chemical contamination from the production environment
					Contamination with chemical hazards and allergens by improperly cleaned cooking tools, or reused oil and water	PRP 5: Physical and chemical contamination from the production environment PRP 6: Allergens
Adding raw ingredients/RTE	Y	Y	Y	Y	Contamination with biological, chemical or physical hazards or allergens from the environment, personnel, etc., due to a failure to clean and disinfect equipment properly and lack of personal hygiene	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
					Cross-contamination with microbial hazards due to a failure to separate raw from cooked/RTE products	PRP 4: Technical maintenance and calibration
					Cross-contamination via contaminated surfaces that are used in common for raw and RTE foods	PRP 7: Waste management

Stage	Hazard identification ^(a)				Activities contributing to increased/decreased occurrence of the hazard	Control measures
	B	C	P	A		
All stages						PRPs 1, 2, 3, 9, 12
Cooling	Y	Y	N	Y	Microbial growth due to failure to achieve low temperatures within a certain time	PRP 4: Technical maintenance and calibration PRP 11: Temperature control
					Contamination with chemical hazards and allergens	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 (i.e. correct temperature and time) or due to storage for too long period	PRP 4: Technical maintenance and calibration PRP 11: Temperature control PRP 14: Expiration date control
					Cross-contamination due to a failure to separate raw from cooked/RTE products	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
					Contamination with biological/chemical/physical hazards or allergens from the environment, personnel, etc.	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
Final preparation/plating	Y	Y	Y	Y	Contamination with biological, chemical or physical hazards or allergens from the environment, personnel, etc., due to a failure to clean and disinfect equipment properly and lack of personal hygiene	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
					Cross-contamination with microbial hazards due to a failure to separate raw from cooked/RTE products	PRP 4: Technical maintenance and calibration
					Cross-contamination via contaminated surfaces that are used in common for raw and RTE foods	PRP 7: Waste management
Serving (cold and/or hot)	Y	Y	Y	Y	Microbial growth due to failure to chill properly and temperature abuse of products for longer than the specified period	PRP 4: Technical maintenance and calibration PRP 11: Temperature control
					Microbial growth due to failure to reach by heating and maintain high temperatures that prevent microbial proliferation	PRP 4: Technical maintenance and calibration PRP 11: Temperature control
					Contamination with microbial/chemical/physical hazards or allergens via contaminated serving utensils and/or improper handling	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens PRP 13: Product information and customer awareness

Stage	Hazard identification ^(a)				Activities contributing to increased/decreased occurrence of the hazard	Control measures
	B	C	P	A		
All stages						PRPs 1, 2, 3, 9, 12
					Contamination with allergens due to failure in segregation between allergen-containing and non-allergen-containing products or ingredients	PRP 6: Allergens PRP 13: Product information and customer awareness
Serving (ambient)	Y	Y	Y	Y	Contamination with biological/chemical/physical hazards or allergens via contaminated serving utensils and/or improper handling	PRP 4: Technical maintenance and calibration PRP 5: Physical and chemical contamination from production environment
					Contamination with allergens due to failure in segregation between allergen-containing and non-allergen-containing products or ingredients	PRP 6: Allergens PRP 13: Product information and customer awareness
Outdoor Transportation						
Ambient transportation	Y	Y	Y	Y	Contamination with biological/chemical/physical hazards or allergens via contaminated serving utensils and/or improper handling	PRP 8: Water and air control PRP 11: Temperature control PRP 14: Expiration date control PRP 16: Evaluation for food donation and allocation of remaining shelf-life
					Contamination with microbial/chemical/physical hazards or allergens from the environment, personnel, etc.	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
					Contamination with allergens due to failure in segregation between allergen-containing and non-allergen-containing products (e.g. dust, aerosols, etc.)	PRP 6: Allergens
Hot transportation	Y	N	Y	N	Microbial growth due to failure to reach by heating and maintain high temperatures that prevent microbial proliferation	PRP 11: Temperature control
					Contamination with physical hazards from the transportation environment, personnel, etc. or due to packaging damage	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens

PRP: prerequisite programme; RTE: ready-to-eat; PAH: polycyclic aromatic hydrocarbon.

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

A.4. Simplified food safety management system for food donation

Table A.4: Simplified food safety management system for food donation: Donors

Stage	Hazard identification ^(a)				Activities contributing to increased/decreased occurrence of the hazard	Control measures
	B	C	P	A		
All stages						PRPs 1, 2, 3, 9, 12
Decision on foods to be donated						
Can food still be donated? Decision on acceptability of food to be donated	Y	Y	Y	Y	A critical review has to be undertaken by the donating organisation to establish if foods are still suitable for donation based upon shelf-life evaluation, status of packing material, label information, etc.	PRP 16: Evaluation for food donation and allocation of remaining shelf-life
Freezing						
Freezing (prepacked foods)	Y	N	N	N	Decision if prepacked foods still can be frozen including ensuring there is sufficient shelf-life remaining	PRP 17: Freezing for food donations
					Failure to ensure the microbiological quality of food products to be frozen (quick frozen)	PRP 11: Temperature control
					Re-attributing a date of freezing – labelling	PRP 17: freezing for food donations
Storage						
Frozen storage	Y	Y	Y	Y	Microbial growth due to failure in freezing temperature	PRP 4: Technical maintenance and calibration PRP 11: Temperature control PRP 14: Expiration date control
					Contamination with biological/chemical/physical hazards or allergens from the environment, personnel, etc.	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 (i.e. correct temperature and time), or due to storage for too long period	PRP 4: Technical maintenance and calibration PRP 11: Temperature control PRP 14: Expiration date control
					Cross-contamination due to a failure to separate raw from cooked/RTE products	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
					Contamination with biological/chemical/physical hazards or allergens from the environment, personnel, etc.	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens

Stage	Hazard identification ^(a)				Activities contributing to increased/decreased occurrence of the hazard	Control measures
	B	C	P	A		
All stages						PRPs 1, 2, 3, 9, 12
Ambient storage	Y	Y	Y	Y	Microbial growth due to failure to store in dry conditions	PRP 8: Water and air control PRP 11: Temperature control PRP 14: Expiration date control PRP 16: Evaluation for food donation and allocation of remaining shelf-life
					Contamination with microbial/chemical/physical hazards or allergens from the environment, personnel, etc.	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
					Contamination with allergens due to failure in segregation between allergen-containing and non-allergen-containing products (e.g. dust, aerosols, etc.)	PRP 6: Allergens
Packing/Wrapping						
Packing	Y	Y	Y	Y	Contamination with biological/chemical/physical hazards or allergens from the environment, personnel, etc.	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
					Cross-contamination with microbial hazards due to a failure to separate raw from cooked/RTE products	PRP 4: Technical maintenance and calibration
					Chemicals released from food contact materials	PRP 10: Raw materials (supplier selection, specifications)
					Presence of incomplete/wrong label information	PRP 13: Product information and consumer awareness PRP 14: Expiration date control
					Microbial growth to wrong attribution of shelf life period on the wrapped/prepacked foods	PRP 13: Product information and consumer awareness PRP 16: Evaluation for food donation and allocation of remaining shelf-life
Communication/agreements with recipient						
Communication/agreements with recipient	Y	Y	Y	Y	Clear communication is necessary with recipient on donated foods, e.g. shelf life, temperature control, transport conditions, freezing conditions, etc.	PRP 13: Product information and consumer awareness PRP 16: Evaluation for food donation and allocation of remaining shelf-life PRP 17: Freezing for food donations (shelf life date and conditions of freezing)

Stage	Hazard identification ^(a)				Activities contributing to increased/decreased occurrence of the hazard	Control measures
	B	C	P	A		
All stages						PRPs 1, 2, 3, 9, 12
Transportation						
Ambient transportation	Y	Y	Y	Y	Microbial growth due to failure to store in dry conditions	PRP 8: Water and air control PRP 11: Temperature control PRP 14: Expiration date control PRP 16: Evaluation for food donation and allocation of remaining shelf-life
					Contamination with microbial/chemical/physical hazards or allergens from the environment, personnel, etc.	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
					Contamination with allergens due to failure in segregation between allergen-containing and non-allergen-containing products (e.g. dust, aerosols, etc.)	PRP 6: Allergens
Refrigerated transportation	Y	Y	Y	Y	Microbial growth due to failure to chill properly (i.e. correct temperature and time), or due to storage for too long period	PRP 4: Technical maintenance and calibration PRP 11: Temperature control PRP 14: Expiration date control
					Cross-contamination due to a failure to separate raw from cooked/RTE products	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
					Contamination with biological/chemical/physical hazards or allergens from the environment, personnel, etc.	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
Frozen transportation	Y	Y	Y	Y	Microbial growth due to failure in freezing temperature	PRP 4: Technical maintenance and calibration PRP 11: Temperature control PRP 14: Expiration date control
					Contamination with microbial/chemical/physical hazards due to environment	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens

PRP: prerequisite programme; RTE: ready-to-eat.

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

Table A.5: Simplified food safety management system for food donation: Recipients

Stage	Hazard identification ^(a)				Activities contributing to increased/decreased occurrence of the hazard	Control measures
	B	C	P	A		
All stages						PRPs 1, 2, 3, 9, 12
Receiving	Y	Y	Y	Y	Failure to ensure the microbiological quality of incoming raw materials	PRP 10: Raw materials (supplier selection, specifications)
						PRP 11: Temperature control
						PRP 14: Expiration date control
					Presence of chemical/physical hazards or allergens in incoming raw materials	PRP 6: Allergens
					PRP 10: Raw materials (supplier selection, specifications)	
				Incomplete shelf-life data	PRP 14: Expiration date control	
				Mixing returns with other products	PRP 15: Returns management	
Storage						
Ambient storage	Y	Y	Y	Y	See above	See above
Refrigerated storage	Y	Y	Y	Y	SEE ABOVE	See above
Frozen storage	Y	Y	Y	Y	See above	See above
Sorting						
Inspection and sorting	Y	N	N	N	Microbial contamination of food products sorted out (e.g. mould growth on fruits)	No additional PRPs
					Contamination with biological/chemical/physical hazards or allergens from the environment, personnel, etc.	PRP 5: Physical and chemical contamination from production environment PRP 6: Allergens
Evaluation of shelf-life						
Evaluation of shelf-life	Y	N	N	N	Before products are entering the food donation organisation the attributed shelf life has to be evaluated if products still can be donated, stored, frozen, relabelled, etc.	PRP 16: Evaluation for food donation and allocation of remaining shelf-life PRP 17: Freezing for food donations
Repacking/relabelling						
Packing	Y	Y	Y	Y	See above	See above
Freezing						
Freezing (pre packed foods)	Y	N	Y	N	See above	See above

Stage	Hazard identification ^(a)				Activities contributing to increased/ decreased occurrence of the hazard	Control measures
	B	C	P	A		
All stages						PRPs 1, 2, 3, 9, 12
Storage						
Ambient storage	Y	Y	Y	Y	See above	See above
Refrigerated storage	Y	Y	Y	Y	See above	See above
Frozen storage	Y	Y	Y	Y	See above	See above
Transportation						
Ambient transportation	Y	Y	Y	Y	See above	See above
Refrigerated transportation	Y	Y	Y	Y	See above	See above
Frozen transportation	Y	Y	Y	Y	See above	See above

PRP: prerequisite programme.

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