Official Journal of the European Union

C 355

English edition

Information and Notices

Volume 65

16 September 2022

Contents

EN

II

(Information)

INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN COMMISSION

COMMISSION NOTICE

on the implementation of food safety management systems covering Good Hygiene Practices and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses

(2022/C 355/01)

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1. INTRODUCTION

In 2016, the Commission adopted the Commission Notice on the implementation of food safety management systems covering prerequisite programmes (PRP) and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses ([1]) ('the 2016 Notice'). The 2016 Notice provided guidance as a follow-up of the 'Overview Report on the State of Implementation of HACCP in the EU and Areas for Improvement' prepared by the former Food and Veterinary Office of the Commission's Health and Food Safety Directorate-General after a number of fact-finding missions. Before the 2016 Notice, a comprehensive consultation of Member States and Stakeholders was carried out.

Since 2016, a number of revisions of relevant legislation took place (e.g. the introduction of allergen control and food safety culture as requirements in Regulation (EC) No 852/2004 ([2]) by Regulation (EU) 2021/382 ([3]) and international standards (e.g. the revision of ISO 22000 ([4]) and of the Codex Alimentarius General principles of Food Hygiene ([5]), and the adoption of the Codex Alimentarius Code of Practice on Food Allergen Management for Food Business Operators ([6])). A number of relevant scientific opinions were published by the European Food Safety Authority (EFSA) ([7]) and further experiences were also gained from the practical implementation of the recommendations.

A revision of the 2016 Notice was therefore considered appropriate.

While preparing this revision, the Commission held a series of meetings with experts from Member States in order to examine and reach consensus on these issues. In addition the Advisory Board on the Food Chain was consulted.

2. PURPOSE AND SCOPE

The purpose of this guidance is to facilitate and harmonise the implementation of the EU requirements on Good Hygiene Practices (GHP) and procedures based on the Hazard Analysis and Critical Control Points principles (HACCP-based procedures) as parts of Food Safety Management Systems (FSMS) by providing practical guidance on:

— the relevant legislation, the link between GHP, prerequisite programmes (PRP), operational PRP (OPRP) and HACCP-based procedures within a FSMS, the relationship with international standards and training and the use of guides to good hygiene practices;

— the implementation of GHP including the flexibility provided for certain food establishments by EU legislation related to their implementation (Annex I)

— the implementation of HACCP-based procedures, including the flexibility provided for certain food establishments by EU legislation related to their implementation (Annex II)

— the auditing of FSMS (Annex III).

Major attention is paid to the flexibility provided for in the application of GHP and procedures based on the HACCP principles, taking into account the nature of the activity and the size of the establishment.

This Commission Notice replaces the 2016 Notice.

This guidance is not legally binding in contrast with the legal requirements referred to in Section 4. This guidance provides tools or examples to all food business operators of how to implement the EU requirements and may be supplemented by guidance at sectorial and national level to be directly applicable in specific establishments. It is directed at competent authorities to promote a common understanding of legal requirements and at food business operators to help with implementing EU requirements after the establishment of business specific adaptations and without prejudice to their primary responsibility in matters of food safety.

([1]) OJ C 278, 30.7.2016, p. 1.

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

([3]) Commission Regulation (EU) 2021/382 of 3 March 2021 amending the Annexes to Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs as regards food allergen management, redistribution of food and food safety culture (OJ L 74, 4.3.2021, p. 3).

([4]) ISO 22000:2018 Food safety management systems – Requirements for any organization in the food chain (https://www.iso.org/standard/65464.html)

([5]) CXC 1-1969

([6]) CXC 80-2020

([7]) 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) and Hazard analysis approaches for certain small retail establishments and food donations: second scientific opinion (*EFSA Journal* 2018;16(11):5432).

3. **DEFINITIONS**

— **Acceptable level:** A level of hazard in a food at or below which the food is considered to be safe according to its intended use.

— **Control measure:** Any action or activity that can be used to prevent or eliminate a hazard or reduce it to an acceptable level ([8]).

— **Corrective action:** Any action taken when a deviation occurs in order to re-establish control, segregate and determine the disposition of the affected product if any and prevent or minimize reoccurrence of the deviation[8].

— **Critical control point(s) (CCP):** A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level. Most typical CCP to control microbiological hazards are temperature requirements e.g. the time/temperature conditions to reduce or eliminate a hazard (e.g. pasteurisation). Other CCP may be checking for micro-lesions in canned food, checking for physical hazards by sieving or metal detection or checking time/temperature of frying oil to avoid chemical process contaminants.

— **Critical limit:** A criterion, observable or measurable, relating to a control measure at a CCP which separates acceptability from unacceptability of the food[8]. In the CCP examples above, they refer respectively to the minimum temperature (hazard reduction/elimination) and the (likely) presence of contamination.

— **Food Safety Management system (FSMS):** Prerequisite programmes, supplemented with control measures at CCP, as appropriate, that when taken as a whole, ensure that food is safe and suitable for its intended use[8]. The FSMS is also the combination of control measures and assurance activities. The latter aims at providing evidence that control measures are working properly such as validation and verification, documentation and record keeping.

— **Good Hygiene Practices (GHP):** Fundamental measures and conditions applied at any step within the food chain to provide safe and suitable food[8]. GHP include also good manufacturing practice(s) (GMP, stressing correct work methodologies e.g. correct dosage of ingredients, appropriate processing temperature, checking that packages are clean and non-damaged), good agriculture practice(s) (GAP, e.g. use of water of appropriate quality for irrigation, all in/all out system in animal rearing), good veterinarian practice(s) (GVP), good production practice(s) (GPP), good distribution practice(s) (GDP) and good trading practice(s) (GTP).

— **GHP plan:** Documentation and records, providing and justifying the applied GHP, as well as records on the monitoring, verification and corrective actions, if applicable, available in any format. The GHP plan can be integrated in the HACCP plan.

— **Hazard:** A biological (e.g. *Salmonella*), chemical (e.g. dioxin, allergens) or physical (e.g. hard, sharp foreign bodies as pieces of glass, metal) agent in food with the potential to cause an adverse health effect[8].

— **Hazard analysis:** The process of collecting and evaluating information on hazards identified in raw materials and other ingredients, the environment, in the process or in the food, and conditions leading to their presence to decide whether or not these are significant hazards[8].

— **HACCP-based procedures or 'HACCP':** Procedures based on the hazard analysis and critical control points (HACCP) principles i.e. an own-check system which identifies, evaluates and controls hazards which are significant for food safety consistent with the HACCP principles.

— **HACCP plan:** Documentation or set of documents, prepared in accordance with the principles of HACCP to ensure control of significant hazards in the food business[8], available in any format. The initial HACCP plan shall be updated if there are changes in the production and must be supplemented with records from outcomes of monitoring and verification, and from corrective actions taken.

— **Monitor:** The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is under control[8].

([8]) CXC 1-1969, Rev. 2020

— **Operational prerequisite programme(s) (OPRP):** control measure or combination of control measures applied to prevent or reduce a significant food safety hazard to an acceptable level and where action criterion and measurement or observation enable effective control of the process and/or product. They are typically linked to the production process and are identified by the hazard analysis as essential, in order to control the likelihood of the introduction, survival and/or proliferation of food safety hazards in the product(s) or in the processing environment.

— **Prerequisite programme(s) (PRP)**: Preventive practices and conditions including all GHP, as well as other practices and procedures such as training and traceability, that establish the basic environmental and operating conditions that set the foundation for implementation of HACCP-based procedures ([9]). See also Section 5.

— **Risk:** means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard ([10]).

— **Significant hazard:** A hazard identified by a hazard analysis, as reasonably likely to occur at an unacceptable level in the absence of control, and for which control is essential given the intended use of the food[8].

— **Validation**: Obtaining evidence that a control measure or combination of control measures, if properly implemented in the HACCP-based procedures and by the OPRP, is capable of controlling the hazard to a specified outcome. Revalidation may be required in case of changes[9]. Detailed examples can be found in CAC/GL 69-2008.

— **Verification:** The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended[8]. Verification is conducted periodically to demonstrate that the HACCP system and the management of the OPRP are working as planned.

4. **LEGISLATION**

4.1. **GHP**

Article 4 of Regulation (EC) No 852/2004 requires food business operators (FBOs) to comply with the general hygiene requirements detailed in its Annex I for primary production and associated operations and in its Annex II for other stages of the food production chain. They are supplemented by specific hygiene requirements for food of animal origin, provided for in Regulation (EC) No 853/2004 ([11]).

4.2. **HACCP based procedures**

Article 5 of Regulation (EC) No 852/2004 requires FBOs to put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles. HACCP principles are generally considered and internationally recognised to be a useful own check system for food business operators in order to control hazards that may occur in food.

Regulation (EC) No 852/2004 clearly excludes primary production and associated operations from the requirement for HACCP-based procedures. Nevertheless, that Regulation requests Member States to encourage operators at the level of primary production to apply such principles as far as possible (see the last example of GHP requiring greater attention in Section 5).

At other stages of the food chain, Regulation (EC) No 852/2004 recognises that, in certain food businesses, it is not possible to identify critical control points and that, in some cases, GHP are sufficient to control the hazards. In addition, the requirement of retaining documents needs to be flexible in order to avoid undue burdens for very small businesses. The obligation, laid down in Article 5 of Regulation (EC) No 852/2004 that food business operators must put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles, is an obligation to carry out a hazard analysis and consider if critical control points can be identified, being the first two HACCP principles (at least in a simplified way or based on a guide). Where no critical control points or OPRP are identified, it might be concluded that the GHP are sufficient. This does not exclude the need for the monitoring, validation and verification of certain GHP.

([9]) Slightly adapted from the definition in CXC 1-1969, Rev. 2020.
([10]) Article 3(9) of the Regulation (EC) No 178/2002 and the procedural manual of the Codex Alimentarius Commission.
([11]) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

4.3. **Other legal obligations within a FSMS**

A number of other principles and mandatory requirements within a FSMS are laid down in Regulation (EC) No 178/2002 ([12]): risk analysis approach, precautionary principle, transparency/communication, primary responsibility of FBOs, traceability and withdrawal/recall procedures. More detailed requirements might be laid down such as in Commission Implementing Regulation (EU) No 931/2011 ([13]) on traceability in food of animal origin.

These principles and requirements are not further addressed in this Commission Notice but guidance can be found at https://ec.europa.eu/food/horizontal-topics/general-food-law/food-law-general-requirements_en .

5. **RELATIONSHIP BETWEEN FSMS, PRP, GHP, OPRP AND HACCP, AND WITH INTERNATIONAL STANDARDS**

Overall an FSMS ([14]) is a holistic system of prevention, preparedness ([15]) and own-check activities to manage food safety, including food hygiene, in a food business. An FSMS should be seen as a practical tool to control the food production environment and process and ensure that the food produced is safe. It includes:

— GHP (e.g. appropriate cleaning and disinfection, personal hygiene), being a number of fundamental preventive measures and conditions applied at any step within the food chain to provide safe and suitable food. They contain three elements i.e. structural (e.g. facilities, equipment), operational (work flow, handling of food) and personal behaviour (personal hygiene). GHP are all prerequisite programmes (PRP) e.g. practices and procedures that establish the basic environmental and operating conditions for safe food. PRP set the foundation for the implementation of a HACCP system. Additional PRP for prevention and preparedness, other than GHP, are traceability and efficient withdrawal/recall systems.

— HACCP-based procedures, being mandatory in all food establishments except activities of primary producers and associated operations. They are part (with the GHP) of a system for the business itself to evaluate if sufficient and effective GHP are in place and if the hazard analysis reveals the presence of significant hazards and consequently, the need for the implementation of critical control points, requiring the full application of the HACCP-based procedures.

Gradually stakeholders pointed out that, there was often in practice a gap between the GHP and the CCP to address intermediate and certain significant hazards and concepts were introduced such as points of attention, control points, etc. Codex and ISO 22000 took two different approaches to manage these risks:

— The Codex Alimentarius' CXC 1-1969 '*General Principles of Food Hygiene*' refers to 'GHP requiring greater attention' to address identified significant hazards. Thus, for some GHP, based on safety concerns with the food, 'greater attention' may be needed to provide safe food. Greater attention may include a higher frequency of application, of monitoring and of verification.

— ISO 22000 introduced in 2005 operational prerequisite programmes (OPRP) to fill this gap. They are control measures which are implemented to prevent or reduce a significant food safety hazard to an acceptable level. They are identified during the hazard analysis as important to control certain significant hazards.

([12]) 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).

([13]) Commission Implementing Regulation (EU) No 931/2011 of 19 September 2011 on the traceability requirements set by Regulation (EC) No 178/2002 of the European Parliament and of the Council for food of animal origin (OJ L 242, 20.9.2011, p. 2).

([14]) In the Codex Alimentarius Principles of Food Hygiene, FSMS is called a 'Food hygiene system'. The FSMS can be part of a broader quality management system (such as ISO 9000) which also includes quality aspects of food (composition, nutritional values, etc.). Quality aspects are outside the scope of this guidance.

([15]) Preparedness refers to measures in place such as traceability provisions, communication tools, withdrawal/recall system, etc. allowing the FBO to directly and efficiently take the necessary measures to protect and inform the consumer in case of non-compliance.

Typical examples of GHPa and/or OPRP are:

— the cleaning of equipment and surfaces which come into contact with ready-to-eat food should warrant greater attention than other areas such as the cleaning of walls and ceilings, because if food contact surfaces are not properly cleaned, this could lead to direct contamination of food with *Listeria monocytogenes*;

— more intensive cleaning and disinfection and more strict personal hygiene (e.g. mouth masks and extra protection of personnel) in high risk areas, for example in packaging areas of ready to eat food;

— checking of packaging of canned food on cleanness and damages;

— more stringent incoming checks upon reception of raw materials if the supplier is not guaranteeing the desired quality/safety level (e.g. mycotoxins in spices);

— intermediate efficient cleaning to control cross-contamination between batches of production containing different allergens (nuts, soy, milk, …). The severity of the health effect is high and the risk of deviation (presence by cross-contamination) might be substantial, however, real-time monitoring is impossible. See also Section 3.7 of Annex I;

— consideration of the bacteriological quality of irrigation water as control points might be appropriate in particular for ready-to-eat crops.

— control of the washing process of vegetables (e.g. by frequency of wash water refreshment to avoid microbial cross-contamination, mechanical action in the water to remove physical hazards such as stones, or pieces of wood);

— control of blanching process for the deep freezing industry (time/temperature); washing and blanching processes can usually not be considered as CCP because neither full elimination of the significant microbial hazards nor reduction to an acceptable level can be achieved or is aimed for; however, they will impact the microbial load of the processed products and contribute, when associated with other control measures to the elimination of the significant hazards or their reduction to an acceptable level;

In the EU, a central role is given to the hazard analysis, considered as essential to identify the different levels of risks, e.g. if GHP are sufficient, or if intermediate and/or risks for significant hazards need to be addressed respectively by OPRP and/or CCP. Since GHP requiring greater attention are not necessarily identified by the hazard analysis in the Codex General Principles of Food Hygiene, but OPRP are in ISO 22000, reference is made to OPRP in this document.

Due to the lack of coordination between Codex and ISO 22000, the guidance provided in this document had to make this choice to avoid confusion by operators between the two different approaches or by the unneeded split between two kinds of similar risks. Nevertheless, the guidelines in this document are considered in line with both international standards, which can be additionally used as source material on the implementation of a FSMS. It is recognised that Codex Alimentarius is the official reference in a global trade context.

A visual overview of the EU approach on FSMS is provided in Appendix 1.

Prior to the application of the HACCP-based procedures to any business, the food business operator should have implemented the PRP, including GHP and the other measures laid down in Regulation (EC) No 178/2002. These are the prevention and preparedness pillars of each FSMS and are needed to develop HACCP-based procedures, representing a systematic control by the FBO of significant, specific hazards, not sufficiently controlled by PRP only.

A 2 step approach (PRP/CCP, see also 'ALTERNATIVE APPROACH' in Appendix 2) is the minimum legal requirement but it can be recommended to use the 3 step approach identifying PRP, OPRP and CCP. Many businesses could apply a 2 step approach while the 3 step approach might be more suitable for larger and more complex businesses.

6. FLEXIBILITY IN APPLYING GHP AND HACCP

There are differences in risk depending on the nature of the activity which should be taken into account when considering flexibility in the application of GHP. One example is retail of pre-packaged food as opposed to retail including further handling of the food (e.g. butcher or delicatessen shop handling exposed ready-to-eat foods). Another example is the difference between a complex manufacturing/ processing activity and a simple one such as storage/transport.

In order to ensure proportionality in administrative burdens, a number of requirements such as documentation and record keeping, can be simplified in small business compared to larger ones carrying out the same activity.

HACCP-based procedures should provide sufficient flexibility to be applicable in all circumstances ([16]).

Annexes I and II, respectively on GHP and HACCP-based procedures, include guidance on a simplified implementation of the FSMS for appropriate FBOs, taking into account their nature and size and provide examples:

— To identify those food businesses where flexibility would be appropriate based on their risk and size,

— To explain the concept of 'simplified HACCP-based procedures',

— To explain the role of guides to good practice and generic HACCP guides, including the need for documentation, and

— To identify the extent of flexibility applicable to the procedures based on the HACCP principles.

The outcome of a validated private quality control scheme audit may be used as a source of information and taken into account in the development and implementation of a FSMS.

Avoiding languages that small FBOs may find difficult to understand, in particular in national or generic guides, can reduce barriers to FBOs using such guides.

Flexibility is not primarily intended to reduce the number of CCP and should not compromise food safety.

7. GUIDES TO GOOD HYGIENE PRACTICE AND HACCP-BASED PROCEDURES

National and EU guides provide useful recommendations how to implement GHP and HACCP-based procedures. It can be integrated but should not replace the FBO specific hazard analysis.

7.1. National guides in accordance with Article 8 of Regulation (EC) No 852/2004

Guides to good practice have already been developed or assessed by the competent authorities for many food sectors ([17]). These guides can also be developed together with sectorial stakeholder organisations. The guides mostly focus on GHP but sometimes combine GHP with other PRP and with some or all of the procedures based on the HACCP principles.

The use of guides to good practice may help FBOs to control hazards and demonstrate compliance with legal requirements. They can be applied by any food sector, and in particular where the handling of food is in accordance with procedures that are well known and that are often part of the usual vocational training.

Such guides can also highlight the possible hazards linked to certain foods (e.g. the presence of *Salmonella* in raw eggs), and the methods used to control food contamination (e.g. the purchase of raw eggs from a reliable source, time/temperature combinations for processing, separation of ready and non-ready-to-eat foods, etc.).

Competent authorities should consider the development of guides themselves, in particular in sectors where no sectorial stakeholders' organisations exist or for activities typically carried out by small or very small businesses, which need some generic guidance to start from for their specific establishment.

([16]) Recital 15 of Regulation (EC) No 852/2004.

([17]) http://ec.europa.eu/food/safety/docs/biosafety_food-hygiene_legis_guidance_good-practice_reg-nat.pdf

7.2. **EU guides in accordance with Article 9 of Regulation (EC) No 852/2004**

Several European sectorial stakeholders' organisations have developed EU guides for good hygiene practice. The list of these guides can be consulted at: https://ec.europa.eu/food/food/biological-safety/food-hygiene/guidance-platform_en. In some cases, the European Commission provided sector specific guidance itself, in particular when the FBOs are often small businesses:

— Commission Notice providing guidance on food safety management systems for food retail activities, including food donations ([18]) ('Commission Notice on retail');

— Commission notice on guidance document on addressing microbiological risks in fresh fruits and vegetables at primary production through good hygiene ([19]).

8. **TRAINING**

Staff of FBOs should be supervised and instructed and/or trained in food hygiene matters appropriate to their role, and those responsible for developing and maintaining the food safety management system should be suitably trained in the application of GHP, other PRP and HACCP–based procedures.

The management shall make sure that staff taking part in the relevant processes demonstrate sufficient skills and are aware of the hazards identified (if any) and of the critical points in the production, storage, transport and/or distribution process. They must also show awareness of the corrective measures, the preventive measures and monitoring and recording procedures applicable in the business, in accordance with Chapter XII of Annex II to Regulation (EC) No 852/2004.

A distinction should be made between training on hygiene in general (all employees) and specific HACCP training. The employees who monitor/manage or verify critical control points (CCP) should be trained in the procedures based on the HACCP principles appropriate to their tasks (for example, a waiter/waitress will need a certain level of hygiene training, while a cook will need additional training related to the hygienic preparation of food). Possible refresher training and its frequency should be considered according to the needs of the establishment and demonstrated skills.

The stakeholders' organisations of different food industry sectors should endeavour to prepare information on training for the FBOs.

Training as referred to in Chapter XII of Annex II to Regulation (EC) No 852/2004 must be seen in a broad context. In such context, appropriate training does not necessarily involve participation in formal training courses. Skills and knowledge can also be achieved through access to technical information and advice from professional organisations or from the competent authorities, suitable on-the-job/in house training, and guides to good practice etc.

GHP, other PRP and HACCP training of staff in food businesses should be proportionate to the size and the nature of the business and take into account specific risks related to the nature of the activity.

The importance of training has been enhanced due to the introduction of the (mandatory) requirement for a food safety culture in Regulation (EC) No 852/2004 in March 2021. Training will often be the most important tool to achieve a good food safety culture or to serve as corrective action in case shortcomings are detected when evaluating the extent of the food safety culture (See Annex I, section 4.14).

The competent authority may, when needed, assist in developing training activities as mentioned in previous paragraphs, especially in those sectors which are poorly organised or are shown to be insufficiently informed. Such assistance is comprehensively elaborated in the 'FAO/WHO guidance to governments on the application of HACCP in small and/or less-developed food businesses ([20])'.

([18]) OJ C 199, 12.6.2020, p. 1.
([19]) OJ C 163, 23.5.2017, p. 1.
([20]) http://www.fao.org/docrep/009/a0799e/a0799e00.HTM

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ANNEX I

Good hygiene practices

GHP are a number of preventive measures and conditions applied at any step within the food chain to provide safe and suitable food. They should be understood broadly, e.g. including GMP, GAP, etc. Most GHP are not specific for a given hazard, but are designed to keep below acceptable levels or to bring from above to below acceptable levels, hazards arising from the production environment that may adversely affect the products safety.

Each FBO must implement GHP that are prerequisites to ensure an efficient FSMS. Together with other PRP of the FSMS, such as traceability provisions and withdrawal/recall systems, they provide the foundation for effective HACCP implementation and should be in place before any HACCP-based procedures are established.

1. LEGISLATION

Article 4 of Regulation (EC) No 852/2004 lays down general and specific hygiene requirements, described as GHP in this Notice, and in particular, that:

'1. Food business operators carrying out primary production and those associated operations listed in Annex I shall comply with the general hygiene provisions laid down in part A of Annex I and any specific requirements provided for in Regulation (EC) No 853/2004.

2. Food business operators carrying out any stage of production, processing and distribution of food after those stages to which paragraph 1 applies shall comply with the general hygiene requirements laid down in Annex II and any specific requirements provided for in Regulation (EC) No 853/2004.'

The most important provisions for GHP are therefore laid down in:

a) The general hygiene requirements laid down in Annex I of Regulation (EC) No 852/2004 for primary production and associated operations. Separation of GHP for this stage compared to later stages of the food chain is needed because of the nature of primary production (live animals, plants before harvest) and because primary production cannot take place in fully controlled conditions for premises, equipment, water and other environmental control. Guidance on what is covered by 'primary production and associated activities' can be found in the *Guidance document on the implementation of certain provisions of Regulation (EC) No 852/2004 on the hygiene of foodstuffs* ([1]).

b) The general hygiene requirements laid down in Annex II of Regulation (EC) No 852/2004 for activities after primary production further on in the production chain.

The specific hygiene requirements for food of animal origin laid down in Annex III of Regulation (EC) No 853/2004. Some of these requirements are directed to primary producers (e.g. for eggs, raw milk, live bivalve molluscs, fishery products): see Section 3.7 of the *Guidance document on the implementation of certain provisions of Regulation (EC) No 853/2004 on the hygiene of food of animal origin* ([2]). Since these GHP are sector/food specific, they are not further addressed in this (general) guidance Notice.

2. FLEXIBILITY IN THE IMPLEMENTATION OF GHP

GHP apply to all FBOs. Overall, the requirements in Annexes I and II of Regulation (EC) No 852/2004 are described relatively generally since they need to be applied by all (and very different) sectors of food production. They therefore include automatically a high degree of flexibility as to how they should be complied with in practice.

It should not be assumed that all GHP as detailed in Section 4 apply to all establishments. A case by case assessment should be made to identify relevant GHP for each establishment which should be implemented in a manner that is proportionate to the nature and size of the establishment.

Regulations (EC) Nos 852/2004 and 853/2004 contain several flexibility provisions, which are mainly intended to facilitate the implementation of GHP in small businesses:

(a) GHP laid down in Annex I of Regulation (EC) No 852/2004, intended for primary production and associated activities, are more general than those in Annex II for other FBOs;

([1]) https://ec.europa.eu/food/system/files/2018-10/biosafety_fh_legis_guidance_reg-2004-852_en.pdf
([2]) https://ec.europa.eu/food/system/files/2020-05/biosafety_fh_legis_guidance_reg-2004-853_en.pdf

(b) within Annex II of Regulation (EC) No 852/2004, simplified general and specific requirements for premises and rooms are laid down for movable and/or temporary premises, premises used primarily as a private dwelling-house but where foods are regularly prepared for placing on the market, and vending machines (Chapter III of the Annex II);

(c) exclusions from the scope (Article 1) of Regulation (EC) No 852/2004, for example the direct supply by the producer of small quantities of primary products to the final consumer or to a local retail establishment directly supplying the final consumer;

(d) exclusions from the scope (Article 1) of Regulation (EC) No 853/2004, for example the direct supply by the producer of small quantities of meat from poultry and lagomorphs slaughtered on the farm to the final consumer or to local retail establishment directly supplying such meat to the final consumer;

(e) exclusion of most retailers from Regulation (EC) No 853/2004 (Article 1(5));

(f) the possibility to adapt GHP under national law in accordance with Article 10(4) of Regulation (EC) No 853/2004:

i. to enable the continued use of traditional methods;

ii. to accommodate the needs of FBO situated in regions that are subject to special geographic constraints (e.g. remote areas, mountain areas and remote small islands;

iii. in any establishment as regards construction, layout and equipment.

A number of examples of flexibility are provided in the specific GHP below. Details on flexibility also can be found in the following dedicated guidance documents:

— Commission Staff Working Document on the Understanding of certain provisions on Flexibility provided in the Hygiene Package - Guidelines for the competent authorities: https://ec.europa.eu/food/system/files/2016-11/biosafety-hygiene-faq_all_public_en.pdf

— Commission Staff Working Document on the Understanding of certain provisions on Flexibility provided in the Hygiene Package - Frequently Asked Questions - Guidelines for food business operators: https://ec.europa.eu/food/system/files/2016-11/biosafety-hygiene-faq_all_business_en.pdf

Generic sectorial guides on GHP may sometimes be used by small businesses to comply with GHP or to help them in the description of their own GHP.

GHP are tools to achieve safe food, being a legal requirement, so flexibility may be applied to the documents and records kept, but never to the objectives of the GHP.

3. **EXAMPLES OF GHP**

The FBO should document the GHP measures to ensure safe conditions for food production, taking into account the size and nature of the business, with an indication of the person(s) responsible for their implementation.

The GHP provided below provide a non-exhaustive list, while each establishment must comply with the legal requirements referred to in Section 1 of this Annex. The GHP below are therefore possible examples of how to comply with the legal requirements in practice. These examples tend to focus on food manufacturing/processing establishments. They may also provide a possible source of inspiration for other stages such as primary production, catering and other retail activities, including food distribution, but may not be applicable in every case.

The examples below remain quite general. An extensive list of sector specific guides to GHP has been developed (See Section 7 of main document).

3.1. **Infrastructure (building, equipment)**

a) When assessing the risk from the location and surrounding areas, the proximity of potential sources of contamination, water supply, wastewater removal, power supply, access for transport, climate, possible flooding, etc. should be taken into account. This should also be considered for primary production (fields).

b) Lay-out should strictly separate contaminated (high risk) from clean areas (low risk) (or there should be a separation in time and suitable cleaning in between); suitable arrangements of rooms should be made for one-direction production flow and cooled rooms or heating facilities should be insulated.

c) Non-slippery floors should be constructed with waterproof, non-absorbent material, and should be washable and without fissures. Walls should be likewise at least up to appropriate height. It is also recommended that walls and floors are in light colors that facilitate visual hygiene assessment.

d) Doors should have smooth and non-absorbent surfaces. Automatic opening and closing should be considered to avoid contamination by touching.

e) There should be sufficient lighting in all areas, with special attention paid to the provision of suitable lighting to food preparation and inspection areas. Lighting should be easy to clean, with protective covers to prevent contamination of food in the event of lights breaking.

f) Clearly defined storage facilities should be available for raw material, and receptacles for food and packaging materials. Only products that may be added to food (e.g. additives) should be stored in the area with the food, excluding common storage with toxic products (e.g. pesticides).

g) The specific clothes changing room(s) should be clean and ordered and, where possible, not used as a refectory or a smoking room. A separation between normal clothing, clean work clothing and used work clothing should be facilitated.

h) Toilets should not open directly to food handling areas. Preferably water flushing with use of foot/arm pedals should be present and reminders to wash hands and strategically placed signs informing about the obligation, when applicable, to remove protective clothing before using the toilets.

i) Hand washing facilities should be positioned conveniently between toilets/ changing rooms and the food handling area, not excluding the possible need for additional wash hand basins in production areas near work stations; disinfectants, soap and towels for single use should be available; installations blowing warm air should only be present in rooms without food and non-hand-operable taps are desirable.

j) Barriers should be in place to avoid access of stray animals.

k) Equipment and monitoring/recording devices (e.g. thermometers) should be clean and the equipment suitable for contact with food products.

l) Attention should be paid to the different possibilities whereby the use of equipment can result in (cross-) contamination of food:

   i. Prevention of contamination of the equipment by the environment e.g. condensation dripping from ceilings;

   ii. Prevention of contamination within the food handling equipment e.g. accumulation of food residues in slicing devices;

   iii. Prevention of contamination by raw materials: separate equipment (or cleaning and disinfection between uses) for raw products and cooked products (chopping boards, knives, dishes, clothing of staff, thermometers etc.).

m) There should be an appropriate number of monitoring devices to measure critical parameters e.g. temperature.

3.2. **Cleaning and disinfection**

a) What, when, how and by who to clean and disinfect should be considered.

b) Typical steps should be the removal of visible dirt, followed by cleaning, followed by rinsing, followed by disinfection and rinsing again.

c) Cleaning should start in high risk areas and should end in low risk areas. Materials and equipment for cleaning equipment should be different between low and high risk areas and in any case never move from a high contaminated area to a low one. Special attention must be paid to the contamination of disinfected surfaces due to splash when rinsing other surfaces.

d) Potable water and/or cleaning agent or disinfectant should be used as much as needed to gain the desired effect in cleaning and/or disinfection. The water should be at an appropriate temperature and the chemicals should be used as per the manufacturer's instructions.

e) Technical information should be available in your native language regarding detergents, disinfection agents (e.g. instructions for use, active component, contact time, concentration, use of potable water if appropriate).

f) Visual checks on cleaning and sampling for analysis should be used to control disinfection activities.

g) FLEXIBILITY EXAMPLE: Cleaning and disinfection in a small butcher shop might be very close to good hygiene practices in a kitchen, while specialised external companies might be needed in a large slaughterhouse.

3.3. **Pest control: emphasis on preventive activities**

a) External walls should be free of cracks or chinks, surroundings should be neat and free from debris which could provide harborage from pests, and areas for cleaning should be accessible. Access by pets or wild animals must be prohibited/ prevented.

b) Insect screen should be placed at windows. When electronic devices are used for insect control, the device has to be used according to its specification.

c) Doors should be kept closed except when loading and/or unloading. Gaps between doors and floors should be pest-proofed.

d) Unused equipment and rooms should be kept clean.

e) The presence of an indoor pool of water should be addressed as soon as possible. Ponding or pooling of water must be prevented or avoided.

f) A pest control programme should be available:

   i. Baits and traps (inside/outside) should be considered in appropriate numbers and also their strategic placement;

   ii. The programme should cover rodents, crawling, walking and flying pests;

   iii. Dead pests and insects should be frequently removed ensuring no possible contact with food;

   iv. The cause should be determined in case of a recurrent problem;

   v. Chemicals used to control harmful organisms have to be authorized by the Biocidal Products Regulation ([3]). Pesticides should be stored safely and used so that there is no possible contact with, inter alia, food, packaging material and equipment. Fly traps (including electric fly killers) should not be placed directly above areas where food is processed or stored.

   vi. Chemical substances (e.g. biocidal products used for the control rodents) should not be used to monitor the occurrence of pests but restricted to pest control activities only.

   vii. FLEXIBILITY EXAMPLE: professional pest control is preferable, but in most cases, it is not compulsory, provided the staff can demonstrate competence. In particular, small business can apply this flexibility.

3.4. **Raw materials (supplier selection, specifications)**

a) Consideration should be given not only to the supply of raw materials themselves but also to the supply of additives, processing aids, packaging material and food contact material.

b) A strict supply policy, containing an agreement on specifications (e.g. microbiological) and hygiene assurance and/or the request for a certified quality management system can be taken into account in respect of the extent of details on the GHP and HACCP plan of the establishment itself. It is recommended that raw materials are labelled when allergens are present (See Section 3.7).

([3]) Regulation (EU) No 528/2012.

c) Apart from agreements with and the possible auditing of the supplier, a number of issues might give a good indication on the reliability of the supplier such as homogeneity of delivered goods, compliance with the agreed delivery period, accuracy of the information added, sufficient shelf life or freshness, use of clean and suitably equipped transportation, hygiene awareness of the driver and other food handlers transporting the food, correct temperature during transport, long term satisfaction, etc. Most of these issues should be part of delivery checks. It may be necessary to be aware of previous cargoes of a transport vehicle in order to implement adequate cleaning procedures to reduce the likelihood of cross contamination, also by allergens.

d) Legal requirements during transport (e.g. temperature conditions) should be verified and maintained during unloading.

e) Storage conditions at the establishment itself should take into account any instructions provided by the supplier, 'first in, first out' or 'first expired, first out' principles, accessibility for inspection from all sides (e.g. not placed directly on the ground, against walls, etc.).

f) FLEXIBILITY EXAMPLE: Delivery checks of prepacked food at retail can be limited to checking if packages are undamaged and temperatures during transport were acceptable, without the need for regular sampling and testing.

g) FLEXIBILITY EXAMPLE: in some cases the supplier approval policy can be based on simple procedures as at least checking its register/approval number that guarantees that they are subjected to official control activities. In higher risk activities it can be supplemented with additional requests.

3.5. **Technical maintenance and calibration**

a) The maintenance plan should be considered with a technical specialist. The plan should include 'emergency' procedures when equipment is defective and instructions for preventive replacement of seals, gaskets, etc.

b) Attention should be paid to hygiene during maintenance operations.

c) Calibration of monitoring devices (e.g. weighing scales, thermometers, flow meters) is important in controlling food safety and hygiene. Records of calibration should be kept.

d) FLEXIBILITY EXAMPLE: testing the accuracy of thermometers may be based on a simple comparison with another, if possible, calibrated thermometer. Another simple procedure if the thermometer is used to take the temperature of cold foods, testing it in a glass with ice water and if used to take the temperature of hot foods, testing with boiling water.

3.6. **Physical and chemical contaminations from production environment (e.g. oils, inks, use of (damaged) wooden equipment, etc.)**

a) The frequency of the control of physical hazards (such as glass, plastic and metal) should be determined using a risk-based analysis (how big is the likelihood of occurrence in an establishment in question?).

b) A procedure should be available explaining what to do in case of the breakage of glass, hard plastic, knives, etc.

c) Only cleaning products suitable for food contact surfaces should be used in food processing environments where there is some possibility of incidental food contact. Other cleaning products should be only used outside periods of production.

d) Lubricants must be food grade when used in environments in which foods are processed and where there is the possibility of accidental contact with food.

e) Possible chemical hazards should only be dealt with by specialized, trained staff. Weighing scales for additives should be preferably automatic.

3.7. **Allergens**

Allergens must be considered as part of the food safety management system. The possible and unintentional presence in food of substances or products causing allergies or intolerances poses a hazard to food allergic consumers.

Regulation (EU) No 1169/2011 ([4]) on food information to consumers requires that the information is always provided to the consumers on the presence of any ingredient or processing aid causing allergies or intolerances, or derived from a substance or product causing allergies or intolerances used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form. The list of regulated substances or products causing allergies or intolerances can be found in Annex II of Regulation (EU) No 1169/2011 and includes the following: cereals containing gluten, crustaceans, eggs, fish, peanuts, soybeans, milk, nuts, celery, mustard, sesame seed, sulphur dioxide and sulphites, lupin and molluscs. Guidance on the allergen labelling requirements can be found in Commission Notice 2017/C 428/01 ([5]).

Regulation (EC) No 852/2004 lays down provisions on allergen management both in primary production and stages thereafter, underlining the need for a comprehensive preventive approach along the whole food chain. Good hygiene practices are required to prevent or limit the presence of substances causing allergies or intolerance due to contamination of foodstuffs (cross-contamination). The production process and working methods might have to be reviewed to comply with this requirement.

At primary production, harvesting or slaughter, allergen management should consider the following in order to prevent or minimize the risk for allergen contamination:

— Awareness by the primary producers on the use of products (e.g. crops unintentionally contaminated with cress of celery or mustard), substrates (e.g. straw of cereals used for growing mushrooms) and plant protection products, including basic substances (e.g. sulphites), that are recognized as allergens;

— Consideration of crop rotation, in particular if products (allergens) grown from previous crops may contaminate new crops;

— Avoidance and checking of cross-contamination during harvesting, slaughter (e.g. egg yolk in slaughtered laying hens, cereals in crop of poultry), handling, storage and transport.

At the next stages of food production, the following should be considered to prevent or minimize the risk for allergen contamination:

— Attention being paid to incoming raw materials, including requests for specifications of the ingredients of these raw materials if not obvious; in case unintended allergen presence is mentioned in raw materials, the supplier should provide a quantification (mg allergenic protein / kg food) to enable the food manufacturer to apply risk assessment;

— If regulated allergens or products containing these allergens are used as raw materials or ingredients, awareness of staff on allergen management should be ensured and specific attention should be paid to the correct storage (minimum risk of cross-contamination of other products), allergen labelling and recipe application of these products;

— Procedures should be in place to prevent the exchange of products (raw materials, intermediated products and finished end products) and labels;

([4]) Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18)

([5]) COMMISSION NOTICE of 13 July 2017 relating to the provision of information on substances or products causing allergies or intolerances as listed in Annex II to Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers (OJ C 428, 13.12.2017, p. 1.)

— Strict measures to minimize cross-contamination should be applied with products potentially containing regulated allergen(s) to other products without allergens or containing different allergens. Segregation should be applied by the use of segregated production lines, receptacles and storage facilities (e.g. closed packages where appropriate) when possible, or by a specific work methodology/production order e.g. by scheduling (end of the day production of products with (the highest amount of) allergens), awareness (specific training) of workers and compliance with hygiene rules before returning to work from breaks for eating or drinking;

— Attention to the potential for cross-contamination should also be paid at preparatory stages (debagging, preliminary handling and weighting of ingredients, etc.) and post-production stages e.g. bulk transport.

At all stages where routine checking on the absence of visible debris is not possible, increased attention should be paid to the frequency and the robustness of cleaning of the equipment. Also validation/verification of the cleaning method is relevant. Example: chocolate production is 'closed' and it is not possible to look into pipes to see if something is left. It is also difficult to clean easily with water. In this example validation/verification of the cleaning method by sampling and analysis is therefore relevant. In other cases, when wet cleaning is used, the cleaning water can be analysed for allergen residues. Precaution must however be taken when interpreting the analytical result due to dilution and the distribution of the specific allergen.

The extent of control measures for the prevention of cross-contamination of allergens needs to be elaborated depending on the number and amount of allergens used, the complexity of the handling (e.g. processing with mixing compared to pure handling of prepacked food), the number of change-overs of products (risk of cross-contamination) and the frequency and robustness (easy to apply or not) of cleaning procedures.

According to Regulation (EU) No 1169/2011 mandatory labelling only applies where allergenic products or substances have been intentionally added as ingredients or processing aids. Information on the possible and unintentional presence in food of substances or products causing allergies or intolerances may be provided on a voluntary basis ([6]) (Article 36 of Regulation (EU) No 1169/2011, paragraph 3, point a)). Voluntary information provided to the consumers has to comply with the provisions of Article 36 of the Regulation. In particular, such voluntary information must not be misleading ambiguous or confusing for the consumer; and must, as appropriate, be based on the relevant scientific data. Pending the adoption of such harmonised provisions, food business operators are responsible to ensure that such information when provided is not misleading, ambiguous or confusing for consumers.

Precautionary allergen labelling (PAL), should only be used where a preventive strategy cannot be efficiently implemented and the product may present a risk to allergic consumers. Precautionary allergen labelling is a separate statement next to the list of ingredients and should be based on the findings of an appropriate risk assessment, conducted by the food manufacturer, to evaluate the possible and unintended presence of allergens. Allergens (potentially) present in the product via cross-contamination should not be included in the list of ingredients as they are not intentionally added and are no part of the formula of the product. Such labelling should never be used as an alternative to preventive measures.

More detailed guidance can be found in:

— Codex Alimentarius Code of Practice on Food Allergen Management for Food Business Operators ([7])

— Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens - Part 3: Review and establish precautionary labelling in foods of the priority allergens ([8])

— The Guidance on Food Allergen Management for Food Manufacturers, developed by FoodDrinkEurope ([9])

— Precautionary Allergen Labelling (PAL): a science-based approach based on Quantitative Risk Assessment ([10])

([6]) Regulation (EC) No 178/2002 lays down the general principals and requirements of food law. It states in Article 14(3) that 'In determining whether any food is unsafe, regard should be had to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods'.

([7]) CXC 80-2020; http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B80-2020%252FCXC_080e.pdf

([8]) https://www.who.int/news-room/events/detail/2021/10/18/default-calendar/ad-hoc-joint-fao-who-expert-consultation-on-risk-assessment-of-food-allergens-part-3-review-and-establish-precautionary-labelling-in-foods-of-the-priority-allergens

([9]) https://www.fooddrinkeurope.eu/uploads/press-releases_documents/temp_file_FINAL_Allergen_A4_web1.pdf

([10]) https://www.fooddrinkeurope.eu/wp-content/uploads/2021/05/Precautionary-Allergen-Labelling.pdf

3.8. **Food redistribution and donation**

Food redistribution and donation can occur at any stage of the food chain when there is an excess of production/stock but often occurs at retail level. In particular at retail, such food may be approaching the end of its shelf-life, either expressed as 'use by' or 'best before', and the presence of possible additional hazards must be prevented by additional GHP (see below). Facilitating food donation is a priority under the Circular Economy Action Plan of the Commission as a means of preventing food waste and promoting food security, in line with the United Nations Sustainable Development Goals. Therefore, a number of initiatives has been taken to assure the safe redistribution of food, even if it is of utmost importance that food waste is prevented as early as possible:

— Introduction of a specific Chapter Va 'Redistribution of food' in Annex II of Regulation (EC) No 852/2004, containing conditions for the safe redistribution of food for donations.

— Retailers may freeze fresh meat of domestic ungulates (cattle, pigs, sheep, goats), poultry and lagomorphs, in view of its redistribution for the purpose of food donations, under certain conditions in accordance with a recent amendment ([11]) of Regulation (EC) No 853/2004. The advantage of this operation must be balanced against certain microbiological risks that may occur with freezing and thawing.

— Further guidance on these hygiene aspects related to food redistribution and donations in Section 5 of the Commission Notice on retail. The guidance contains specific recommendations for additional GHP on:

  — shelf-life control;

  — handling returned foods;

  — evaluation for food donation including assessment of remaining shelf-life;

  — Freezing food intended for donation.

3.9. **Waste management**

Compliance with the requirements in Chapter VI of Annex II to Regulation (EC) No 852/2004 can be best achieved and illustrated by the FBO by implementing procedures for each type of waste (animal by-products, spoiled food, chemical waste, redundant/used packing material). When applicable, it should be recorded who is responsible for the removal, how it is collected, where it is stored and how it is removed from the establishment.

3.10. **Water and air control**

In addition to the quite detailed requirements in Chapter VII of Annex II to Regulation (EC) No 852/2004:

a) Regular own microbiological and chemical analysis of water directly in contact with food (unless community potable water) should be carried out. Factors such as the source, intended use of the water, etc. will determine the frequency of analysis.

b) If community water is held in a tank prior to use, the tank must be part of a regular cleaning schedule.

c) As a general rule, only potable water may be used on food of animal origin. At least clean water or where applicable clean sea water should be used in other cases.

d) Control of water is an important way of controlling microbiological and chemical hazards in the primary production of fruit and vegetables (irrigation, washing at harvest). Additional specific guidance has therefore been developed in Section 7.3 of the Commission Notice on guidance document on addressing microbiological risks in fresh fruits and vegetables at primary production through food hygiene ([12]). Potable water is strongly recommended in washing of fruit and vegetables for direct consumption.

e) Ventilation systems should be robust and reliable. Ventilation systems should be kept clean, so that they do not become a source of contamination. For high risk/care areas requiring air control, the implementation of positive air pressure systems and appropriate air filtering systems should be considered.

([11]) Commission Delegated Regulation (EU) 2021/1374 of 12 April 2021 amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council on specific hygiene requirements for food of animal origin (OJ L 297, 20.8.2021, p. 1–15)

([12]) Official Journal C 163, 23 May 2017, p. 1.

f) Condensation is mostly the result of poor ventilation. Condensation should be avoided in areas where food is being produced, handled or stored, especially if exposed or not packed.

g) FLEXIBILITY EXAMPLE: Control of water can be negligible if community potable water is used, but should be included if a business's own source is used or recycling takes place.

3.11. **Personal (hygiene, health status)**

a) Personnel should be aware of hazards from gastro-intestinal infections, hepatitis and wounds with appropriate exclusion from food handling or suitable protection; relevant health problems should be reported to the manager. Special consideration should be given to temporary workers who might be less familiar with potential hazards.

b) Hands should be washed regularly (and disinfected if necessary), as a minimum, before starting work, after using the lavatory, after breaks, after rubbish disposal, after coughing or sneezing (in a disposable paper or, if no alternative, into your elbow), after handling of raw materials, between tasks, etc. Disposable gloves used hygienically can be effective in preventing cross contamination when handling ready-to-eat foods. Hands must be washed thoroughly before and after use. Gloves must be used only once and should be changed between tasks to prevent cross contamination.

c) Hair covers (and beard snoods) should be considered and appropriate clothing with high degree of cleanliness, minimum of pockets, absence of jewelry and watches. The use by workers of clothing or items of clothing with different colors is recommended in different microbiological risk areas.

d) Protective clothing should preferably not be worn when using the toilets or when wheeling the rubbish bins onto the street.

e) Eating, drinking and/or smoking rooms should be separated and clean.

f) First aid kits should be easily accessible and available for immediate use.

g) The number of visitors should be minimized and visits should follow the conditions set by the FBO so as not to compromise the food safety. Visitors should at least wash hands and wear appropriate protective clothing, provided by the FBO.

3.12. **Temperature control of working and storage environment**

a) Temperature and humidity should be (automatically) recorded where relevant.

b) Alarm devices should preferably be automatic.

c) Temperature fluctuations should be minimized e.g. by using a separate room/freezer to freeze products from that used for storage of frozen products.

d) Chilling/heating capacity should be adapted to the amounts handled.

e) Temperatures in the product during storage and transport should also be monitored.

f) Verification should occur regularly.

g) FLEXIBILITY EXAMPLE: Visual monitoring of the temperature at the shelf can occur while serving clients at retail, while automatic recording and alerts are employed in larger chilling facilities. For smaller establishments a max/min thermometer could be used.

3.13. **Working methodology**

Clear instructions should be provided on proper operation of equipment e.g. avoidance of overloading or exceeding the equipment's capacity, leading to cracks, (too) hot food in cooling systems preventing a quick cooling, too low (re)heating capacity for the amount of food put in warming tables of food service establishments, etc.

Work instructions or standard operation procedures should be clear, accurate and simple, visible or easily accessible. They may include instructions to clean and remove broken glass immediately and report it, not to leave inspection places unmanned, put finished products in cooled room as soon as possible if cooled storage is required, fill in records correctly as soon as possible, etc.

Posters or signs placed strategically, can substantially contribute to the awareness and application of correct working methodologies.

3.14. **Food Safety culture (FSC)**

In autumn 2020, the revision of the General Principles of Food Hygiene (CXC 1-1969) introduced the establishment and maintenance of FSC as fundamental to the successful functioning of any food hygiene system. In March 2021, a specific Chapter XIa on FSC was introduced in Annex II of Regulation (EC) No 852/2004 by the adoption of Commission Regulation (EU) 2021/382, defining the components of FSC. Food business operators, carrying out activities other than primary production and associated operations, therefore must comply with this requirement.

Chapter XIa of Annex II to Regulation (EU) 852/2004 refers to the following components of a FSC:

a) **commitment** of the management and all employees to the safe production and distribution of food; requirements on management commitment are further elaborated and laid down in the Regulation (EC) No 852/2004; commitment of employees is the perception of the extent of engagement and involvement concerning food safety of all employees in the FBO.

b) **leadership** towards the production of safe food and to engage all employees in food safety practices; leadership can be defined as the perception of the extent to which the leader(s) of the FBO are able to engage staff in food safety performance and compliance to meet the requirements concerning food safety and to ensure the adequate reaction to risks, deviation and changing circumstances;

c) **awareness** of food safety hazards and of the importance of food safety by all employees in the business; awareness is the perception of the extent to which all staff in an FBO are aware of the risks concerning food safety relevant within their tasks, and has these under control;

d) open and clear **communication** between all employees in the business, within an activity and between consecutive activities, within one production site or different locations of an FBO, including communication of deviations and expectations; communication refers to the perception of the extent of transfer or diffusion of information related to food safety within the organisation;

e) availability of **sufficient resources** to ensure the safe and hygienic handling of food; sufficient resources is defined as the perception of the extent to which physical and non-physical means, necessary to operate in a food safe way, are present in the FBO (e.g. time, personnel, infrastructure, education/training and procedures).

Although the components are subjective (perception), tools have been developed to measure objectively FSC in a FBO, see the example in Appendix 3. They allow to compare the extent to which FSC and its components are met between FBOs, between different groups of employees within a FBO (e.g. operators versus management, different sites, in direct contact with foods or not) or to evaluate trends in time (by repeating the tool). This can trigger corrective action such as additional training of certain staff on some or all of the components of FSC, enhancement of communication channels, investment in resources, etc.

An example of such a tool that can be used as a basis to develop and assess FSC can be a survey with a number of indicators/statements for each of the components of FSC. Respondents can express the extent to which they agree or disagree (e.g. on a scale from 1 to 5). Such tool can also be used as a basis to verify food safety culture in a FBO during an audit (see Annex III). Other tools may be published on the website of the European Commission when they become available.

Slightly alternative approaches and assessment tools (guiding questions) are developed by the Global Food Safety Initiative (GFSI) ([13]).

FLEXIBILITY EXAMPLE: The Regulation (EC) No 852/2004 explicitly recognized that 'The implementation of the FSC shall take account of the nature and size of the food business'. It is obvious that the nature of the product e.g. its vulnerability to contamination and growth of hazards and the handling in the FBO, influences the need for the extent of a food safety culture, but the commitment to produce safe food must be present in all businesses. In very small establishments, for example a retail establishment owned by a family without or with a very limited number of external staff, the food safety

([13]) https://mygfsi.com/wp-content/uploads/2019/09/GFSI-Food-Safety-Culture-Full.pdf

culture, e.g. the engagement and awareness of the importance to work in a food safe way can probably already be observed by the consumer itself and may become evident by normal inspection and auditing by competent authorities. In large businesses with different plants, regular assessment of food safety culture, possibly by external companies, using these tools, should result in the detection of weaknesses in (certain plants) and can substantially contribute to an enhanced food safety.

4. MONITORING, VALIDATION AND VERIFICATION OF GHP

Several GHP, in particular GHP requiring greater attention, require monitoring, validation to the extent possible and verification, similar to CCP. The frequency of monitoring and the extent of validation and verification should take into account the nature of the activity and the size of the business. Monitoring is typically required for:

— Steps with temperature or temperature/time conditions (e.g. chilling, blanching)

— Other specifications that are essential to ensure Safety such as pH and water activity (a_w) (in case where they are not considered as a CCP);

— Visual inspection to check the efficiency of cleaning (while verification should happen e.g. by regular microbiological testing of surfaces);

— Allergen management when such risks is assessed as high or control measures are less easy to apply (e.g. monitoring/checking on the absence of visible debris, see Section 4.7);

— Visual inspection of packages to detect the presence of gases, damage or inaccurate labelling;

— Water quality in case of recycling or non-use of community water.

Validation and verification will, in a number of cases, require sampling and testing for microbiological or chemical hazards.

Records should be kept on the results of monitoring, validation and verification procedures.

Corrective action in case of deviation from set food safety standards should at least result in a revision of the implementation of the GHP. The need for withdrawal and recall should be assessed on a case by case basis, in particular in the case of deviation from GHP requiring greater attention.

In case non-compliances and deviations are observed frequently, the risk should be reassessed and control measures possibly reviewed.

More details on what is meant by monitoring, validation and verification can be found in Section 9 of Annex II.

5. DOCUMENTATION AND RECORD KEEPING ON GHP

Regulation (EC) No 852/2004 does not explicitly require the documentation of GHP. However, it seems difficult to carry out a hazard analysis and demonstrate compliance with GHP, if these are not documented and some records kept. GHP should be documented in the GHP plan and may need to be continuously supplemented by records when GHP requiring greater attention have been identified. Such GHP plan should be part of (integrated in) the HACCP plan (see Annex II, Section 11). Procedures on documentation and record keeping recommended in the HACCP plan apply: adapted to the nature and size of the business, use of generic guidance, nominated responsible person, period kept, etc.

Recommended documentation for GHP includes:

— GHP applied,

— working instructions, standard operational procedures, control instructions;

— Verification activities;

— Corrective actions anticipated;

— Supporting documents (generic guides, scientific evidence, etc.).

FLEXIBILITY EXAMPLES:

— In certain very small businesses it may not be necessary to have documented procedures for the cleaning and disinfection activities or visual checks as very few peoples are involved in all the activities. The staff must be always able to explain the cleaning and disinfections activities regardless of the presence of documented procedures.

— Carrying out monitoring effectively is in general more important than recording it. Therefore, flexibility on the recording could be more easily accepted than flexibility concerning the monitoring itself (e.g. its frequency). In particular for small businesses keeping the right temperature is far more important than actually recording it and records can be produced only in case of deviations or when non-compliance has been measured (e.g. failure of equipment to maintain the correct temperature).

Record examples are:

— Outcome of monitoring activities on control measures;

— Observed deviations and executed corrective actions;

— Outcome of verification activities.

FLEXIBILITY EXAMPLE: records can be kept electronically as long as they can be made available to the competent authorities at their request e.g. during an audit, to verify the effective application of the requirements.

ANNEX II

Procedures based on the hazard analysis and critical control points (HACCP) principles and guidelines for their application

1. INTRODUCTION

HACCP-based procedures are mandatory for all food business operators except primary producers in accordance with Article 5 of Regulation (EC) No 852/2004. HACCP-based procedures represent a systematic approach to the identification, evaluation and control of food safety hazards e.g. biological, chemical (including allergens) and physical hazards.

HACCP-based procedures provide a tool for FBO

— to identify potential hazards,

— to identify where these hazards are reasonably likely to occur at each step

— to identify which of these reasonably likely to occur hazards are such that their prevention, elimination, or reduction to acceptable levels is essential to the production of safe food (significant hazards)

— to consider if additional control measures are needed, in particular OPRP or CCP, if some significant hazards are not controlled by the preventive measures.

This Annex II describes in a simple way recommendations how the HACCP-based procedures can be applied. It is in line with Chapter II of the Codex Alimentarius document CXC 1-1969 ([1]).

HACCP-based procedures are considered to be a useful tool for food business operators to identify and control hazards that may occur in food and during food processing in their own establishment. In view of the wide range of food businesses to which Regulation (EC) No 852/2004 is addressed, and in view of the great diversity of food commodities and manufacturing procedures that are applied to food, it is appropriate to issue general guidance on the development and implementation of HACCP based procedures.

2. GENERAL PRINCIPLES

Prior to application of the HACCP-based procedures to any business, the food business operator should have implemented GHP (See Annex I) and other relevant PRP (See Section 5 of the main document).

The HACCP-based procedures should be science/risk-based and systematic, identifying significant hazards at each step of the production chain, and measures for control of those hazards, to ensure the safety of food. HACCP-based procedures are tools to identify and assess hazards and establish control systems that focus on prevention, as opposed to older systems that relied mainly on end product testing. All HACCP-based procedures should be capable of accommodating changes, such as advances in equipment design, processing procedures or technological developments as they include a requirement to review the procedures to ensure that new hazards haven't been introduced when such changes are made.

As well as enhancing food safety, implementation of the HACCP-based procedures can provide other significant benefits, e. g. for inspection/auditing by regulatory authorities and promote international trade by increasing confidence in food safety.

The implementation of HACCP-based procedures is based on the following seven principles, laid down in points (a) to (g) of Article 5(2) of Regulation (EC) No 852/2004:

(1) Point (a): identifying any hazards that must be prevented, eliminated or reduced to acceptable levels (hazard analysis) and identify control measures, see Section 5;

(2) Point (b): identifying the critical control points at the step or steps at which control is essential to prevent or eliminate all relevant hazards or to reduce them to acceptable levels, see Section 6;

([1]) http://www.codexalimentarius.org/standards/list-of standards/en/?provide=standards&orderField=fullReference&sort=asc&num1=CAC/RCP

(3) Point (c): establishing critical limits at critical control points (CCP), which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards, see Section 7;

(4) Point (d): establishing and implementing effective monitoring procedures at critical control points, see Section 8;

(5) Point (e): establishing corrective actions when monitoring indicates a deviation at a critical control point, see Section 9;

(6) Point (f): validating the HACCP plan and establishing procedures, which shall be carried out regularly, to verify that the measures outlined in principles 1 to 5 are working effectively, see Section 10;

(7) Point (g): establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in principles 1 to 6, see Section 11.

During the development and application HACCP-based procedures, laid down in a HACCP plan, the FBO should give consideration to the likely intended use of the product (e.g. cooked or not), categories of vulnerable consumers and epidemiological evidence related to food safety.

The intent of HACCP-based procedures is to focus on control at CCP. They should be applied to each specific operation/step separately. The application of the HACCP-based procedures should be reviewed and necessary changes made when any modification is made in the product, process, or any step. It is important when applying the HACCP-based procedures to be flexible where appropriate, given the context of the application taking into account the nature and the size of the operation.

3. FLEXIBILITY ON THE IMPLEMENTATION OF HACCP-BASED PROCEDURES

3.1. **Legal requirements**

Article 5 of Regulation (EC) No 852/2004 requires food business operators to put in place, implement and maintain a permanent procedure or procedures **based on** HACCP principles.

The concept allows HACCP principles to be implemented with the required flexibility.

In Regulation (EC) No 852/2004, key issues for flexibility are:

(a) Recital 15 of the same Regulation which states that:

'The HACCP requirements should take account of the principles contained in the Codex Alimentarius. They should provide **sufficient flexibility to be applicable in all situations**, including in small businesses. In particular, it is necessary to recognise that, in certain food businesses, it is not possible to identify critical control points and that, in some cases, good hygienic practices can replace the monitoring of critical control points. Similarly, the requirement of establishing "critical limits" does not imply that it is necessary to fix a numerical limit in every case. In addition, the requirement of retaining documents needs to be flexible in order to avoid undue burdens for very small businesses.'

(b) The clear statement in Article 5(1) that the procedure **must be based on** the HACCP principles.

(c) The statement in Article 5(2)(g) that the need for establishing documentation and records must be **commensurate to the nature and the size of the food business**.

(d) Article 5(5) of the Regulation, which allows the adoption of arrangements to facilitate the implementation of the HACCP requirement by certain FBOs. These include the use of **guides for the application of HACCP-based procedures**.

The Article 5(2)(g) of the Regulation (EC) No 852/2004 identifies two main criteria that render a FBO eligible for flexibility as regards HACCP-based procedures: its nature and its size.

a) The **nature** is the basis for a risk-based approach and depends on the activity of the FBO, for example:

— Ready- or non-ready-to-eat food

— The length of the supply chain

— Processing, wrapping, etc. or just storage of prepacked food

— Hazard reducing/eliminating (e.g. pasteurisation) step at end or not

— Food of animal origin (still far more associated with food-borne outbreaks than other foods) or not

— Hazards associated with raw materials/ingredients

— Temperature requirements at handling/storage or not

— Intended use and target consumers specific issue

The hazard analysis plays a crucial role in assessing the risk.

b) The **size** (Volume of production, throughput, etc…) is linked to proportionality for small business operators and is mainly reflected in a reduction of administrative burden (use of generic guides, extent of documentation, records, etc.).

Although both criteria for flexibility might be relevant for certain FBOs (e.g. retailer), these criteria should be considered separately.

3.2. **Simplified HACCP-based procedures**

The seven HACCP principles are a practical model for identifying and controlling significant hazards on a permanent basis. This implies that where that objective can be achieved by equivalent means that substitute in a simplified but effective way some of the seven principles, it must be considered that the obligation laid down in Article 5, paragraph 1 of Regulation (EC) No 852/2004 is fulfilled.

Recital 15 of Regulation (EC) No 852/2004 clearly recognises that CCP might not be identified in all cases. In such cases the application of procedures based on the HACCP principles is limited to the first principle i.e. a hazard analysis required to justify in a risk-based manner why no CCP needs to be considered and to demonstrate that GHP, possibly including GHP requiring greater attention, are sufficient to control the hazards.

When CCP are identified in small businesses, proportionality in administrative burden additionally justifies a simplified approach to comply with the other HACCP principles.

Hazards may be grouped for the implementation of HACCP-based procedures if they are controlled in a similar way. In addition, similar products can be grouped together if they are produced in the same way and share common hazards.

Whenever there are needs connected with export or specifications of customers, all FBOs are free to use and fully implement HACCP-based procedures and get a certification on them, even if they would be eligible for a more flexible approach as described in this document.

Examples of such simplified HACCP-based procedures for retail activities, based on two opinions of the European Food Safety Authority ([2]), can be found in Commission Notice on retail.

3.3. **Generic guides to the implementation of HACCP-based procedures**

Generic HACCP guides have been developed addressing all the HACCP principles to be complied with when significant hazards are identified.

The generic guides could suggest hazards and control measures common to certain food businesses and assist the FBO or the HACCP team through the process of producing food safety procedures or methods based on a generic hazard analysis, and appropriate record keeping.

Food business operators should be aware however that other hazards may be present, e.g. those linked to the layout of their establishment or to the process that is applied, and that such hazards cannot be predicted in a generic HACCP guide. When generic HACCP guides are used, the FBO should check to ensure that all the activities in the business are covered in the guide. If not, then the FBO should develop its own procedures based on the HACCP principles for the additional activities.

([2]) 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) and Hazard analysis approaches for certain small retail establishments and food donations: second scientific opinion (EFSA Journal 2018;16(11):5432)

In those sectors where there is a lot of commonality between businesses or the manufacturing process is linear and short, and where the hazard prevalence is well known, generic HACCP guides may be appropriate, e.g.:

— For slaughterhouses, establishments handling fishery products, dairy establishments etc.;

— For businesses that apply standard food processing procedures such as the canning of food, the pasteurisation of liquid food, the freezing/quick-freezing of food etc.

The Commission Notice on retail provides generic guidance on the hazard analysis for certain retailers. The content of generic HACCP guides where flexibility can be considered should respect the recommendations in Section 4.4.

4. **PRELIMINARY ACTIVITIES**

The preliminary activities below are not explicitly laid down in EU legislation, nevertheless they are considered as essential when developing and implementing HACCP-based procedures. These preliminary activities traditionally consist of 5 steps and when combines with the 7 HACCP principles, result a 12-steps approach.

4.1. **Assembly of a multidisciplinary HACCP team**

This team, which involves all parts of the food business concerned with the product, should include the whole range of specific knowledge and expertise appropriate to the product under consideration, its production (manufacture, storage, and distribution), its consumption and the associated potential hazards and should also involve as much as possible the higher management levels. The team should get the full support of the management who should consider itself owner of the HACCP plan and the overall FSMS.

Where necessary, the team should be assisted by specialists who will help it to solve difficulties in the development and implementation of the HACCP-based procedures.

The team may include specialists and technicians:

— who understand the biological, chemical or physical hazards connected with a particular product group;

— who have responsibility for, or are closely involved with, the technical process of manufacturing the product under study;

— who have a working knowledge of the hygiene and operation of the process plant and equipment;

— any other person with specialist knowledge of food microbiology, legislative requirements, machinery used for food manufacturing, its maintenance and cleaning.

One person may fulfill several or all of these roles, provided all relevant information is available to the team and is used to ensure that the system developed is reliable. Where expertise is not available in the establishment in specific areas, advice should be obtained from other sources (consultancy, guides of good hygiene practices, etc. not excluding other companies of the same group (at sectorial or association level) where expertise is available).

FLEXIBILITY EXAMPLE: In small businesses, HACCP/FSMS activities might be carried out by one person who is (temporarily or regularly) assisted by external expertise. Where external expertise is used, it is essential that there is sufficient ownership of the FSMS by the food business itself. FBOs using this route should make sure that they know how the system works and how it is being applied to their business, and that their staff is suitably trained to ensure effective implementation.

4.2. **Description of the product(s) at the end of process (called hereafter ‘end product’)**

A full description of the end product should be drawn up, including relevant safety information such as:

— Origin of ingredients/raw materials, which may help identify certain hazards;

— composition (e.g. raw materials, ingredients, additives, possible allergens etc.);

— structure and physico-chemical characteristics (e.g. solid, liquid, gel, emulsion, moisture content, pH, water activity, etc.);

— processing (e.g. heating, freezing, drying, salting, smoking, etc. and to what extent);

— packaging (e.g. hermetic, vacuum, modified atmosphere) and labelling;

— storage and distribution conditions, including transport and handling;

— required shelf life (e.g. 'use by date' or 'best before date');

— instructions for use;

— any microbiological or chemical criteria applicable.

FLEXIBILITY EXAMPLE: When there is no processing or other manufacturing (e.g. cutting, wrapping), the description of the product can be limited to information available on the label (prepacked food) or other information on the food extracted from reliable sources.

4.3. **Identification of intended use**

The HACCP team should also define the reasonably foreseeable use of the product by the customer and by the consumer target groups for which the product is intended. In specific cases, the suitability of the product for particular groups of consumers, such as institutional caterers, travelers, etc. and for vulnerable groups of the population may have to be considered.

4.4. **Construction of a flow diagram (description of manufacturing process)**

All steps involved in the process should be studied in sequence and presented in a detailed flow diagram.

All processes (from receiving the raw materials to placing the end product on the market) including delays during or between steps, should be mentioned together with sufficient technical data that is relevant for food safety, such as temperature and the duration of heat treatment.

Types of data may include but are not limited to:

— plan of working premises and ancillary premises;

— equipment layout and characteristics;

— sequence of all process steps (including the incorporation of raw materials, ingredients or additives and delays during or between steps) and the disposal of waste/by-products;

— technical parameters of operations (in particular time and temperature, including delays);

— flow of products (including potential cross-contamination);

— segregation of clean and dirty areas (or high/low risk areas).

The nature of the business will define the complexity of the required flow diagram, which might be very simple in certain businesses (See examples for different retailers in the Commission Notice on retail).

4.5. **On-site confirmation of flow diagram**

After the flow diagram has been drawn up, the HACCP team should confirm it on site during operating hours. Any observed deviation must result in an amendment of the original flow diagram to make it accurate.

5. **HAZARD ANALYSIS (PRINCIPLE 1)**

5.1. **Identification of relevant hazards**

A hazard is a biological, chemical (including allergens) or physical agent in food or feed with the potential to cause an adverse health effect ([3]). While allergens are considered a chemical hazard, some FBOs find it easier to treat allergens as a fourth hazard during hazard analysis (see worksheet in section 5.3).

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

All major potential biological, chemical or physical hazards that may be reasonably expected to occur in a product should be identified and listed. It may be useful to consult external source of information (e.g. the Rapid Alert System for Food and Feed).

The HACCP team should then identify where these potential hazards are reasonably likely to occur at each process step (including production, acquisition, storage, transport and handling of raw materials and ingredients and delays during manufacture).

The HACCP team should next evaluate the hazards to identify at which hazards are of such a nature that their prevention, elimination or reduction to acceptable levels is essential to the production of a safe food (end product).

In conducting the hazard analysis to determine whether there are significant hazards, wherever possible the following should be considered:

— hazards associated with producing or processing the type of food, including its ingredients and process steps (e.g. from surveys or sampling and testing of hazards in the food chain, from recalls, from information in the scientific literature or from epidemiological data);

— the likelihood of occurrence of hazards, taking into consideration prerequisite programmes, in the absence of additional control;

— the likelihood and severity of adverse health effects associated with the hazards in the food in the absence of control;

— identified acceptable levels of the hazards in the food e.g. based on regulation, intended use, and scientific information;

— the nature of the facility and the equipment used in making the food product;

— survival or multiplication of pathogenic microorganisms;

— production or persistence in foods of toxins (e.g. mycotoxins), chemicals (e.g. pesticides, drug residues, allergens) or physical agents (e.g. glass, metal);

— the nature of the product as an intermediate product which is further processed by another FBO

— the intended use and/or probability of product mishandling by potential consumers that could render the food unsafe; and,

— conditions leading to the above.

5.2. **Control measures**

The FBO should consider and describe what control measures, if any, can be applied for each hazard at each process step.

Control measures are those actions and activities that can be used to prevent hazards, eliminate or reduce them to acceptable levels. Many control measures to prevent hazards are part of GHP and are intended to avoid contamination from the production environment (e.g. personnel, pest, water, maintenance which are listed as examples in Annex I). Other control measures aiming at reduction or elimination of hazards are more specifically linked to a particular production process e.g. pasteurization, thorough fermentation or are intended to avoid multiplication of the hazard (e.g. chilling), and may result in the establishment of CCP or OPRP.

In some cases a control measure may require to monitor more than one parameter e.g. pasteurization controlled by time, temperature and flow rate of the fluid and more than one hazard may be controlled by one control measure e.g. pasteurization or controlled heat treatment may provide sufficient assurance of reduction of the level of several pathogenic micro-organisms such as *Salmonella* and *Listeria monocytogenes*.

Control measures must be validated.

Control measures should be supported by detailed procedures and specifications to ensure their effective implementation.

5.3. **Hazard analysis worksheet**

A way to document the hazards analysis is the use of a hazard analysis worksheet.

Step	Identify potential hazards introduced, controlled or enhanced at this step B = biological C = chemical P = physical A = allergen (*)		Is this potential hazard reasonably likely to occur?		Justify your decision for column 3	What measure(s) can be applied to prevent or eliminate the hazard or reduce it to an acceptable level?
			Yes	No		
	B					
	C					
	P					
	A					
	B					
	C					
	P					
	A					
	B					
	C					
	F					
	A					

(*) Allergens are chemical hazards, however it might be more practical to assess them separately for the purpose of the hazard analysis since control measures can be quite specific.

Hazards can be grouped when they are derived from the same possible source and control measures are similar without the need for a comprehensive hazard analysis on each of the specific hazards. For example microbiological hazards can be grouped in vegetative (*Salmonella, Campylobacter,* VTEC, etc.) and spore forming (*Clostridium, Bacillus*) bacteria as origin and controls can be similar for each category.

Fully elaborated examples of hazard analyses for retailers, grouping biological, chemical and physical hazards, can be found in the Commission Notice on retail.

In small businesses it may suffice that the hazard analysis in the HACCP plan describes in a practical and simple way the methods to control hazards without necessarily entering into detail on the nature of the hazards. Such analysis should nevertheless cover all significant hazards in a business and should clearly define procedures to control these hazards and the corrective action to be taken in case of problems.

Specific HACCP guides can suggest the significant hazards linked to specific products and processes.

6. **IDENTIFICATION OF CRITICAL CONTROL POINTS (CCP) (PRINCIPLE 2)**

The identification of a CCP requires a logical approach. Such an approach can be facilitated by the use of a decision tree or other methods, according to the knowledge and experience of the HACCP team.

The identification of CCP has two consequences for the HACCP team which should then:

ensure that appropriate control measures are effectively designed and implemented. In particular, if a hazard has been identified as significant and no control measure exists at that step, or at any other step further on in the production process, then the product or process should be modified at that step or at an earlier or later stage, to include a control measure;

establish and implement principles 3 to 7 of the procedures based on the HACCP principles at each CCP.

CCP are intended to address only **significant hazards** in an establishment.

In addition, for each control measure, the systematic approach shall include an **assessment of the feasibility** of:

— establishing measurable/observable critical limits and/or measurable/observable action criteria;

— monitoring to detect any failure to remain within critical limit and/or measurable/observable action criteria;

— applying timely corrections in case of failure.

When carrying out the hazard analysis by a semi-quantitative risk evaluation such as in Appendix 2, CCP are implemented to control significant hazards identified by the hazard analysis. Other examples of tools are the decision trees shown in Appendices 4A and 4B. The tools in Appendices 2 and 4 can be used separately or in combination, using the risk evaluation for identifying the significant hazards and for initial screening of required control measures and the decision tree for further refining of the control measures. For a high level of risks, which are not controlled by GHP, either a CCP or an OPRP should be established. Ideal decision trees, applicable in all kind of situations/steps, do not exist. Therefore decision trees might be rather considered as tools for the understanding how to decide whether GHP are sufficient or OPRP or CCP should be considered, than representing the incontestable way to make such evaluation.

CCP or OPRP?
Both CCP and OPRP represent a step at which a control measure applies in order to control a significant hazard. CCP are intended to control the highest risks, while OPRP can be used to control intermediate risks or for any significant hazard when
— no critical limit can be set, example: absence of visual contamination, integrity of packaging,.. or
— no real time detection of a deviation/non-compliance is possible, example: allergen cross-contamination.
Principles applicable to CCP also apply to OPRP e.g.
— action criteria must be established to contribute to the assurance that the acceptable level of the hazard is not exceeded;
— need for monitoring, validation and verification
— Documentation and record keeping.
The guidance provided for in this Section, as well as in Sections 7 to 11 are therefore also relevant to OPRP.

A comparison of GHP, OPRP and CCP is provided in Appendix 5.

Each process step identified in the flow diagram (see Section 4.4 of this Annex) should be considered in sequence. At each step, the decision tree and/or risk evaluation should be applied to each significant hazard. Application should be flexible, considering the whole manufacturing process.

Training in the application of a method to identify CCP is recommended.

CCP and OPRP depend on the result of the hazard analysis in each establishment and need to be assessed on a case by case basis:

— if the control measure cannot be used at the process step, then this step should not be considered as a CCP/OPRP for the significant hazard.

— If the control measure can be used at the step being analysed, but can also be used later in the process, or there is another effective control measure for the hazard at a later step, the step being analysed should not be considered as a CCP/OPRP.

— Determine whether a control measure at a step is used in combination with a control measure at another step to control the same hazard; if so, both steps should be considered as CCP/OPRP.

FLEXIBILITY EXAMPLES:

In certain cases, due to the nature of the food business and the food that is handled by it, a (generic) hazard analysis may demonstrate that no significant hazard has been identified and therefore there is no need for CCP or OPRP. In this case all food hazards can be controlled by the implementation of the GHP only. It must however be stressed that flexibility on identifying a hazard as significant or not in the hazard analysis is not directly linked to the size of the establishment and is not appropriate always even when the business is small e.g.

— when there is a high likelihood of failure in the method of processing such as canning;

— food production for vulnerable groups of consumers;

— allergen controls in products declared to be allergen free.

For certain categories of food businesses with very identical, standardised and limited handling of the food (e.g. retail shops, see the Commission Notice providing guidance on food safety management systems for food retail activities, including food donations (OJ C 199, 12.6.2020, p. 1.)), it may be possible to pre-determine hazards that need to be controlled. Guidance on such hazards and on their control can be addressed in a generic HACCP guide or a generic hazard analysis only.

Frying or grilling in a restaurant to control the survival of pathogens might not be a CCP since the high temperature of the oil/fat is easily observable and leads systematically to the elimination of a possible significant hazard

7. **CRITICAL LIMITS AT CCP (PRINCIPLE 3)**

Each control measure associated with a critical control point should give rise to the specification of critical limits.

Critical limits correspond to the extreme values acceptable with regard to product safety. They separate acceptability from unacceptability. They are set for observable or measurable parameters which can demonstrate that the critical point is within critical limits. They should be based on substantiated evidence that the chosen values will result in the correct application of a control measure.

Examples of such parameters include temperature, time, pH, moisture content, amount of an additive or salt, sensory parameters such as visual appearance or texture, etc.

In some cases, to reduce the likelihood of exceeding a critical limit due to process variations, it may be necessary to specify more stringent levels (i.e. target levels) to assure that critical limits are not exceeded.

Critical limits should be validated and should have clear, specific values.

Critical limits may be derived from a variety of sources. When not taken from regulatory standards or from guides of good hygiene practices, the HACCP team should ascertain their validity relative to the control of identified hazards at CCP.

Critical limits at CCP can be established on the basis of:

— experience (best practice);

— international documentation for a number of operations, e.g. canning of food, pasteurisation of liquids etc. for which internationally accepted standards (Codex Alimentarius) exist; critical limits can also be established;

— advice on specific steps in guides to good practice;

— scientific publications;

— EU legislation, EFSA opinions.

The requirement to establish a critical limit at a CCP does not always imply that a numerical value must be fixed. This is in particular the case where monitoring procedures are based on visual observation e.g.

— The faecal contamination of carcases after dressing in a slaughterhouse;

— The boiling temperature of liquid food;

— The change of physical properties of food during processing (e.g. the thorough cooking of food).

FLEXIBILITY EXAMPLE

Critical limits must have a scientific basis, however, is some cases they can based on experience. For many food production and processing scenarios, there is extensive history that specific measures used to control food borne hazards are effective.

8. MONITORING PROCEDURES AT CCP (PRINCIPLE 4)

An essential part of HACCP-based procedures is a programme of observations or measurements performed at each CCP to ensure compliance with specified critical limits.

Observations or measurements must be able to detect deviation at CCP and provide information in time for corrective action to be taken such that unsafe food is not placed on the market.

Where possible, process adjustments should be made when monitoring results indicate a trend towards deviation at a CCP. The adjustments should be made before a deviation occurs (the critical limit is not met). Data derived from monitoring must be evaluated by a designated and experienced person with knowledge and authority to carry out corrective actions when indicated.

Observations or measurements can be made continuously or periodically. When observations or measurements are not continuous, it is necessary to establish a frequency of observations or measurements which detect deviations in time for corrective actions to be taken. Monitoring procedures for CCP should be capable of timely detection of a deviation from the critical limit to allow isolation of the affected products. The method and frequency of monitoring should take into account the nature of the deviation (e.g. a broken sieve, deviation from pasteurization conditions, or a gradual increase of temperature in cold storage). Where possible, monitoring of CCP should be continuous.

The HACCP plan should describe the methods, the frequency of observations or measurements and the recording procedure for monitoring at CCP:

— who is to perform monitoring and checking;

— when monitoring and checking is performed;

— how monitoring and checking is performed.

Records associated with monitoring CCP must be signed by the person(s) doing the monitoring and when records are verified by staff of the company responsible for reviewing.

FLEXIBILITY EXAMPLES:

Monitoring is not only achieved by measuring. Monitoring may in many cases be a simple procedure, e.g.

— a regular visual checks of the temperature of cooling/freezing/heating facilities;

— a visual observation (of a cut surface) to verify whether a food preparation submitted to a particular heat treatment has the correct physical properties reflecting the level of heat treatment (e.g. boiling or steaming hot all the way through).

Monitoring should be as frequent as necessary to ensure that critical limits are permanently met. It should confirm that the critical limit or target is not exceeded. The type of CCP determines the frequency of monitoring. A reduced frequency of monitoring can sometimes be considered after prolonged period of good results.

When the critical limit is exceeded, all the production since the last satisfactory monitoring must be checked for compliance.

Certain foods may sometimes be processed in a standard way using a standard calibrated equipment, e.g. certain cooking operations, roasting chicken etc. Such equipment ensures that the correct time/temperature combination is respected as a standard operation. The cooking temperature of the product then needs not to be systematically measured if it is ensured that the equipment is functioning properly, that the required time/temperature combination is respected and that the necessary controls for that purpose are carried out (and corrective action taken where necessary).

9. CORRECTIVE ACTIONS (PRINCIPLE 5)

For each CCP, corrective actions should be planned in advance by the HACCP team, so that they can be taken without hesitation when monitoring indicates a deviation from the critical limit.

Such corrective actions should include:

— identification of the person(s) responsible for the implementation of the corrective action;

— means and action required to correct the observed deviation in the process;

— action(s) to be taken with regard to products that have been manufactured during the deviation;

— written record of measures taken indicating all relevant information (for example: date, time, type of action, actor and subsequent verification check) ;

— consideration of (long term) actions to avoid repetition of the deviation.

Monitoring may indicate that preventive measures (GHP or their robustness) or the process and its CCP shall have to be reviewed if corrective actions for the same procedure have to be taken repeatedly.

Root cause analysis should be a generic corrective action as very often it is impossible to know the cause of the deviation in advance.

If the critical limit is exceeded, there is an analysis of the situation to identify the causes and implement the most appropriate corrective actions. However, in the case of a one-off incident, it may happen that the analysis of the situation does not allow the precise identification of the cause; generic corrective actions can then be implemented to cover several suspected causes. If the incident is repeated, then the information collected can be cross-referenced and this can help better understand the situation and identify the most likely cause.

10. VALIDATION AND VERIFICATION PROCEDURES (PRINCIPLE 6)

At the start of a new process or in case of a change to an existing process that is likely to affect food safety, the HACCP team should carry out validation activities, in particular gather evidence to confirm the capability of all elements of the HACCP plan, even if not explicitly mentioned in Article 5 of Regulation (EC) No 852/2004. Such evidence includes scientific publications, in-house testing (sampling and testing to see if biological and chemical hazards are under control), predictive microbiology, guidance developed by competent authorities, … demonstrating that the critical limits set, will result in the intended effect on the hazard (no growth, reduction, …).

Additional guidance and examples of validation activities are in CXG 69-2008.

Examples of changes that may require re-validation include:

change in raw material or in product, processing conditions (factory layout and environment, process equipment, cleaning and disinfection programme);

change in packaging, storage or distribution conditions;

change in consumer use;

receipt of any information on a new hazard associated with the product.

Where necessary, such a review must result in the amendment of the procedures laid down. The changes should be fully incorporated into the documentation and record-keeping system in order to ensure that accurate up-to-date information is available.

After the procedures based on the HACCP principles have been implemented, the HACCP team should establish verification procedures to confirm that the HACCP-based procedures are working correctly. Methods for verification may include:

— random sampling and analysis, reinforced analysis or tests at selected critical points:

  — intensified analysis of intermediate or end products e.g. on compliance with microbiological criteria (see Section 12);

  — process hygiene criteria for spoilage bacteria such as aerobic colony count;

  - Time/Temperature hazard reduction/elimination: follow up of relevant pathogens in heat-treated food products e.g. absence of *Listeria monocytogenes, Salmonella* etc.;

  - Damaged packages: testing for the most likely bacterial or chemical contamination a product might be exposed to if its package was damaged;

- surveys on actual condition (e.g. temperature) during storage, distribution and sale and on actual use of the product;

- internal audits of HACCP-based procedures and their records;

- inspection of operations (people compliance);

- confirmation that CCP monitoring is implemented and maintained by:

  - control of the procedures/instructions;

  - physical check on the process being monitored;

  - verifying the calibration of instruments used for monitoring;

  - verification of records (frequency, outcome of measuring results over period of time);

- review of deviations and product dispositions; corrective actions taken with regard to the product;

- check on the person monitoring processing, storage and/or transport activities.

The frequency of verification should be sufficient to confirm that HACCP-based procedures are working effectively. The frequency of verification shall depend on the characteristics of the business (output, number of employees, nature of the food handled), the monitoring frequency, the accuracies of the employees, the number of deviations detected over time and the hazards involved.

When the verification detects failures in the HACCP system, review of the system must be carried out

FLEXIBILITY EXAMPLE: The use of alternative analytical methods instead of the reference method and exemptions of the sampling frequencies are authorised in accordance with Regulation (EC) No 2073/2005 as regards possible microbiological criteria that are applied for verification purposes.

Verification should be carried out by someone other than the person who is responsible for performing the monitoring and corrective actions. Where certain verification activities cannot be performed in house, verification should be performed on behalf of the business by external experts or qualified third parties.

FLEXIBILITY EXAMPLE: Verification may in many cases be a simple procedure by which it is possible to check that monitoring like the one described in Section 8 is done in a proper way in order to achieve a required food safety level.

Simple verification procedures may include:

- physical audit or check on the monitoring;

- physical audit or check on the monitoring records including the checking of corrective actions whenever a non-compliance or exception reporting has been recorded;

- In very small FBOs where very few persons are involved in the implementation of the FSMS, owner/managers usually use visual inspection for ongoing confirmation that the system is running according to plan. Thus, documented verification may be perceived to be a pointless, double checking exercise. This is especially true for micro businesses where the owner is the self-employed manager.

- External assistance for simplified audits could be used.

Generic HACCP guides should include examples of necessary verification procedures, and when standard processes are concerned, there should be a validation of the considered control measures on the targeted hazards as well.

Validation, verification or monitoring?
Example 1: milk pasteurization
— VALIDATION: before production activities: Experimental proof that the process used will heat milk to 72 °C for 15 seconds and will destroy *Coxiella burnetti*. Calibrated probes, predictive microbiology and microbiological tests can be used.
— MONITORING: during production activities: System (time – temperature – pressure – volume throughput) which will enable the companies to see that the critical limit (72 °C for 15s) is attained during process.
— VERIFICATION: fixed frequency per year: Periodic microbiological tests on the end product, regular check of temperature of the pasteurizer with calibrated probes.
Example 2: Fermentation of dry cured sausages
— VALIDATION: pH, water activity, time/temperature combination, not allowing *Listeria monocytogenes* to grow by predictive modelling or by challenge testing;
— MONITORING during fermentation: measurement of pH, weight loss, time period, temperature, humidity of fermentation chamber, *L. monocytogenes* sampling in fermentation environment;
— VERIFICATION: *L. monocytogenes* sampling plan in the end product.
See also CXG 69-2008

11. **DOCUMENTATION AND RECORD KEEPING (PRINCIPLE 7)**

Efficient and accurate record keeping is essential to the application of HACCP-based procedures. HACCP-based procedures should be documented in the HACCP-plan and continuously supplemented by records on findings. Documentation and record keeping should be appropriate to the nature and size of the operation and sufficient to assist the business to verify that the HACCP-based procedures are in place and being maintained. Expert developed HACCP guidance materials (e.g. sector-specific HACCP guides) may be utilized as part of the documentation, provided that those materials reflect the specific food operations of the business. Documents should be reviewed and signed and any deviation should be recorded and followed up by the person responsible for HACCP in the business.

Recommended documentation includes:

— GHP documentation, see Annex I, Section 6.

— Description of the preparatory stages (before 7 principles);

— Hazard analysis, including hazard identification;

— CCP (and OPRP) identification;

— Critical limit (action criteria) determination;

— Validation activities;

— Corrective actions anticipated;

— Description of planned monitoring and verification activities (what, who, when);

— Record forms;

— Modifications to the HACCP-based procedures;

— Supporting documents (generic guides, scientific evidence, etc.).

A systematic, integrated approach can be taken by using worksheets for the development of the HACCP plan as provided in the Annex to CXC 1-1969, Diagram 3. Starting from the flow diagram, at each step of processing the potential hazards are described, relevant control measures (GHP) listed, CCP identified (if appropriate based on the hazards analysis) along with their critical limits, monitoring procedures, corrective actions and available records.

The documentation should be kept permanently available in any format for the HACCP team and at the request of the competent authorities e.g. for auditing purposes.

Record examples are:

— Outcome of monitoring activities on control measures;

— Observed deviations and executed corrective actions;

— Outcome of verification activities.

Records should be kept for an appropriate period of time in any format. That period should be long enough to ensure information to be available in case of an alert that can be traced back to the food in question. For certain foods the date of consumption is certain. For instance, in food catering, consumption takes place shortly after the time of production. For food for which the date of consumption is uncertain, records should be kept for a reasonably short period after the expiry date of the food. Records are an important tool for the competent authorities to allow verification of the proper functioning of the food businesses' FSMS and should therefore be kept long enough for the performance of official controls by competent authorities.

FLEXIBILITY EXAMPLES:

A simple system for documentation and record-keeping can be effective and easily communicated to employees. It may be integrated into existing operations and may use existing paperwork, such as delivery invoices and checklists to record, for example, product temperatures.

The examples referred to below must be seen in the light of Article 5, paragraph 2(g) of Regulation (EC) No 852/2004 where it is stated that under the HACCP-based procedures, documents and records must be commensurate to the nature and the size of the food business.

As a general rule, the need for HACCP-related record keeping should be well- balanced and can be limited to what is essential with regard to food safety. It is important to consider that recording is necessary but not the goal in itself.

Taking into account the above, the following general guidelines could be used:

— Where generic HACCP guides exist, documentation on hazard analysis, CCP determination, critical limit determination, possible modification of the FSMS and validation activities can be substituted for individual documentation on HACCP-based procedures. Such guides could also clearly indicate where there is a need for records and the period of time during which records must be kept.

— The records of non-compliance should include the corrective action that has been taken. The use of a diary or a checklist might be a suitable way of record keeping in such cases. FBOs can simply tick boxes to indicate how they act or provide more detailed information by writing in text boxes how they comply with a control point. Daily record-keeping is based on confirming opening and closing checks with a tick and a signature to confirm that safe methods have been followed. When a box ticking approach is used, only problems or changes to procedures are recorded in more detailed additional writing (i.e. exception reporting).

— (Generic) models regarding own-check documents should be provided by stakeholders' organisations or competent authorities. These should be easy to use, understandable and simple to implement.

— A x-weekly review of methods only requires completing a check list of activities and possible impact on safe methods.

12. **THE ROLE OF MICROBIOLOGICAL CRITERIA, CHEMICAL LIMITS AND OTHER LEGAL LIMITS SET IN THE EU OR NATIONAL LAW**

EU legislation provides for microbiological criteria ([4]), chemical limits ([5]) and other parameters such as temperature/time conditions. Such criteria, limits or conditions are often considered very important for the safety of the products and are therefore often associated with a CCP. For example, heat treatment of dairy products is intended to kill bacteria and freezing of fish essential for the control of parasites as laid down in Regulation (EC) No 853/2004. Microbiological criteria and chemical limits normally cannot be used as critical limits for a CCP because they don't allow a real-time measurement. They are used as parameters for the validation of HACCP-based procedures and GHP, as well as for the verification of the correct functioning of these control measures. Process hygiene as well as food safety criteria, and environmental monitoring e.g. for *Listeria monocytogenes*, can be used. Further guidance on the use of microbiological criteria for verification purposes can be found in the WHO document 'Statistical Aspects of Microbiological Criteria Related to Foods' ([6]).

For a particular operation or type of food, the guides to good practice can also include these limits.

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

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

([6]) https://www.who.int/foodsafety/publications/mra_24/en/

ANNEX III

Auditing of GHP and procedures based on the HACCP principles

1. LEGISLATION

Food Business Operators (FBOs) shall put in place, implement and maintain a permanent procedure or procedures based on the principles of hazard analysis critical control points (HACCP based procedures). To verify that this requirement is fulfilled, competent authorities must perform official controls.

Article 14 of Regulation (EU) No 2017/625 ([1]) lays down that official controls methods and techniques shall include, among others, an assessment of procedures on good manufacturing practices, good hygiene practices, good farming practices, and of HACCP based procedures. Some of the methods used in official control activities includes audits, examination of documents and records, interviews and examination of the controls that operators have put in place and of the results obtained.

In addition, Article 18(2)(d)(iii) establishes that official controls in relation to the manufacturing of products of animal origin intended for human consumption shall include audits of good hygiene practices and HACCP-based procedures. Articles 3 and 4 of Commission Implementing Regulation (EU) 2019/627 ([2]) lay down requirements to audits in establishments handling products of animal origin, including the nature and frequency of these audits and taking into account of implemented integrated systems, private control systems or independent third-party certification. Articles 7 and 8 of that Regulation establish additional requirements for audits in establishments producing fresh meat, including the relevance of audit results when carrying out official controls.

Regulation (EU) No 2017/625 also lays down a definition of audit as a systematic and independent examination to determine whether activities and the related results of such activities comply with planned arrangements and whether these arrangements are applied effectively and are suitable to achieve the objectives.

2. SCOPE AND PURPOSE

This Annex is intended for use by competent authorities as appropriate. Its purpose is to provide guidance to the development of audits of food safety management systems (FSMS) including good hygiene practices (GHP) and HACCP-based procedures in food business establishments by competent authorities, helping to identify failings in legal obligations and technical non-compliance.

This guidance is of a general nature and not intended to deal with sector specific requirements.

3. GENERAL PRINCIPLES

Audits carried out during official controls must be based on principles appropriate to make them an efficient and reliable tool and be able to provide useful information to both the FBO and the competent authority for the purposes of improving conformity.

Compliance with such principles is a prerequisite to provide relevant and robust conclusions and, at the same time, to ensure that different auditors, working independently of each other, lead to similar conclusions in similar circumstances.

([1]) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

([2]) Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (OJ L 131, 17.5.2019, p. 51).

Competent authorities as auditors are called to respect general principles as:

— Systematic and professional approach: All aspects of the process of official control must be taken into consideration (identification of priorities considering the risks, documentation of procedures, activity planning, examination of conclusions, and evaluation of the effectiveness of the process).

— Transparency: Planning processes, official control criteria, procedures for approval and distribution of reports must be defined and applied in a transparent way.

— Independence: Official control bodies must be free from any pressure at commercial, financial, hierarchical, political level or anything else that might affect the outcome of official controls.

— Confidentiality: to ensure the security of information.

— Evidence based decisions: rational method to arrive at reliable and reproducible audit findings by a systematic audit process.

4. TYPES OF AUDITS

— Complete Audit: It refers to the audit carried out in a FBO to verify that a FSMS is in place, implemented and effective. The first audit should always be of the complete type, and the following ones could be of the partial type or complete type, when there is a need to go over everything again

— Partial Audit: as long as the self-control systems have already been audited in a comprehensive and complete way, a partial audit may be carried out in order to have a more detailed impact on some aspects such as:

  — Specific audit, review of a particular aspect of the FSMS, for instance, prerequisite programmes, HACCP or its traceability and recall and withdrawal system, and/or

  — Follow-up audit, when a previous audit detects major non-conformities.

5. PLANNING, PREPARATION AND CONDUCTING A FSMS AUDIT

5.1. **Notification of the audit plan**

Article 9(4) of Regulation (EU) 2017/625 lays down that official controls shall be performed without prior notice, except where such notice is necessary and duly justified for the official control to be carried out. Auditing GHP and in particular procedures based on the HACCP principles, might be considered as such exception, since efficient auditing is only possible with prior notice to ensure that the right person or documentation is available. The auditor should communicate to FBOs the audit plan including timing schedule, audit objectives, audit scope (processes, units, documents and procedures to be audited), resources necessary for the audit and audit criteria, among others. A pre-audit questionnaire can be considered.

An example of a communication letter can be found in Appendix 6.

5.2. **Desk audit**

When possible and when the FBO agrees, the auditor may request to receive the documentation of the FSMS in advance. The function of the desk audit is to be sure that FBO has developed GHP and appropriate HACCP-based procedures and these contain all the necessary expected elements, to make a concise review and to prepare the basis to conduct the on-site audit activities.

The main advantages of a prior desk audit include the more effective use of on-site audit time, the possibility to have a better understanding of the FBO's HACCP-based procedures, to focus on particular aspects and also to enable the auditor to prepare relevant checklists.

The desk audit can be carried out in the FBO premises if the documentation has not been provided in advance.

The documents should cover the scope of the audit and provide sufficient information to support the audit objectives.

5.3. **On-site audit**

Conducting on-site audit activities is the main part of an FSMS audit. It must be based on the verification of the GHP and the seven HACCP principles. The steps to conduct on-site activities are:

1) Opening meeting,

The participants of this meeting should be at least:

— FBO and/ or their representatives

— Auditor/Auditors (Audit team)

— Any other member of the competent authorities responsible for the delivery of official controls at the premises (if different from the auditor)

Some points to cover in the meeting are:

— Reasons and scope for the audit.

— Programme for the day/ audit, including possible breaks and likely finishing time. This should also include an agreement on how and when the different parts of the audit will take place (documents review, reality checks), catch-up meetings, if necessary.

— Any other relevant information about how the audit will be conducted and methods to be used (methodology and procedures).

— Reference to previous audits, findings and any outstanding remedial actions if applicable.

— Confirmation of the closing meeting, the purpose and who will be expected to attend

— Opportunity for the FBO or their representatives to ask questions about the running of the day

2) Collecting and verifying information

The relevant documentation of the auditee and the implementation of the related procedures (GHP and HACCP) must be assessed to determine the conformity of the system with the legal requirements.

During the audit, information relevant to the audit objectives, scope and criteria, should be collected and should be verified on the spot, as far as practicable.

During the audit, there should be an effective communication on the progress and a direct sharing of any significant finding. Findings should be explained to the auditee.

Some guidelines for collecting information about the FSMS are:

— GHP documentation and record review (see Annex I), if this has not been done during the desk audit. The documentation management system is an FBO's choice, however it should be easily accessible for verification at the request of competent authorities. The complexity and importance of the documentation systems depends on the characteristics of the establishment and production. In this stage, it is important to verify that GHP designed to eliminate or minimize any hazards arising from the production environment that may adversely affect the products safety, are in place.

Main aspects to verify:

— Checking the knowledge of the responsible staff as regards the hazards identified in the HACCP Plan. The auditor can ask questions about these hazards.

— Checking if the relevant GHP applicable to the FBO have been developed and implemented.

— Checking the result of the monitoring. All measurable aspects should be checked in an on-site audit. For instance, checking chlorine levels in water.

— Checking the corrective actions applied in case of deviation. For example, if the auditor finds in the records one deviation due to a lack of chlorine, it is needed to revise the records of the maintenance programme and to see what was done the same day to solve the problem.

— Checking the reliability of the verification carried out, for instance, reviewing the outcome of internal audits.

— Checking the adequate, training and knowledge on GHP of the personnel or staff. This training should be relevant and proportionate to the tasks and responsibilities assigned to the member of the staff.

— Verify the correct application of generic guidelines, if used.

— HACCP-based procedures documentation and record review (See Annex II), if this has not been done during the desk audit, based on the accurate application of the seven HACCP principles established in Regulation (EC) No 852/2004. In particular, if it is science/risk-based, systematic and it identify the significant hazards at each step of the production chain and the measures to control those hazards, to ensure the safety of food. In addition, the auditor has to verify if the HACCP-based procedures is capable of accommodating changes, such as adaptations in equipment design, processing procedures or technological approaches as they include the requirement to review the procedures to ensure that new hazards have not been introduced when such changes are made.

Main aspects to verify:

— Verify by reviewing the analyses made, the correct control of biological, chemical or physical hazards.

— Verify the correct application of generic guidelines, if used.

— When FBOs use certain OPRP as control measures instead of CCP, they must justify this choice done by a risk assessment. All OPRPs must be monitored and in case of deviations, corrective actions towards the process must be taken; the need for corrective actions towards the product must be assessed whenever deviations occurs.

— For each CCP indicated, FBOs should justify this choice. The auditor should verify in practise if the principles of HACCP are being applied. It is useful to interview the responsible staff of the monitoring of this CCP.

— During audits, the CA may asses if the evaluation of the level of risk has been properly addressed by the FBO. The official control must assess if the implemented control measures are capable of controlling the identified hazards and appropriate and proportionate monitoring and verification/validation activities are in place as well as corrective action defined and taken when there are deviations.

— On-site verification of the flow diagram and procedures described in the documentation. The auditor must confirm the process described in the HACCP plan by checking the installations, ideally from the entry of the raw materials to the place of dispatch of the final product. In this way, the auditor can take notes, see and ask questions on the different aspects of the manufacturing process. In general, to verify if all the arrangements discovered on the desk audit are implemented correctly.

An example of checklist could be found in Appendix 7. However, it is just a general example and they might have to be adapted to the type of establishments.

3) Generating audit findings

The collected information becomes audit findings of compliance or non-compliance when they are evaluated against the audit criteria. Audit criteria in the framework of FSMS are the applicable legislation and the FBO own related procedures. Findings should be supported by observations, statements, answers and records.

4) Closing meeting

The purpose of the closing meeting is to briefly explain findings, resolve doubts or questions, to provide provisional conclusions and to give an estimate of when the audit report will be available. All relevant findings should be mentioned, as the final report should not have any 'surprises' for the FBO. In addition, during the closing meeting the auditors and the FBO can agree on the time period to present the corrective action plan, if applicable. This period should be linked to the importance of the findings.

5.4. **Audit report**

Audit reports should provide detailed evidence of the findings of the assessment, primarily what non-conformities/non-compliances have been found in the FSMS and the timetable to correct them.

Only information that can be subject to some degree of verification should be accepted as audit evidence. For instance, records or answers to questions in an interview.

The audit report should be comprehensive, accurate, succinct and clear. It should be sent to the audited FBO within a reasonable period of time after the audit.

Although there are other ways to categorise non-conformities and each competent authority will have their own system, this is an example of a categorisation system:

— **Minor** non-conformity: an isolated non-conformity/non-compliance within the sub-element of the FSMS being audited; does not compromise the food safety. For example, some non-compliance on the application of the system itself regarding the filling of some records.

— **Major** non-conformity: a non-conformity/non-compliance that compromises the food safety. Some examples are the failure or inappropriate corrective action taken by the company in the case of a food safety risk or the absence at all of corrective action. This includes cumulative or repetitive minor non-conformities/non-compliances, falsification of records, document not submitted to the competent authorities, not valid or not implemented FSMS, etc.

It may also be suitable to include a further category as a **critical** non-conformity, when system requirements are clearly not met or there are systematic failures in the application of requirements that may pose an imminent risk to public health and there is evidence that product safety could be impaired.

5.5. **Follow- up**

After receiving the action plan from FBO, competent authorities should verify the effectiveness of the corrective actions taken, in order to close the dossier of this complete audit, within the period agreed with the FBO.

6. **FLEXIBILITY**

Flexibility could be considered when performing audits of FSMS. For this purpose, competent authorities must consider the nature and size of the business and the history of compliance with official controls carried out. Therefore, after the first complete audit in a food business establishment, if the FSMS is satisfactory, fully implemented and the FBO is operating safely, some flexibility could be applicable in the next follow-up audit, for instance reducing the frequency, time spent and document review.

In addition, in some retailers and very small FBOs, it may be sufficient to verify the control of hazards in the framework of inspections rather than in an audit. This is a risk-based consideration to be made by the CA. For example, a very small FBO with only two workers manufacturing a single product that is not considered as a risk or, small retailers applying guides that base the FSMS only on PRPs.

Moreover, the continuous presence of competent authorities in certain businesses (e.g. slaughterhouses) may be taken into account when preparing and carrying out an audit.

Some examples of the application of flexibility could be:

a) Regarding the auditing when the FBO applies flexibility on the implementation of FSMS (as indicated on Annex I and Annex II):

   — When a FBO prefers to maintain the records in an electronic format, the auditor can accept them, if they were available at the time of the audit.

   — When a FBO applies flexibility on the implementation of GHP, the auditor should verify the assessment done to identify the properly of the implementation and if it is correct, carrying out the audit within this flexibility. For instance, in some small FBOs the auditor could accept when:

      — the responsible person/ staff for monitoring is the same for all GHP, or

      — the monitoring is done visually without hard copy records and only the deviations are being recorded,

— the reception control of prepacked food at retail is limited to checking if packages are in good conditions and temperatures during transport are acceptable,

— the control of water is not needed if only community potable water is used,

— the food safety culture, e.g., the engagement and awareness to work in a food safe way may become evident by normal inspection and auditing.

— When a FBO applies flexibility on the implementation of HACCP-based procedures, the audit should be carried out considering this flexibility.

— There are different approaches to flexibility in Member States (MS) and they must be considered when carrying out official control activities. For example, there are MS that does not require applying the seven HACCP principles to some type of FBOs because they consider that for some food activities of low risk, the application of GHP included in Regulation (EC) No 852/2004 are sufficient to control the significant hazards.

— The contents of this Commission Notice and others related to flexibility (Commission Notice on retail or Commission Notice EU guidelines on food donation ([3])) can be applied by FBOs and therefore FSMS following their guidelines can be considered to comply with the EU requirements. For example, a FBO that applies a simple hazard analysis in which all the hazard have been identified in a simple way grouping microbiological, chemical and physical and, has established effective control measures, it must be considered that the obligation laid down in Article 5, paragraph 1 of Regulation (EC) No 852/2004 is fulfilled (section 3.2 of the Commission Notice).

— Guides to good practice are a common approach to flexibility. There are EU, national and regional guides. A FBO may choose to apply any of the guides applicable in its territory. When carrying out official control, competent authorities must take into account this circumstance and be aware that more than one guide can be used by the FBO as a basis to its FSMS.

— When a FBO applies a guide, the guide can be considered as part of its HACCP documentation. For example, if the applied guide includes a hazard analysis and CCP for its activity, the requirement for principles 1 and 2 must be considered fulfilled. When auditing a FBO following a guide, it is necessary to check if additional hazards to those covered in the guide may be present and therefore the FBO has developed its own HACCP procedures.

— Guides can be adapted by the FBO to its specific particularities. It means that some of the procedures or guidelines included in the guides can be simplified or increased based on an own application of the HACCP principles. When adapting guides, the legal requirements must be fulfilled and this Commission Notice can be considered as a reference for flexibility. For example, when in the case of visual monitoring procedures, a FBO may consider to record only in case of deviations and therefore records only corrective actions, advisable in consultation with the CA (exception reporting). In these cases, the FBO must document its own HACCP procedures if they differ from the guide.

— Some control measures that in a large company are normally classed as CCP can be replaced in some cases, by OPRP. For example, cooking in a big factory of RTE meals is usually a CCP and temperature control is a common way to monitor it. In a small restaurant, it may not be possible to monitor temperatures every time a cooking process is carried out and direct observation of the physical properties of the food can be an effective and practical way to control the cooking process.

b) Regarding the flexibility which could be applied to follow-up audits (risk based):

— For small FBO where risks are low and (supposed to be) under control because the FSMS is effective, well put in place and well implemented, without non conformities/non compliances or weakness, it could be possible to extend the time to program the next audit (risk based). For instance, in storage of shelf-stable packaged products, where the last outcome of the audit is acceptable, competent authorities could extend the scheduling time of the next follow-up audit when it is considered to be accurate within the risk.

— For FBO without changes in the manufacturing process and with an acceptable result of the last audit, competent authorities could program a follow-up audit of the establishment focusing only on the verification of the FSMS.

— For FBO with an acceptable result of the last audit, introducing a change in the FSMS or a new manufacturing procedure, competent authorities could program a follow-up audit focusing on this change.

([3]) OJ C 361, 25.10.2017, p. 1.

7. WAY FORWARD DEPENDING ON THE RESULT OF THE AUDIT

When non-conformities are detected, the auditors should take measures in the event.

The audit team will prepare a report that reflects the result of the evaluation of the FSMS and compliance with the food law, indicating all the non-conformities detected and their classification. The report will urge the correction of the non-conformities and the decision regarding the action or measure to be taken will be recorded.

Taking into account the nature of the non-conformities (NC):

— If only minor NCs are detected, a period may be granted, verifying their correction in the next scheduled audit or after the period granted.

— In the case of detecting a major NC, an immediate correction may be requested or a period may be granted for its correction. Once the maximum period set for their correction has elapsed, a follow-up audit will be carried out to verify that the non-conformities have been corrected.

  If the non-conformities have not been corrected, the competent authority will assess whether to initiate sanctions or some other enforcement action is appropriate. A new correction period will not be granted except for a duly justified reason.

— When in the course of the audits a critical NC is detected, the competent authorities should take immediate steps to address the issue, including the suspension of the establishment's activity where there is a risk to public health, and will take all necessary measures to ensure compliance of the FBO with all legal requirements and the safety of the food already placed in the market.

  When applicable, if, after a period granted from the suspension, the operator has not rectified the non-conformities, which generated it, the procedures will be initiated to remove it from the EU lists.

  It will also proceed to the initiation of disciplinary proceedings.

— In general, the verification that the non-conformities have been corrected may be through documentary justification or after a follow-up audit visit.

  Within flexibility, under a risk assessment, and in cases where the auditor is the same as the one performing the inspections at the FBO, it may be possible to carry out verification of the correction of minor non-conformities at the next scheduled inspection for the concerned FBO. There is no need to give prior notice, it would only be needed to inform and reflect in the audit report that the correction of these minor non conformities will be checked at the next inspection.

Summary of the measures taken by competent authorities:

<table>
<tr><th>Outcome of the audit of FSMS</th><th>Tracking</th></tr>
<tr><td>Acceptable</td><td>Next Audit</td></tr>
<tr><td>Acceptable with minor non-conformity</td><td>Next Audit (Complete or Partial)
Or
Other official control: Inspections.</td></tr>
<tr><td>Minor not corrected non-conformity</td><td rowspan="2">Actions, if needed (immobilisation, precautionary suspension, penalty)
+
Partial follow-up Audit (within the timeframe set by the CA)
Or
New complete audit</td></tr>
<tr><td>Major non-conformity with risk</td></tr>
</table>

8. SOME EXTRA GUIDANCE ON AUDITING FOOD SAFETY CULTURE

Regulation (EC) No 852/2004 establishes the legal obligation of FBO to implement food safety culture, which should be verified by the competent authority.

During the audit, FBOs have to demonstrate that all staff are aware of food safety issues relevant to their tasks and that an appropriate FSC is implemented. The auditor can verify the FSC by:

— Checking FSC surveys (for example, by questionnaires) carried out in the establishment or group of establishments with the same activity.

— Interviewing (see shortened questionnaire below) and observation:

  — Checking knowledge of the staff interviewed about the importance of providing safe and suitable food.

  — Checking the behaviour and attitude of employees as regard food hygiene.

  — Checking the commitment of the management and communication with others departments.

  — Checking the leadership to engage all personnel in food safety practices.

— Checking the resources. The implementation of FSC requests time and resources. High time pressure for production might indicate the absence of a FSC. Organizing a survey using a questionnaire. This extended, FSC specific audit is recommended in large businesses or for groups of establishments carrying out the same activities within a sector or within the same business group.

In particular, in small FBOs the auditor can assess the awareness of the staff only by observation and interviews with the relevant staff.

To avoid subjective perception the verification of FSC should be carried out by verifying objective data, for instance, food hygiene practices, trainings followed by personnel, checking documentation on the flow of information and feedback between employees and managers or checking performance as internal audits results, microbiological analysis, follow-up of non-conformities, etc.

The auditor has also the possibility to organize a survey using a questionnaire.

Table 1

Example of checklist on Food Safety Culture for competent authorities

FOOD SAFETY CULTURE PERCEPTION	YES	NO	COMMENTS
Has the engagement and the involvement concerning hygiene and food safety been extended to the whole organization? — **Commitment** of the management. — **Commitment** of the employees.			
Are sufficient **resources** necessary to operate in a hygienic and food safe way available in the organization?			
Is all staff in the organization **aware of the risks** concerning hygiene and food safety and has these under control?			
Has the transfer of **communication** on hygiene and food safety issues been ensured within the organization?			
Is the **leadership** able to engage staff in hygiene/safety performance and compliance?			
Are sufficient objective data available to verify the FSC principles?			

Other tools may be published on the website of the European Commission when they become available.

(Example developed by the Food Standards Agency of the United Kingdom: https://www.food.gov.uk/sites/default/files/media/document/803-1-1431_FS245020_Tool.pdf)

Appendix 1

Overview of food safety management systems for activities other than primary production and associated activities

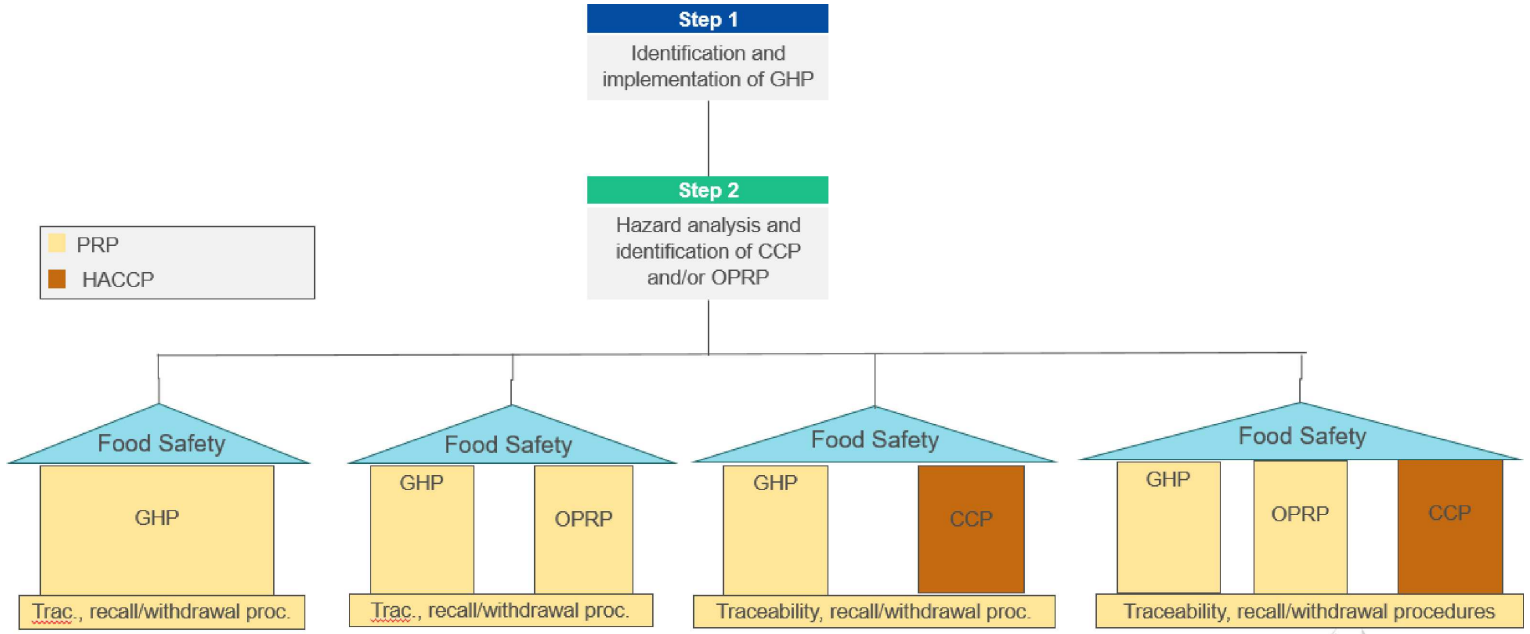
In a first step, all GHP (and other PRP) should be identified and implemented (step 1) in any FSMS.

As a second step, the hazard analysis at each process step (see Annex II, Sections 5 and 6) should identify hazards reasonably likely to occur and at the third step identify different levels of risks (see Appendices 2, 4A and 4B):

— For lower risk levels it can be concluded that, if robust GHP are in place, GHP are sufficient to ensure safety of the product;

— For intermediate levels of risks identified, 'intermediate' measures can be proposed e.g. OPRP;

— For high risks, critical control points should be established where possible and may result in the assurance of food safety by a combination of GHP, and, if also identified, OPRP



Appendix 2

Example of a hazard analysis – (semi-quantitative) risk evaluation procedure

(Based on: FAO/WHO Guidelines on 'Risk characterisation of microbiological hazards in food ([4])')

The risk level is defined at each process step by the severity or the effect of the hazard in relation to the likelihood in which the hazard can occur, to identify whether it's significant or not, and therefore if a control measure is necessary at this step or a subsequent step:

L = **Likelihood** = the probability that the hazard is occurring at a particular process step (raw material, (end) product,…), considering correctly applied preventive (GHP) and control measures in previous steps of the process

S = **Severity** = the effect or the severity of the hazard related to human health.

RISK LEVEL (R = L x S): SCALE 1 TO 7 Risk can be defined as the number of expected incidents (likelihood) in relation to the expected harm (severity) per incident

LIKELIHOOD	**High**	**4**	4	5	6	7
	Medium	**3**	3	4	5	6
	Small	**2**	2	3	4	5
	Very small	**1**	1	2	3	4
			1	**2**	**3**	**4**
			Limited	**Moderate**	**Serious**	**Very serious**
				SEVERITY		

LIKELIHOOD

1 = **very small**

— Theoretical chance – the hazard never occurred before;

— The control measure or the hazard are of such a nature that when the control measure is failing, no production is possible any more or no useful end products are produced (e.g. too high a concentration of colorants as additives);

— It is a very limited and/or local contamination.

2 = **small**

— The control measures for the hazard are of a general nature (GHP) and these are well implemented in practice;

3 = **medium**

— Failing or lacking of the (specific) control measure does not result in the systematic presence of the hazard at this step but the hazard can be present in a certain percentage of the product in the associated batch.

4 = **high**

— Failure or absence of the (specific) control measure will result in a systematic error, there is a high likelihood that the hazard is present at this step.

([4]) http://www.who.int/foodsafety/publications/micro/MRA17.pdf

SEVERITY

1 = **limited**

— There is no problem for the consumer related to food safety (nature of hazard e.g. paper, soft plastic, large size foreign materials);

— The hazard can never reach a dangerous concentration (e.g. colorants, *S. aureus* in a frozen food where multiplication to higher counts is highly unlikely or cannot happen because of storage conditions and cooking).

2 = **moderate**

— No serious injuries and/or symptoms or only when exposed to an extremely high concentration during a long period of time;

— A temporary but clear effect on health (e.g. small pieces).

3 = **serious**

— A clear effect on health with short-term or long-term symptoms which results rarely in mortality (e.g. gastro-enteritis, microbiological hazards such as *Campylobacter* or *Bacillus cereus*);

— The hazard has a long-term effect; the maximal dose is not known (e.g., residues of pesticides, ,…).

4 = **very serious**

— The consumer group belongs to a risk category and the hazard can result in mortality;

— The hazard results in serious symptoms from which mortality may result, including on the long-term (e.g. *Salmonella, Listeria monocytogenes*, dioxins, aflatoxins…);

— Permanent injuries.

EXAMPLE OF DETERMINATION OF GHP, OPRP and CCP

Risk levels 1 & 2: no specific actions, control covered by 'routine' GHP.

Risk levels 3 & 4: possible OPRP. Additional question to be answered by the HACCP team: Are the general preventive measures as described in the GHP enough to control the identified hazard?

— If YES: GHP

— If NO: OPRP.

Risk levels 5, 6 and 7: look into for CCP determination.

When taking a final decision on a CCP/OPRP at a certain step, consideration should be given to:

— the presence of a following step that will eliminate the risk or reduce its occurrence to an acceptable level: SEE DECISION TREES IN APPENDIX 4

— the severity and likelihood of deviation and capacity to detect deviations.

SEVERITY AND LIKELIHOOD OF DEVIATION AND CAPABILITY TO DETECT DEVIATIONS

In case of serious and various effects, it can be useful to assess also the likelihood of deviation and the capability to detect and correct the deviation in a timely way. ISO 22000 states that, when the probability of deviation is high but monitoring results in a high capability of detecting such deviation (immediate detection and quick corrective action), this is a typical CCP.

In cases where the feasibility is low of establishing critical limits, monitoring to detect all deviations and implementing corrective actions, OPRP are identified or the process should be modified. There is a particular challenge for control measures for which the severity x likelihood of deviation is high while the capability to detect and correct the deviation is low. FBO's shall take action to either increase the capability of detection and correction of deviations or to decrease the likelihood and/or severity of deviations. Precautionary labelling (cooking instructions, allergen control), should only be used where a preventive strategy cannot be efficiently implemented and the product may present a risk to consumers.

In other cases where the likelihood of deviation is high and the capacity to detect low, the FBO must be very careful and check the robustness of the whole FSMS.

		Severity and likelihood of deviation		
		Low	Moderate	High
Capacity to detect and correct deviation	High	GHP	OPRP	CCP
	Low	GHP	OPRP	Review the process or OPRP if possible

ALTERNATIVE APPROACH

In a number of cases (for example but not exclusively, small FBO's or simple, non-complex processes) the same approach can be used in a simpler way, for example:

— Risk levels 1 to 5 instead of 1 to 7 by using 3 instead of 4 subdivisions of the probability and effect (subdivisions 3 and 4 are merged).

— Considering the likelihood of the hazard on the end product by considering the effect of later steps (and not using the decision trees in Appendix 4.

— OPRP are not included when identifying 'intermediate' risk, but only differentiation is made between hazards that can be controlled by PRP only and those requiring a CCP.

Appendix 3

Example of indicators of the food safety culture assessment tool ([5])

The questionnaire below should be sent and completed to as much staff as possible. Respondents can answer by means of a five-point Likert scale (1-> 5: totally disagree, disagree, neutral, agree or totally agree).

By comparing the results, weaknesses can be identified in certain principles of food safety culture (E.g. communication). In addition, an overall assessment of the food safety culture can be made by comparing results:

— in different divisions of a (large) establishment

— in different branches of the same group e.g. supermarkets or butcher shops belonging to the same group

— in different establishments in the same sector (e.g. food safety authorities using the same questionnaire when auditing food safety culture throughout a certain sector).

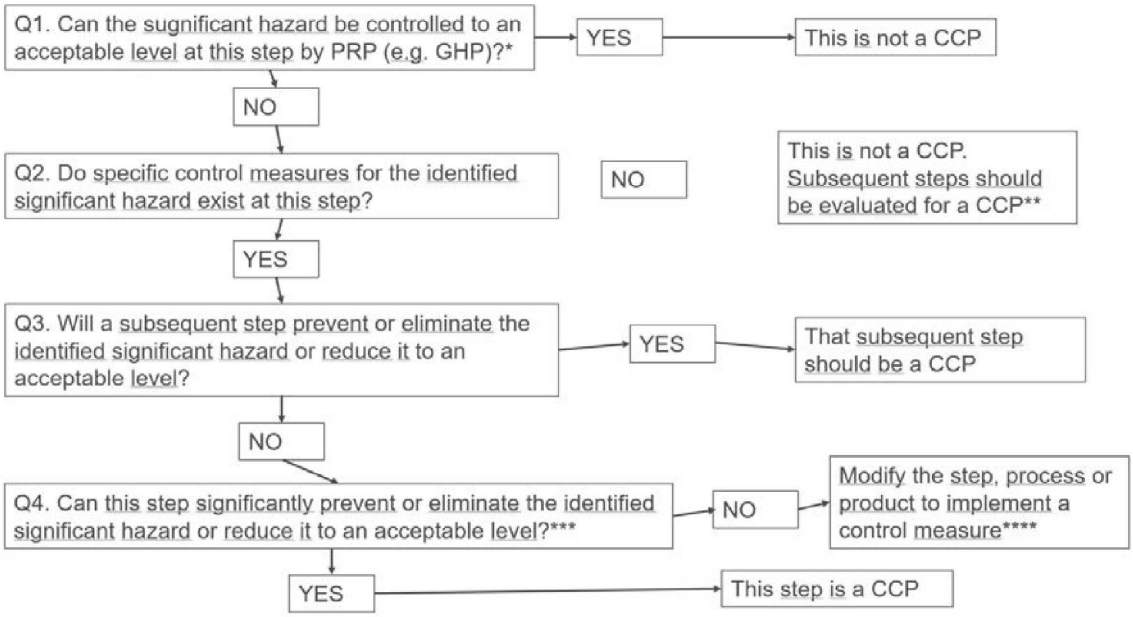
		Totally disagree	Disagree	Neutral	Agree	Totally agree
LEADERSHIP						
L.1	The managers set clear objectives concerning food safety.	1	2	3	4	5
L.2	The managers are clear about the expectations concerning food safety towards employees.	1	2	3	4	5
L.3	The managers are able to motivate their employees to work in a food safe way.	1	2	3	4	5
L.4	The managers set a good example concerning hygiene and food safety.	1	2	3	4	5
L.5	Food safety issues are addressed quickly constructively by the managers	1	2	3	4	5
L.6	The managers strive for a continuous improvement of food safety.	1	2	3	4	5
COMMUNICATION						
C.1	The managers communicate regularly with the employees about food safety	1	2	3	4	5
C.2	The managers communicate in a clear way with the employees about food safety.	1	2	3	4	5
C.3	It is possible for the employees to communicate food safety with the managers.	1	2	3	4	5
C.4	The importance of food safety is permanently present by means of, for example, posters, signs and/or icons related to food safety.	1	2	3	4	5
C.5	I can discuss problems concerning food safety with colleagues in my organization	1	2	3	4	5

([5]) After' De Boeck E., Jacxsens L., Bollaerts M. and Vlerick P. (2015). Food safety climate in food processing organizations: Development and validation of a self-assessment tool.' Trends in Food Science and Technology, 46, 242-251.

ENGAGEMENT and COMMITMENT						
E.1	I am convinced of the importance of food safety for the organization	1	2	3	4	5
E.2	My colleagues are convinced of the importance of food safety for the organization.	1	2	3	4	5
E.3	Working in a food safe way is recognized and rewarded	1	2	3	4	5
E.4	I feel that I can contribute to the safety of our products.	1	2	3	4	5
E.5	I am motivated to always try to reach the highest level of food safety.	1	2	3	4	5
E.6	I feel sharing the responsibility for the safety of our products.	1	2	3	4	5
AWARENESS						
A.1	I know the risks related to food safety relevant for carrying out my tasks.	1	2	3	4	5
A.2	My colleagues know the risks related to food safety relevant for carrying out my tasks.	1	2	3	4	5
A.3	My colleagues are alert and attentive to potential problems and risks related to food safety	1	2	3	4	5
A.4	The managers have a realistic picture of the potential problems and risks related to food safety	1	2	3	4	5
A.5	The risks related to food safety are under control in my organization.	1	2	3	4	5
RESOURCES						
R.1	Employees get sufficient time to work in a food safe way.	1	2	3	4	5
R.2	Sufficient staff is available to follow up food safety	1	2	3	4	5
R.3	The necessary infrastructure (e.g. good work space, good equipment, etc.) is available to be able to work in a food safe way	1	2	3	4	5
R.4	Sufficient financial resources are provided to support food safety (e.g. lab analyses, extern consultants, extra cleaning, purchase equipment, etc.).	1	2	3	4	5
R.5	Sufficient education and training related to food safety are given.	1	2	3	4	5
R.6	Good procedures and instructions concerning food safety are in place.	1	2	3	4	5

Appendix 4A

Example of a decision tree to identify critical control points (CCP)



* Consider the significance of the hazard (i.e., the likelihood of occurrence in the absence of control and the severity of impact of the hazard) and whether it could be sufficiently controlled by prerequisite programmes such as GHPs. GHPs could be routine GHPs or GHPs that require greater attention to control the hazard (e.g. monitoring and recording).

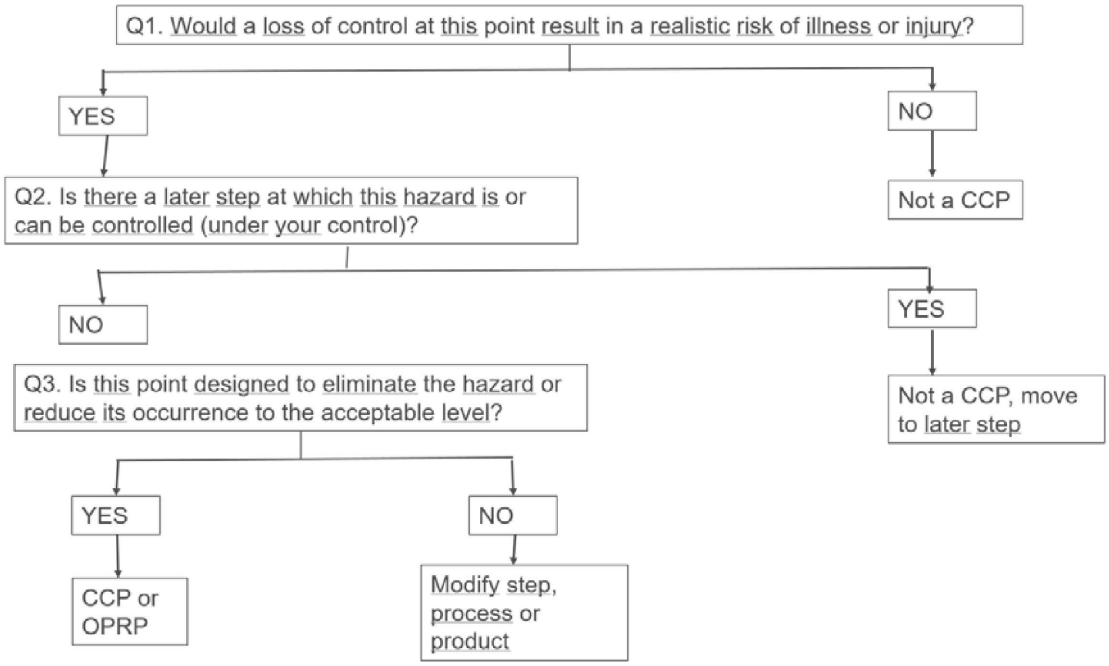
** If a CCP is not identified at questions 2-4, the process or product should be modified to implement a control measure and a new hazard analysis should be conducted.

*** Consider whether the control measure at this step works in combination with a control measure at another step to control the same hazard, in which case both steps should be considered as CCPs.

**** Return to the beginning of the decision tree after a new hazard analysis.

Appendix 4B

Example of simplified decision tree



Appendix 5

Comparison of GHP, OPRP and CCP

Type of Control measure	GHP	OPRP	CCP
Scope	Measures related to creating the environment for safe food: measures impacting food suitability and safety	Measures related to the environment and/or product (or combination of measures) to prevent contamination, or to prevent, eliminate or reduce hazards to an acceptable limit in the end product. These measures are implemented after the implementation of GHP.	
Relation to hazards	Not specific to any hazard	Specific to each hazard or group of hazards	
Determination	Development based on: — Experience, — Reference documents *(guides, scientific publications)*, — Confirmed by the hazard analysis.	Based on the hazard analysis taking GHP into account. CCP and OPRP are product and/or process specific	
Validation	Not necessarily carried out by FBO. *(ie: cleaning products manufacturer has validated the efficiency of the product and determined product spectrum and instructions of use – FBO has to follow instructions and keep technical specifications of product)*	Validation has to be carried out *(in some cases, guides to good practice provide guidance on a validation methodology or gives validated critical limits)*	
Criteria	/	Measurable or observable criteria	Measurable or observable criteria
Monitoring	Where relevant and feasible	Frequency determined by probability and severity of failure	Frequency enables real time detection of non-compliances of critical limits
Deviation: corrective actions	Corrective actions on the process Corrective actions on the product mostly not needed but to be assessed on a case by case basis	Corrective actions on the process Possible corrective actions on the product (case by case) Records kept	Pre-determined corrective actions on the product Necessary corrective actions to restore control and prevent reoccurrence on the process Records kept
Verification	Scheduled verification of implementation when appropriate	Scheduled verification of implementation, verification of achievement of planned hazard control	

Appendix 6

Example of communication letter

[Food Business Operator name]

[Date]

[Address]

[Postcode]

[Activity of the establishment to be audited]

Audit Plan

Dear *[FBO contact name]*

As part of *[Competent Authority name]* official controls to verify Food Business Operator compliance with food safety legislation, especially Regulations (EC) 852/2004, 853/2004 and 178/2002, I am writing to confirm that an audit team will carry out an audit of the FSMS in place at your establishment on *[day, month, year]*.

The audit will start at *[time]*. You should be aware that the length of the audit may vary depending on the findings. However, you can find the expected schedule below.

It would be useful if you could ensure that relevant members of your team are available during the audit visit. You will also need to make documentation relating to your HACCP-based procedures available.

AUDIT OBJECTIVES

— To determine whether activities and related results comply with your FSMS and related rules,

— To evaluate compliance with applicable legal and regulatory requirements

— To verify whether these FSMS are operating effectively.

AUDIT SCOPE

The audit scope will include assessments under the following categories:

— Potential hazards (microbiological, chemical and physical).

— Hygienic conditions and type of process carried out.

— Good Hygiene Practices and other PRP, including: cleaning and sanitation, maintenance, pest control, suppliers control, personnel training, traceability and recall, temperature controls, etc.

— HACCP-based procedures in place.

AUDITOR

[auditor's name]

[auditor's name]

TIME SCHEDULE

Total expected time: X hours.

Opening meeting	X min
Document review	X- h
On-site visit	X- h
Closing meeting	X- min

If you have any questions about the planned audit, please contact me on *[Competent Authority address and telephone]*

Yours sincerely

[Leader auditor name and signature]

Appendix 7

Example of checklist HACCP

DOCUMENT	YES	NO	COMMENTS
PREREQUISITES			
There is an effective GHP plan that underpins the HACCP Plan?			
HACCP TEAM			
Has a HACCP Coordinator been appointed?			
Has a HACCP Team been selected?			
Is information on the skills and experience of the team available and are they appropriate?			
Are external resources being used to increase the knowledge of skills and/or to increase the skills?)			
PRODUCT			
Has a product description/product specification been prepared for each product?			
Has the intended use been specified?			
Can the FBO provide an overview of the different steps in this production (for example by a flow diagram)?			
Is the flow diagram (or the overview mentioned above) complete and corresponding to the situation on the work floor?			
PRINCIPLE 1 - HAZARD ANALYSIS			
Have all reasonably likely to occur biological, chemical or physical hazards been identified and correctly described at each step?			
Have these hazards been assessed for significance?			
Have validated control measures been developed and implemented for the control of those hazards at each step where they are identified or subsequent steps? Are they set on the cause of the hazards?			
Where the hazard analysis indicates that GHP are sufficient to control the hazards, is this considered satisfactory?			
Have operational prerequisite programmes been identified?			
PRINCIPLE 2 – DETERMINATION OF CRITICAL CONTROL POINTS			
Have the Critical Control Points (and potentially OPRPs) for each significant hazard been clearly identified?			
Are the Critical Control Points (and potentially OPRPs) reasonable and justifiable, based on a risk analysis?			

Have work instructions been completed for each Critical Control Point (and potentially OPRPs)?			
Is the outcome of the hazard analysis and CCP determination satisfactory (appropriate GHP, OPRP and CCP, if applicable)?			
PRINCIPLE 3 - CRITICAL LIMITS			
Have critical limits/ action criteria been established for each Critical Control Point/OPRPs? Have target levels been set?			
Is the relationship between the control measure and the critical limit / action criteria correct?			
Are they supported by documented evidence? (Legislation, experimental evidence, published results or other references)			
PRINCIPLE 4 - MONITORING PROCEDURES			
Have monitoring procedures in place for all Critical Control Points/ OPRPs?			
Do the monitoring procedures specify what, when, how, where and who is the responsible person/staff?			
Is the frequency of monitoring sufficient? Do they allow corrective actions to be implemented in real time?			
Are monitoring records kept and reviewed by the responsible person/ staff?			
Do staff members show sufficient training to carry out the monitoring operations?			
PRINCIPLE 5 - CORRECTIVE ACTIONS			
Have corrective actions been developed for each critical control point?			
Do the corrective actions ensure that the CCP/ OPRPs is brought under control?			
Were the corrective actions applied effective?			
Do the corrective actions cover product, process and do the corrective measures prevent of recurrence?			
Are corrective actions implemented if necessary?			
PRINCIPLE 6 - VERIFICATION PROCEDURES			
Have verification procedures been put in place to demonstrate that the HACCP programme is effective? — Review of records — Direct observation — Microbiological, physical and/or chemical analysis — Internal and external audits — Complaint management — Others			
Have the critical limits been validated? How?			

Do the verification activities demonstrate that the CCP are under control?			
Do verification activities demonstrate that the HACCP programme is effective?			
Has the HACCP Plan been re-evaluated and modified when it has proven insufficient?			
Has the HACCP Plan been re-evaluated whenever raw materials, methods and/or formulas of the product are changed?			
PRINCIPLE 7 - RECORD KEEPING			
Have records been maintained for validation of all critical limits?			
Have records been maintained for all monitoring procedures?			
Have records been maintained for all corrective actions?			
Have records been maintained of all HACCP verification activities?			
Are the records kept as long as necessary?			
Have records been signed and verified?			
Are the records consistent with the actual values observed by the auditor during the audit?			
HACCP PLAN			
Does a HACCP plan or plans for each type or group of products?			
Is the written HACCP plan(s) effectively implemented?			
Is the plan dated and signed?			

ISSN 1977-091X (electronic edition)
ISSN 1725-2423 (paper edition)

Publications Office
of the European Union
L-2985 Luxembourg
LUXEMBOURG

EN