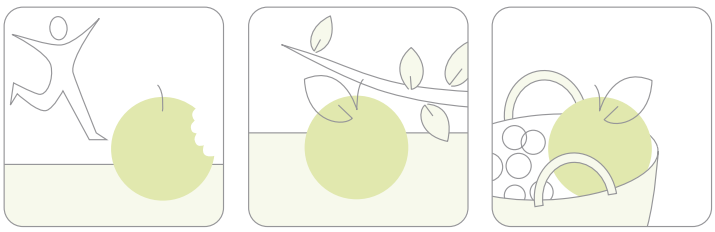
EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

GUIDANCE DOCUMENT

Implementation of procedures based on the HACCP principles, and facilitation of the implementation of the HACCP principles in certain food businesses



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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Guidance document

on the implementation of procedures based on the HACCP principles, and

on the facilitation of the implementation of the HACCP principles in certain food businesses

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PURPOSE OF THIS DOCUMENT

This document is mainly directed at food business operators and competent authorities, and aims to give guidance on the implementation of procedures based on the HACCP principles and on flexibility with regard to the implementation of such procedures, especially in small businesses.

NOTE

This document is an evolving document and will be updated to take account of experiences and information from food business operators and from competent authorities.

1. INTRODUCTION

Article 5 of Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs requires food business operators to put in place, implement and maintain a permanent procedure based on Hazard Analysis and Critical Control Point (HACCP) principles.

HACCP systems are generally considered to be a useful tool for food business operators in order to control hazards that may occur in food. 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 seems useful to issue general guidance on the development and implementation of HACCP based procedures.

Regulation (EC) No 852/2004 allows the HACCP based procedures to be implemented with flexibility so as to ensure that they can be applied in all situations. Since the adoption of Regulation the Commission has been requested to clarify to what extent flexibility with regard to the implementation of the procedures based on the HACCP principles can be applied.

This document aims to issue guidance on the requirement laid down in Article 5 of Regulation (EC) No 852/2004, and on the flexibility that can be applied in particular in small businesses.

The Commission's Health and Consumer Protection Directorate General has held a series of meetings with experts from the Member States in order to examine and reach consensus on these issues.

In addition, and in the interest of transparency, the Commission has promoted discussion with stakeholders so as to allow different socio-economic interests to express an opinion. To this end the Commission has organised a meeting with representatives from producers, industry, commerce and consumers to discuss issues related to the implementation of HACCP based procedures and to HACCP flexibility.

It was considered that this is a useful procedure, which should continue in the light of the experience gained by the full application of the Regulation from 1 January 2006.

The present document aims to assist all players in the food chain to better understand HACCP implementation and HACCP flexibility. However, this document has no formal legal status and in the event of a dispute, ultimate responsibility for the interpretation of the law lies with the Court of Justice.

2. THE HACCP PRINCIPLES AND GUIDELINES FOR THEIR APPLICATION.

When they put in place, implement and maintain a permanent procedure based on the seven Hazard Analysis and Critical Control Point (HACCP) principles, it is recommended that food business operators take into account the principles laid down in **Annex I** hereto.

Annex I describes in a simple way how the seven HACCP principles can be applied. It is largely inspired by the principles set out in Codex Alimentarius document CAC/RCP 1-1996, rev. 4-2003.

3. FLEXIBILITY

The HACCP concept is an appropriate tool to control hazards in food businesses, and in particular in those food businesses that proceed to operations that are likely to introduce hazards when not carried out properly.

The HACCP concept allows HACCP principles to be implemented with the required flexibility so as to ensure that it can be applied in all circumstances. **Annex II** hereto explores the extent of such flexibility and gives guidance on a simplified implementation of the HACCP requirements **particularly in small food businesses**.

ANNEX I[1]

HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) PRINCIPLES AND GUIDELINES FOR THEIR APPLICATION

Introduction

These guidelines are meant for those food business operators applying a procedure based on HACCP principles.

General principles

HACCP is science based and systematic, identifies specific hazards and measures for their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing. Any HACCP system is capable of accommodating change, such as advances in equipment design, processing procedures or technological developments.

HACCP can be applied throughout the food chain from primary production to final consumption and its implementation should be guided by scientific evidence of risks to human health. As well as enhancing food safety, implementation of HACCP can provide other significant benefits, such as the application of HACCP can aid inspection by regulatory authorities and promote international trade by increasing confidence in food safety.

The successful application of HACCP requires the full commitment and involvement of management and the work force. It also requires a multidisciplinary approach; this multidisciplinary approach should include, when appropriate, expertise in agronomy, veterinary hygiene, production, microbiology, medicine, public health, food technology, environmental health, chemistry and engineering.

Prior to application of HACCP to any business the food business operator should have implemented the prerequisite food hygiene requirements. Management commitment is necessary for implementation of an effective HACCP. During hazard identification, evaluation, and subsequent operations in designing and applying HACCP, consideration must be given to the impact of raw materials, ingredients, food manufacturing practices, role of manufacturing processes to control hazards, likely end-use of the product, categories of consumers of concern, and epidemiological evidence relative to food safety.

The intent of HACCP is to focus control at critical control points (CCP's). HACCP should be applied to each specific operation separately. The HACCP application should be reviewed and necessary changes made when any modification is made in the product, process, or any step. It is important when applying HACCP to be flexible where appropriate, given the context of the application taking into account the nature and the size of the operation.

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[1] adapted from Codex Alimentarius documents: Codex Alinorm 03/13A Appendix II (at step 8 of the procedure) and CAC/RCP 1-1969 (Rev. 3- 1997).

HACCP consists of the following seven principles:

(1) identifying any hazards that must be prevented, eliminated or reduced to acceptable levels (hazard analysis);

(2) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;

(3) establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;

(4) establishing and implementing effective monitoring procedures at critical control points;

(5) establishing corrective actions when monitoring indicates that a critical control point is not under control;

(6) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in paragraphs 1 to 5 are working effectively;

(7) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in paragraphs 1 to 6.

Application of the seven principles

It is recommended to proceed to the following activities in sequence.

1. HAZARD ANALYSIS

1.1. Assembly of a multidisciplinary team (HACCP team)

This team, which involves all parts of the food business concerned with the product, needs to 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.

Where necessary, the team will be assisted by specialists who will help it to solve its difficulties as regards assessment and control of critical points.

The team may include specialists:

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

- who have responsibility for, or is 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 microbiology, hygiene or food technology.

One person may fulfill several 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, advice should be obtained from other sources (consultancy, guides of good hygiene practices, etc.).

The scope of the HACCP plan should be identified. The scope should describe which segment of the food chain is involved, which process of the business and the general classes of hazards to be addressed (biological, chemical and physical).

1.2. Description of the product

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

- composition (e.g. raw materials, ingredients, additives, etc.),
- structure and physico-chemical characteristics (e.g. solid, liquid, gel, emulsion, moisture content, pH etc.),
- processing (e.g. heating, freezing, drying, salting, smoking, etc. and to what extent),
- packaging (e.g. hermetic, vacuum, modified atmosphere),
- storage and distribution conditions,
- required shelf life (e.g. “use by date” or “best before date”),
- instructions for use,
- any microbiological or chemical criteria applicable.

1.3. Identification of intended use

The HACCP team should also define the normal or expected use of the product by the customer and 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.

1.4. Construction of a flow diagram (description of manufacturing process)

Whatever the format chosen all steps involved in the process, including delays during or between steps, from receiving the raw materials to placing the end product on the market, through preparation, processing, packaging, storage and distribution, should be studied in sequence and presented in a detailed flow diagram together with sufficient technical data.

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),
- 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 following requirements are prerequisites and can be integrated in the HACCP system:

- cleaning and disinfection procedures,
- hygienic environment of the establishment,
- personnel routes and hygiene practices,
- product storage and distribution conditions.

1.5. On-site confirmation of flow diagram

After the flow diagram has been drawn up, the multidisciplinary 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.

1.6. Listing of hazards and control measures

1.6.1. list all potential biological, chemical or physical hazards that may be reasonably expected to occur at each process step (including acquisition and storage of raw materials and ingredients and delays during manufacture). Hazard has been defined in Article 3 (14) of Regulation (EC) No 178/2002.

The HACCP team should next conduct a hazard analysis to identify for the HACCP plan which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food.

In conducting the hazard analysis, the following should be considered:

- the likely occurrence of hazards and severity of their adverse health effects;
- the qualitative and/or quantitative evaluation of the presence of hazards;

- survival or multiplication of pathogenic micro-organisms and unacceptable generation of chemicals in intermediate products, final products, production line or line environment;

- production or persistence in foods of toxins or other undesirable products of microbial metabolism, chemicals or physical agents or allergens;

- contamination (or recontamination) of a biological (micro-organisms, parasites), chemical or physical nature of raw materials, intermediate products or final products.

1.6.2. consider and describe what control measures, if any, exist which can be applied for each hazard.

Control measures are those actions and activities that can be used to prevent hazards, eliminate them or reduce their impact or occurrence to acceptable levels.

More than one control measure may be required to control an identified hazard 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 both S*almonella* and *Listeria*.

Control measures need to be supported by detailed procedures and specifications to ensure their effective implementation. For instance, detailed cleaning schedules, precise heat treatment specifications, maximum concentrations of preservatives used in compliance with the applicable Community rules.

2. IDENTIFICATION OF CRITICAL CONTROL POINTS (=CCP)

The identification of a critical point for the control of a hazard requires a logical approach. Such an approach can be facilitated by the use of a decision tree (other methods can be used by the team, according to their knowledge and experience). For the application of the decision tree, each process step identified in the flow diagram should be considered in sequence. At each step, the decision tree must be applied to each hazard that may be reasonably expected to occur or be introduced and each control measure identified. Application of the decision tree should be flexible , having consideration for the whole manufacturing process in order to avoid, whenever possible, unnecessary critical points. An example of a decision tree is shown in Figure 1, but may not be applicable to all situations. Training in the application of the decision tree is recommended.

The identification of critical control points 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 at a step where control is necessary for product safety and no control measure exists at that step, or at any other, 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 a monitoring system at each critical point.

3. CRITICAL LIMITS AT CRITICAL CONTROL POINTS

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 under control. They should be based on substantiated evidence that the chosen values will result in process control.

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

In some cases, to reduce the risk 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 observed.

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

4. MONITORING PROCEDURES AT CRITICAL CONTROL POINTS

An essential part of HACCP is a program of observations or measurements performed at each critical point to ensure compliance with specified critical limits..

Observations or measurements must be able to detect loss of control at critical points and provide information in time for corrective action to be taken.

Where possible, process adjustments should be made when monitoring results indicate a trend towards loss of control at a CCP. The adjustments should be taken before a deviation occurs. Data derived from monitoring must be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated.

Observations or measurements can be made continuously or intermittently. When observations or measurements are not continuous, it is necessary to establish a frequency of observations or measurements which provides reliable information.

The program should describe the methods, the frequency of observations or measurements and the recording procedure and identify each critical point:

- who is to perform monitoring and checking,
- when monitoring and checking is performed,
- how monitoring and checking is performed.

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

5. CORRECTIVE ACTIONS

For each critical control point corrective actions have to 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 action should include:

- proper identification of the person(s) responsible for the implementation of the corrective action,
- description of means and action required to correct the observed deviation,
- action to be taken with regard to products that have been manufactured during the period when the process was out of control,
- written record of measures taken indicating all relevant information (for example: date, time, type of action, actor and subsequent verification check).

Monitoring may indicate:

2. that preventive measures (checking equipment, checking the person handling the food, checking the efficacy of previous corrective measures, etc.) shall have to be taken if corrective actions for the same procedure have to be taken repeatedly.

6. VERIFICATION PROCEDURES

6.1. The HACCP team should specify the methods and procedures to be used for determining if the HACCP is working correctly. Methods for verification may include in particular random sampling and analysis, reinforced analysis or tests at selected critical points, intensified analysis of intermediate or final products, surveys on actual condition during storage, distribution and sale and on actual use of the product.

The frequency of verification should be sufficient to confirm that HACCP is 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.

Verification procedures include:

- audits of HACCP and its records,
- inspection of operations,
- Confirmation that CCP’s are kept under control,
- validation of critical limits,

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

The frequency of verification will greatly influence the amount of recheck or recall required in case a deviation exceeding the critical limits has been detected. Verification shall comprise all of the following elements, but not necessarily all at the same time:

- check on the correctness of the records and analysis of deviations
- check on the person monitoring processing, storage and/or transport activities
- physical check on the process being monitored
- calibration of instruments used for monitoring.

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.

6.2. Where possible, validation activities should include actions to confirm the efficacy of all elements of the HACCP plan. In case of change, it is necessary to review the system, to ensure that it is (or will be) still valid.

Examples of change include:

- change in raw material or in product, processing conditions (factory layout and environment, process equipment, cleaning and disinfection program),
- 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.

7. DOCUMENTATION AND RECORD KEEPING

Efficient and accurate record keeping is essential to the application of a HACCP system. HACCP procedures should be documented. 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 controls are in place and being maintained. Documents and records should be kept for a sufficient time to allow the competent authority to audit the HACCP system. Expertly 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 signed by a responsible reviewing official of the company.

Documentation examples are:

- Hazard analysis;
- CCP determination;
- Critical limit determination;
- Modifications to the HACCP system.

Record examples are:

- CCP monitoring activities;
- Deviations and associated corrective actions;
- Verification activities.

A simple record-keeping system 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.

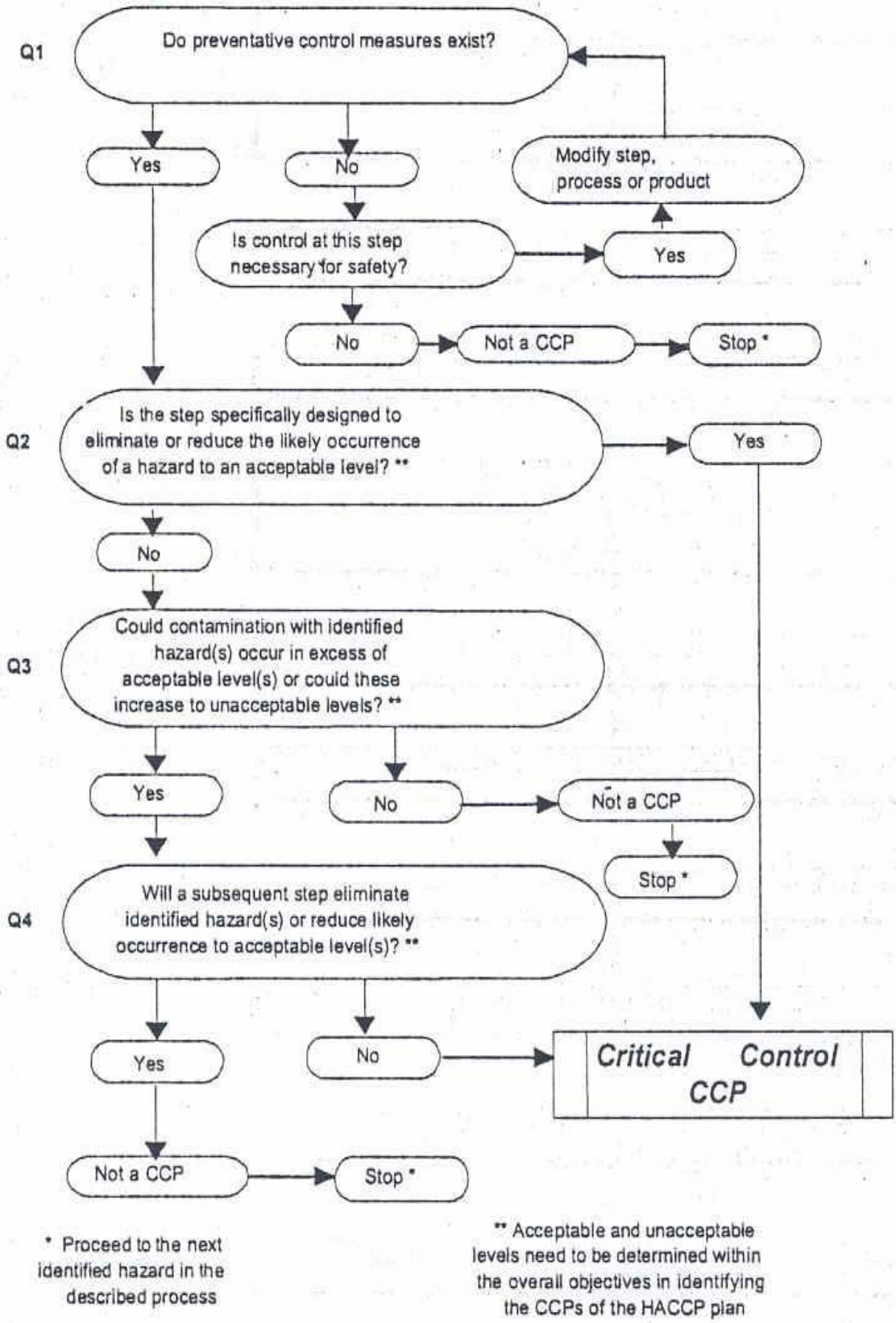
8. TRAINING

1. The food business operator shall make sure that all personnel are aware of the hazards identified (if any), the critical points in the production, storage, transport and/or distribution process and the corrective measures, the preventive measures and documentation procedures applicable in his/her business.

2. The food industry sectors shall endeavour to prepare information such as. (generic) HACCP guides and training for the food business operators.

3. The competent authority shall, when needed, assist in developing similar activities as mentioned in paragraph 2, especially in those sectors, which are poorly organised or are shown to be insufficiently informed.

Figure 1: Example of a decision tree to identify critical control points (CCP's). The questions shall be answered in sequence.


Q1
Do preventative control measures exist?
Yes
No
Modify step, process or product
Is control at this step necessary for safety?
Yes
No
Not a CCP
Stop *
Q2
Is the step specifically designed to eliminate or reduce the likely occurrence of a hazard to an acceptable level? **
Yes
No
Q3
Could contamination with identified hazard(s) occur in excess of acceptable level(s) or could these increase to unacceptable levels? **
Yes
No
Not a CCP
Stop *
Q4
Will a subsequent step eliminate identified hazard(s) or reduce likely occurrence to acceptable level(s)? **
Yes
No
Critical Control CCP
Not a CCP
Stop *
* Proceed to the next identified hazard in the described process
** Acceptable and unacceptable levels need to be determined within the overall objectives in identifying the CCPs of the HACCP plan

ANNEX II

Facilitation of the implementation of the HACCP principles in certain food businesses

1. BACKGROUND

1.1. Article 5 of Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs requires food business operators to put in place, implement and maintain a permanent procedure based on Hazard Analysis Critical Control Point (HACCP) principles.

The concept allows HACCP principles to be implemented with the required flexibility in all cases. The present document explores the extent of the flexibility and gives guidance on a simplified implementation of the HACCP requirements particularly in small food businesses.

1.2. In Regulation (EC) No 852/2004, key issues for a simplified HACCP procedure 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 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 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) of Regulation (EC) No 852/2004 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 that allows the adoption of arrangements to facilitate the implementation of the HACCP requirement by certain food business operators. These include the use of **guides for the application of HACCP principles**.

2. PURPOSE OF THE PRESENT DOCUMENT

The purpose of this document is to give guidance on flexibility with regard to the implementation of HACCP-based procedures, and in particular:

- To identify those food businesses where flexibility would be appropriate,
- To explain the notion "procedure based on the HACCP principles",
- To place HACCP in the wider context of food hygiene and prerequisite requirements,
- 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 HACCP principles.

3. BUSINESSES ELIGIBLE FOR HACCP FACILITATION

Regulation (EC) No 852/2004 is not specific on the nature of food businesses that are eligible for the implementation of a simplified procedure based on the HACCP principles. In the general context of the new food safety rules however, the impact of the requirement to put in place, implement and maintain a permanent procedure based on the HACCP principles should be proportionate and based on risk. In particular, hazards linked to certain types of food and to the process that is applied to food shall be taken into account when considering simplified HACCP based procedures.

The principles set out in the present document are primarily addressed to small businesses, but are not only applicable to small businesses. The examples that are given in the different sections of this document are therefore indicative and not exclusive for the food businesses or food sectors that are cited.

4. WHAT IS A PROCEDURE BASED ON THE HACCP PRINCIPLES?

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 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.

A procedure based on the HACCP principles is a pro-active hazard management system. It aims to keep the contamination of food with micro-organisms, chemical substances or physical contaminants (such as glass particles) under control so as to produce food safely.

The obligation to put in place, implement and maintain a permanent procedure based on the HACCP principles is largely inspired by the "Recommended International Code of Practice-General Principles of Food Hygiene"[2]. The purpose of such a procedure being the control of food hazards, the Code advises food business operators to:

- Identify any steps in their operations which are critical to the safety of food;
- Implement effective control procedures at those steps;
- Monitor control procedures to ensure their continuing effectiveness; and
- Review control procedures periodically, and whenever the operations change.

This means that food business operators should have a system in place to identify and control significant hazards on a permanent basis and adapt that system whenever necessary.

This can be achieved e.g. by the correct implementation of prerequisite requirements and good hygienic practices, by applying HACCP principles (possibly in a simplified way), by using guides to good practice or by a combination of those.

5. HACCP AND PREREQUISITE REQUIREMENTS

Food hygiene is the result of the implementation by food businesses of prerequisite requirements and procedures based on the HACCP principles. The prerequisite requirements provide the foundation for effective HACCP implementation and should be in place before a HACCP based procedure is

[2] CAC/RCP 1-A996, Rev. 4-12003

established.

HACCP systems are not a replacement for other food hygiene requirements, but a part of a package of food hygiene measures that must ensure safe food. It must in particular be borne in mind that prior to establishing HACCP procedures "prerequisite" food hygiene requirements must be in place, including in particular:

- Infrastructural and equipment requirements,
- Requirements for raw materials,
- The safe handling of food (including packaging and transport),
- Food waste handling,
- Pest control procedures,
- Sanitation procedures (cleaning and disinfection),
- Water quality,
- Maintenance of the cold chain,
- The health of staff,
- Personal hygiene,
- Training.

These requirements are designed to control hazards in a general way and they are clearly prescribed in Community law. They may be supplemented with guides to good practices established by the different food sectors.

Other requirements of Community law, such as traceability (Article 18 of Regulation (EC) No 178/2002) and on the withdrawal of food and the duty of informing the competent authorities (Article 19 of Regulation (EC) No 178/2002) could, although not covered under the food hygiene rules, also be considered as prerequisite requirements.

6. PREREQUISITE REQUIREMENTS AND THE CONTROL OF FOOD HAZARDS

Where the prerequisite requirements (whether or not supplemented with guides to good practices) achieve the objective of controlling hazards in food, it should be considered, based on the principle of proportionality, that the obligations laid down under the food hygiene rules have been met and that there is no need to proceed with the obligation to put in place, implement and maintain a permanent procedure based on the HACCP principles.

6.1. A full HACCP-based procedure is a food safety management system that is particularly appropriate for food businesses preparing, manufacturing or processing food.

In certain cases, in particular in food businesses where there is **no preparation, manufacturing or processing of food**, it may seem that all hazards can be controlled through the implementation of the prerequisite requirements. In these cases it can be considered that the first step of the HACCP procedure (hazard analysis) has been performed and that there is no further need to develop and implement the other HACCP principles.

Such enterprises may include (but not exclusively):

- Marquees, market stalls and mobile sales vehicles,
- Establishments mainly serving beverages (bars, coffee shops etc.),
- Small retail shops (such as grocery shops),
- The transport and storage of pre-packed food or non perishable food,

where there is usually no preparation of food.

Such businesses could also undertake simple food preparation operations (such as the slicing of food) that can be carried out safely when applying the prerequisite food hygiene requirements correctly.

6.2. **It is clear however that, where food safety so requires, it must be ensured that the necessary monitoring and verification (and possibly record keeping) are carried out, for example where the cold chain must be maintained.** In that event, monitoring of temperatures, and where necessary, checking the proper functioning of the refrigeration equipment are essential.

7. GUIDES TO GOOD PRACTICE FOR FOOD HYGIENE AND FOR THE APPLICATION OF HACCP PRINCIPLES

Guides to good practice are a simple but efficient way to overcome difficulties that certain food businesses may encounter in implementing a detailed HACCP procedure. Representatives of the different food sectors, and in particular of those sectors where many food businesses find difficulties in developing HACCP procedures, should consider the case for such guides, and competent authorities should encourage sector representatives to develop such guides. Assistance should be given in the development of guides to good practice to those food sectors that are weak or are poorly organised.

7.1. The use of guides to good practice may help food businesses to control hazards and demonstrate compliance. 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 of the operators in the sectors concerned (whether or not at retail level), such as:

- Restaurants, including food handling facilities on board means of transport such as vessels,
- Catering sectors dispatching prepared food from a central establishment,
- The bakery and confectionary sector,
- Retail shops, including butcher shops.

7.2. For such businesses it may suffice that the guides to good practice describe in a practical and simple way the methods to control hazards without necessarily entering into detail on the nature of the hazards and a formal identification of critical control points. These guides 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.

Such guides could also highlight the possible hazards linked to certain food (e.g. raw eggs and the possible presence of *Salmonella* therein), as well as the methods to control food contamination (e.g. the purchase of raw eggs from a reliable source and time/temperature combinations for processing).

7.3. Guides to good practice have already been developed and assessed by the competent authorities for many food sectors. These guides are usually a combination of Good Hygienic Practices (GHP) and HACCP-based elements, and include for example:

- Guidelines for the practical implementation of the prerequisite requirements,
- Requirements for raw materials,
- A hazard analysis,
- Pre-determined critical control points in the preparation, manufacturing and processing of food identifying hazards and specific control requirements.
- The hygienic precautions that need to be taken in the case of handling vulnerable and perishable products (such as ready-to-eat products),
- More elaborate measures in case of food prepared for highly susceptible groups of consumers (children, the elderly, etc.),

- The need for documentation and records,
- Protocols for the validation of use-by dates.

7.4. Generic guides to the implementation of the HACCP system

A special type of guide to good practice is the generic HACCP guide.

The generic guides could suggest hazards and controls common to certain food businesses and assist the manager or the HACCP team through the process of producing food safety procedures or methods 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 there still is a need for additional examination for the possible presence of such hazards and the methods to control them.

In those sectors where there is a lot of commonality between businesses, where the manufacturing process is linear and where the hazard prevalence is likely to be high, generic 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.

8. FLEXIBILITY WITH REGARD TO THE HACCP PRINCIPLES

Taking into account the above, the following are examples of how HACCP principles can be applied in a flexible and simplified way. Guides to good practice are an appropriate tool to give guidance in this matter.

8.1. Hazard analysis and the development of HACCP-based procedures

- In certain cases it can be presumed that, due to the nature of the food business and the food that is handled by it, possible hazards can be controlled by implementing the prerequisite requirements. In such cases, a formal hazard analysis is not needed. It should be recommended that for such food businesses guides to good practice are established.
- In certain cases, the hazard analysis may demonstrate that all food hazards can be controlled by the implementation of the prerequisite food hygiene requirements.

- For certain categories of food businesses it may be possible to pre-determine hazards that need to be controlled. Guidance on such hazards and on the control thereof can be addressed in a generic HACCP guide.

8.2. Critical limits

Critical limits at critical control points 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
- In a guide to good practice.

The requirement of establishing a critical limit at a critical control point 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 in a slaughterhouse,
- The boiling temperature of liquid food,
- The change of physical properties of food during processing (e.g. cooking of food).

8.3. Monitoring procedures

8.3.1. Monitoring may in many cases a simple procedure, e.g.

- A regular visual verification of the temperature of cooling/freezing facilities using a thermometer;
- A visual observation to monitor whether the correct de-hiding procedure is being applied during slaughter where this part of the slaughter process has been identified as a critical control point for preventing carcase contamination;
- A visual observation 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).

8.3.2. Standard processing procedures

- Certain foods may sometimes be processed in a standard way using 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. In such cases the cooking temperature of the product need not be systematically measured as long as 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).

- In restaurants, food is prepared in accordance with well established culinary procedures. This implies that measurements (e.g. food temperature measurements) need not be carried out systematically as long as the established procedures are followed.

8.4. Documents and records

Preliminary remarks:

This section refers to HACCP related documentation only and not to other documentation on issues such as stock management, traceability etc.

The examples referred to hereunder 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.

HACCP related documentation includes:

(a) Documents on the HACCP-based procedures appropriate for a particular food business, and

(b) Records on measurements and analysis carried out.

Taking into account the above, the following general orientations could be used as guidance:

- Where guides to good practice or generic HACCP guides exist, these can substitute individual documentation on HACCP-based procedures. Such guides could also clearly indicate where there is a need for records and the time period during which records must be kept.

- In the case of visual monitoring procedures, it may be considered to limit the need for establishing a record only to measurements of non-compliance (e.g. failure of equipment to maintain the correct temperature) that are detected.

  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.

- Records should be kept for an appropriate time. That period must be long enough to ensure information to be available in case of an alert that can be traced back to the food in question, e.g. two months after the date of consumption, if such a date exists.

  For certain foods the date of consumption is certain, e.g. in the case of 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' food safety procedures.

9. THE ROLE OF CRITERIA AND LIMITS SET IN COMMUNITY OR NATIONAL LAW

Although Community legislation does not provide for critical limits at critical control points, it must be considered that microbiological criteria can be used in validation and verification of HACCP based procedures and other food hygiene control measures, as well as for the verification of the correct functioning of these control measures. Such criteria are in many cases already existing in Community or national legislation. For a particular operation or type of food, the guides to good practice can refer to these limits and the HACCP procedure can be formatted in such a way as to ensure that these limits are met.

10. MAINTENANCE OF THE COLD CHAIN

Under Regulation (EC) No 852/2004, food business operators have the clear obligation to respect the maintenance of the cold chain.

This obligation is therefore part of the prerequisite requirements and must be implemented even when simplified HACCP procedures are applied.

However, nothing prevents food businesses from checking temperature of food at certain points of the production line as Critical Control Points, and from integrating this requirement into their HACCP procedures.

11. REGULATORY ASSESSMENT

HACCP procedures, under whatever form they are applied, must be developed by and under the responsibility of the food business operators.

Regulatory assessment should be carried out taking into account the means that have been chosen by food businesses for ensuring compliance with the HACCP requirement:

- Where food businesses ensure food safety through prerequisite requirements only, the competent authority should verify the correct implementation of these requirements.

- Where guides to good practice for hygiene and for the application of HACCP principles are used by food businesses for ensuring compliance with the HACCP requirement, it is normal practice for the controlling authority to assess such businesses against the guides.

When assessing the implementation of the HACCP requirement, the competent authority may require corrections to be made. This should however not be considered as a formal approval of the procedures.

12. HACCP AND CERTIFICATION

Community legislation does not contain a requirement for HACCP procedures to be certified e.g. under quality assurance schemes. Any initiative to proceed to such certification emanates from private initiatives.

The only assessment that is provided for under Community law is an assessment by the competent authorities in the Member States in the context of their normal official control duties.

13. HACCP AND TRAINING OF STAFF IN FOOD BUSINESSES

Training as referred to in Annex II, Chapter XII of Regulation (EC) No 852/2004 must be seen in a broad context. Appropriate training does not necessarily involve participation in training courses. Training can also be achieved through information campaigns from professional organisations or from the competent authorities, guides to good practice etc.

It must be kept in mind that HACCP training of staff in food businesses should be **proportionate to the size and the nature of the business**.

14. CONCLUSION

Regulation (EC) No 852/2004 states that the HACCP requirements should *provide* ***sufficient flexibility in all situations, including in small businesses.***

The Basic objective of implementing a HACCP based procedure is to control hazards in food. This objective can be achieved using different means, bearing in mind that that the procedures to control hazards are to be risk-based, prioritised and focussed on what is important for food safety in a food business. These procedures can be developed in Guides to Good Practice, in Generic Guides for food safety management, or in accordance with a traditional HACCP process, depending on appropriateness. In a number of cases, especially in food businesses that do not process food, hazards can be controlled by implementing prerequisite food hygiene requirements only.