

EN

SANCO/1515/2005

25 May 2005

Wording document: does not necessarily represent the opinion of the European Commission.

Preliminary version: may be subject to changes and amendments.



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 17.5.2005

DRAFT

Guidance document

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

PURPOSE OF THIS DOCUMENT

This document is mainly directed at food businesses and competent authorities, and aims to give guidance on the flexibility with regard to the implementation of the procedures based on the Hazard Analysis Critical Control Point (HACCP)-system, especially in small businesses.

NOTE

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

1. INTRODUCTION

Since the adoption of Regulation (EC) No 853/2004 on the hygiene of foodstuffs, the Commission has been requested to clarify the principles with regard to flexibility for the implementation of the procedures based on the Hazard Analysis Critical Control Point (HACCP) principles. This document aims to follow-up these requests.

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 a number of issues concerning flexibility with regard to the HACCP principles.

In addition, 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 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 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. BACKGROUND

- 2.1. 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.

- 2.2. 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**.

3. 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.

4. BUSINESSES ELIGIBLE FOR HACCP FACILITATION

Regulation (EC) No 853/2004 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.

5. 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 safe food.

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”¹. 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.

6. 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 established.

¹ CAC/RCP 1-A996, Rev. 4-12003

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.

7. 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.

- 7.1. 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.

- 7.2. **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.

8. 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.

- 8.1. The use of guides to good practice may help food businesses to control hazards and demonstrate compliance without the need to proceed to a formal HACCP procedure. 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.

8.2. 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).

8.3. 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.

8.4. 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.

9. 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.

9.1. 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 case, 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. That makes the development of HACCP procedures in those cases unnecessary.
- 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.

9.2. 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 carcasses in a slaughterhouse,
- The boiling temperature of liquid food,
- The change of physical properties of food during processing (e.g. cooking of food).

9.3. Monitoring procedures

9.3.1. 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 carcass 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).

9.3.2. 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.

9.4. 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 853/2004 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.

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.

10. 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.

11. MAINTENANCE OF THE COLD CHAIN

Under Regulation (EC) No 853/2004, 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.

12. 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.

13. 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.

14. 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.**

15. 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.