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COMMISSION REGULATION (EC) No .../..

of [...]

laying down detailed guidelines for the implementation of HACCP by food business operators

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THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs¹, and in particular Article 5(5) thereof,

Whereas:

- (1) Food hygiene is determined by the implementation of prerequisite requirements laid down in Community and national law, supplemented with the obligation to put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.
- (2) The prerequisite requirements are laid down in Regulation (EC) No 852/EEC and in Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April laying down specific hygiene rules for food of animal origin². The prerequisite requirements include provisions on:
 - food premises including their construction, layout and equipment,
 - foodstuffs, including raw materials and ingredients,
 - cleaning and disinfection,
 - water supply,
 - personal hygiene,
 - health of staff,
 - the transport of food,
 - the need to maintain the cold chain in all circumstances,

¹ OJ L 226, 25.6.2004, p.3

² OJ L 226, 25.6.2004, p.22

- the control of pests,
 - waste disposal,
 - the wrapping and packaging of foodstuffs and
 - training.
- (3) Food business operators shall be able to guarantee the traceability of food in accordance with Regulation (EC) No 178/2002³.
- (4) The procedure or procedures based on the HACCP principles must be flexible enough to ensure their applicability in all situations.
- (5) The design and application of a program based on the HACCP principles will differ from one establishment to another; it is therefore necessary to propose in the form of guidelines, a model of a logical approach intended to facilitate a uniform application.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health.

HAS ADOPTED THIS REGULATION:

Chapter I

Scope, definitions and general principles

Article 1 *Scope*

This Regulation lays down detailed guidelines for the application of a program based on HACCP principles in food establishments.

Article 2 *Definitions*

“A procedure based on the HACCP principles” means a procedure, the objective of which is to identify and control significant hazards on a permanent basis that, where appropriate, has been adapted because the objective can be reached by equivalent means substituting in a simplified, but effective way some or all of the seven HACCP principles. This can be achieved on an individual basis by each food business or through guides to good practice.

“Prerequisite food hygiene requirements” include those requirements mentioned in Chapters I through XII of Annex II of Regulation (EC) No 852/2004 and in Annex II and Annex III of Regulation (EC) No 853/2004.

³ OJ L 31, 1.2.2002, p.1

A “*food safety control system*” is a control system operated by the food business operator and based on HACCP principles, on guides to good practice and/or prerequisite food hygiene requirements.

Article 3

General principles for the application of the HACCP system

Without prejudice to Article 4, when putting in place, implementing and maintaining the permanent procedure referred to in Article 5, paragraph 1 of Regulation (EC) No 852/2004, the guidelines set out in Annex I shall be followed.

Article 4

Entry into force

This Regulation shall enter into force on the 20th day after that of its publication in the *Official Journal of the European Union*.

It shall apply no earlier than 1 January 2006.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, [...]

For the Commission

[...]

Member of the Commission

Green = copied from Codex Alinorm 03/13A Appendix II (at step 8 of the procedure) pages 48-56

Blue = copied from Codex document CAC/RCP 1 -1969 (Rev. 3 – 1997) annex pages 21-30

Red = copied from the annex of Commission Decision 94/356/EC (OJ L 156, 23.6.94, p. 50)

**HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEM AND
GUIDELINES FOR ITS APPLICATION**

Introduction

These guidelines are meant for those food business operators that wish to implement a HACCP programme. Information on alternative programmes, providing details on other ways to produce food in a hygienic manner (such as guides to good practice and prerequisite hygiene requirements) are not covered in this annex.

General principles

The HACCP system, which 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. In addition, the application of HACCP systems 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 sector of the food chain, that sector should have implemented the prerequisite food hygiene requirements. Management commitment is necessary for implementation of an effective HACCP system. During hazard identification, evaluation, and subsequent operations in designing and applying HACCP systems, 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 the HACCP system is to focus control at critical control points (CCP's). Redesign of the operation should be considered if a hazard which must be controlled is identified but no CCP's are found. 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.

The HACCP system 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

This team, which involves all parts of the enterprise 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:

- a quality assurance specialist who understands the biological, chemical or physical hazards connected with a particular product group, .
- a production specialist who has responsibility for, or is closely involved with, the technical process of manufacturing the product under study,
- a technician who has a working knowledge of the hygiene and operation of the process plant and equipment,

- any other person with specialist knowledge of microbiology, hygiene and 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 own-checks system developed is reliable. Where expertise is not available in the establishment, advice should be obtained from other sources (consultancy, guides of good manufacturing practices, etc.).

The scope of the HACCP plan should be identified. The scope should describe which segment of the food chain is involved and the general classes of hazards to be addressed e.g. does it cover all classes of hazards (biological, chemical and physical) or only selected classes.

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, Aw, 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. “sell by date” and “best before date”),
- instructions for use,
- any microbiological or chemical criteria applicable.

1.3. Identification of intended use

The multidisciplinary 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 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),
- 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 multidisciplinary 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, wherever possible the following should be included:

- 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, other undesirable products of microbial metabolism, chemicals or physical agents;
- 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. For instance, pasteurization or controlled heat treatment may provide sufficient assurance of reduction of the level of both *Salmonella* 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

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 and requires common sense, 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 points has two consequences for the multidisciplinary team which should then:

- (1) 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,
- (2) establish and implement a monitoring and checking system at each critical point.

3. CRITICAL LIMITS AT CRITICAL CONTROL POINTS

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

Those 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 readily demonstrate that the critical point is under control ; they should be based on substantiated evidence that chosen values will result in process control.

Examples of such parameters include temperature, time, pH, moisture level, 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 (e.g. frozen storage temperature) or from existing and validated guides of good manufacturing practices, the team should ascertain their validity relative to the control of identified hazard and critical points.

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. The program should describe the methods, the frequency of observations or measurements and the recording procedure.

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 discontinuously. When observations or measurements are not continuous, it is necessary to establish a frequency of observations or measurements which provides reliable information.

The program of observations or measurements should properly identify for each critical point:

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

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

5. CORRECTIVE ACTIONS

Observations or measurements may indicate:

1. that the parameter monitored tends to deviate from its specified critical limits, indicating a trend toward loss of control. Appropriate corrective action to maintain control must be taken before the occurrence of hazard,

2. that the parameter monitored has deviated from its specified critical limits, indicating a loss of control. It is necessary to take appropriate corrective action to regain control.

Corrective action has to be planned in advance by the multidisciplinary team, for each critical point, so that it can be taken without hesitation when a deviation is observed.

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).
3. 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 measures for the same procedure have to be taken repeatedly.

6. VERIFICATION PROCEDURES

- 6.1. The multidisciplinary team should specify the methods and procedures to be used for **determining if the HACCP system 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 the HACCP system 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 accurateness of the employees, the number of deviations detected over time and the hazards involved.

Verification procedures may include:

- audits of the HACCP system 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. 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.

Documentation examples are:

- Hazard analysis;
- CCP determination;

- Critical limit determination;
- Modifications to the HACCP system.

Record examples are:

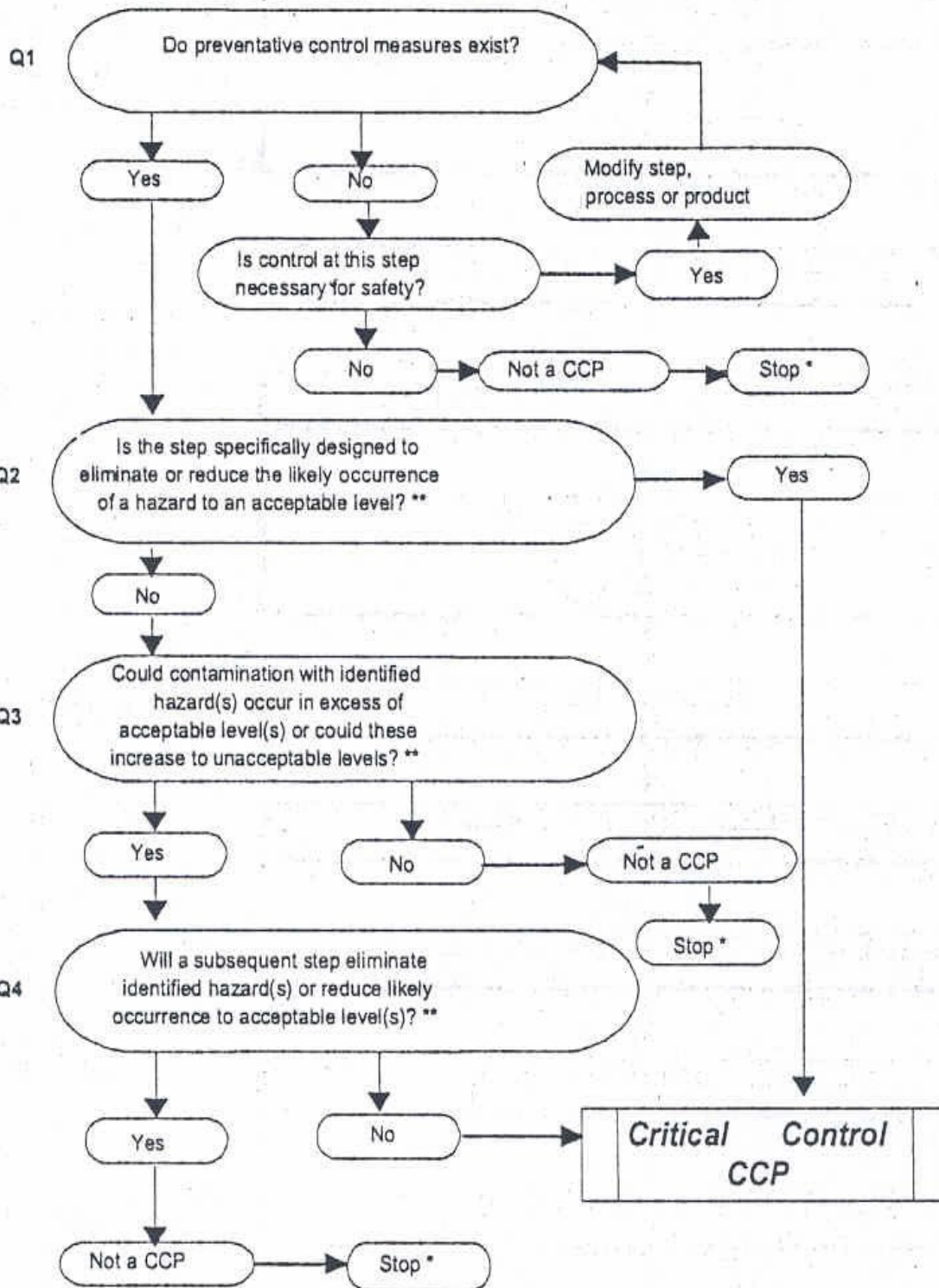
- CCP monitoring activities;
- Deviations and associated corrective actions;
- Verification activities.

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 develop 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.



* 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