COMMISSION

COMMISSION DECISION

of 20 May 1994

laying down detailed rules for the application of Council Directive 91/493/EEC, as regards own health checks on fishery products

(Text with EEA relevance)

(94/356/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and the placing on the market of fishery products [1], and in particular Article 6 (3) thereof,

Whereas, in accordance with Article 6 (3) of the said Directive, rules must be laid down for the application of the principles on which own-checks are based; whereas it is necessary to define what is meant by the identification of critical points and the establishment and implementation of methods for monitoring and checking such critical points;

Whereas laboratories must be approved by the competent authorities on equivalent terms in all the Member States;

Whereas keeping a written record or a record otherwise registered must entail keeping complete documentation containing all information relating to the establishment of own-checks and the results of those checks;

Whereas the design and introduction of own-checks will differ from one establishment to another; whereas it is therefore necessary to propose, in the form of guidelines, a model of a logical approach intended to facilitate the uniform application of Article 6 (1) of Directive 91/493/EEC;

Whereas the measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION:

Article 1

1. 'Own-checks' as referred to in the second subparagraph of Article 6 (1) of Directive 91/493/EEC means all those actions aimed at ensuring and demonstrating that a fishery product satisfies the requirements of that Directive. Those actions must correspond to an approach internal to the establishment; they must be developed and implemented by the persons responsible for each production unit, or under their management, in accordance with the general principles set out in the Annex hereto.

2. As part of the internal approach referred to in paragraph 1, establishments may use guides of good manufacturing practice drawn up by appropriate professional organizations and acceptable to the competent authorities.

3. The persons responsible for the establishment must ensure that all staff concerned by own-checks receive adequate training in order to effectively participate in their implementation.

Article 2

1. 'Critical point' as referred to in the first indent of the second subparagraph of Article 6 (1) of Directive 91/493/EEC means any point, step or procedure at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to acceptable levels. All

[1] OJ No L 268, 24. 9. 1991, p. 15.

critical points which are useful for ensuring compliance with the hygiene requirements of that Directive must be identified.

For the purpose of identifying these critical points, Chapter I of the Annex hereto shall apply.

2. The critical points are specific to each establishment depending on the raw materials it uses and on its manufacturing processes, structures and equipment, end products and marketing system.

Article 3

'Monitoring and checking such critical points' as referred to in the second indent of the second subparagraph of Article 6 (1) of Directive 91/493/EEC includes all those set observations and/or measurements necessary to ensure that critical points are kept under control. Monitoring and checking critical points does not include verifying that end products conform with the standards laid down in Directive 91/493/EEC.

For the purpose of introducing and implementing monitoring and checking, Chapter II of the Annex hereto shall apply.

Article 4

1. Sampling for laboratory analysis as referred to in the third indent of the second subparagraph of Article 6 (1) of Directive 91/493/EEC is intended to confirm that the own-checks system complies effectively with Articles 1, 2 and 3 of this Decision.

2. The persons responsible for the establishment must make provision for a sampling programme which, though not concerning systematically every production batch, nevertheless allows :

(a) validation of the own-checks system when first set up ;

(b) if necessary, revalidation of the system in case of a change to the characteristics of the product or to the manufacturing process ;

(c) verification, at specified intervals, that all provisions are still appropriate and properly applied.

3. Own-checks system shall be confirmed in accordance with the provisions set out in Chapter III of the Annex.

Article 5

For the approval of laboratories mentioned in the third indent of the second subparagraph of Article 6 (1) of Directive 91/493/EEC, the competent authorities of the Member States shall take into account the requirements of EN 45 001 standards or equivalent requirements. However, for the approval of establishments' internal laboratories, the competent authorities may base themselves on less restrictive principles inspired by the relevent points in Annex B to Council Directive 88/320/EEC [1].

Article 6

1. In order to keep 'a written record or a record registered in an indelible fashion', as referred to in the fourth indent of the second subparagraph of Article 6 (1) of Directive 91/493/EEC, the persons responsible for the establishment must document all information relating to the implementation of own-checks and their verification.

2. The documentation referred to in paragraph 1 must include two types of information to be kept for submission to the competent authority :

(a) a detailed and comprehensive document including :

— description of the product,

— description of the manufacturing process indicating critical points,

— for each critical point, identified hazards, assessment of risks and control measures,

— procedures for monitoring and checking at each such critical point, with indication of critical limits for parameters that need to be controlled and corrective action to be taken in case of loss of control,

— procedures for verification and review.

In the case provided for in Article 1 (2), this document may be the guide of good practice drawn up by the professional organization concerned.

(b) records of the observations and/or measurements referred to in Article 3, results of the verification activities referred to in Article 4, reports and written accounts of decisions relating to corrective action when taken. An appropriate document management system must provide, in particular, for the easy retrieval of all documents relating to an identified production batch.

Article 7

The competent authorities shall ensure appropriate training of inspection staff authorized to perform official

[1] OJ No L 145, 11. 6. 1988, p. 35.

checks to allow them to assess the own-checks system set up by the persons responsible for the establishment on the basis of the documents submitted.

Article 8

Member States shall inform the Commission of any difficulties in the application of this Decision which will be reviewed one year following its adoption, in the light of experience acquired.

Article 9

This Decision is addressed to the Member States.

Done at Brussels, 20 May 1994.

For the Commission

René STEICHEN

Member of the Commission

ANNEX

GENERAL PRINCIPLES

It is recommended that a model of a logical approach be followed, of which the following principles form the essential components:

— identification of hazards, analysis of risks and determination of measures necessary to control them,

— identification of critical points,

— establishment of critical limits for each critical point,

— establishment of monitoring and checking procedures,

— establishment of corrective action to be taken when necessary,

— establishment of verification and review procedures,

— establishment of documentation concerning all procedures and records.

Such a model, or the principles on which it is based, should be used with the flexibility appropriate to each situation.

CHAPTER I

IDENTIFICATION OF CRITICAL POINTS

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

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.

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 consist of:

— a quality control 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 fulfil 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.).

2. **Description of the product**

The end product should be described in terms of:

— 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.

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, travellers, etc. and for vulnerable groups of the population may have to be considered.

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 disinfectrion procedures,

— hygienic environment of the establishment,

— personnel routes and hygiene practices,

— product storage and distribution conditions.

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.

6. **Listing of hazards and control measures**

Using the confirmed flow diagram as a guide, the team should :

(a) 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).

A hazard is a potential to cause harm to health and is anything covered by the hygiene objectives of Directive 91/493/EEC. Specifically, it can be any of the following :

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

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

— unacceptable production or persistence of toxins or other undesirable products of microbial metabolism.

For inclusion in the list, hazards must be of a nature such that their elimination or reduction to acceptable levels is essential to the to the production of safe food.

(b) 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 on additives and in particular Directive 89/107/EEC (1).

7. Methods for identification of criticla points

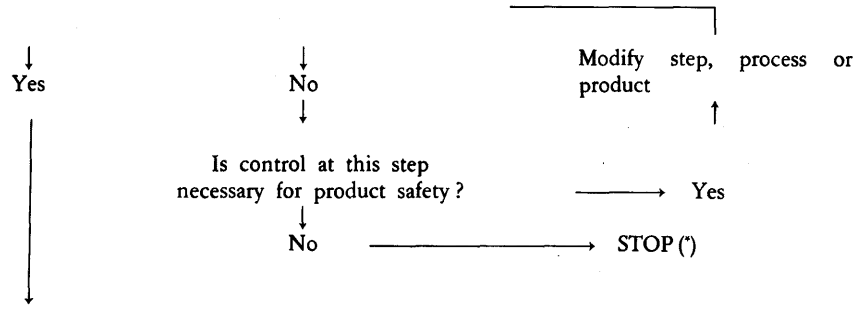
The identification of a critical point for the control of a hazard requires a logical approach. Such an approach can be facilitated by the use of the following decision tree (other methods can be used by the team, according to their knowledge and experience).

Decision tree for the identification of critical points

Answer each question in sequence, at each step and for each identified hazard.

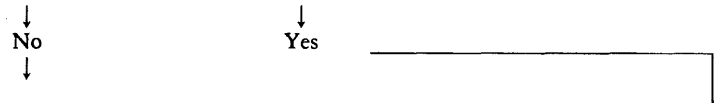
Question 1

Are control measures in place for the hazard?



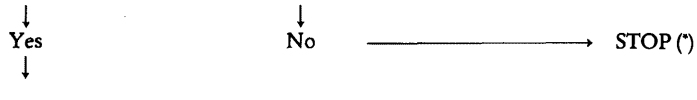
Question 2

Does that step eliminate or reduce the hazard to an acceptable level?



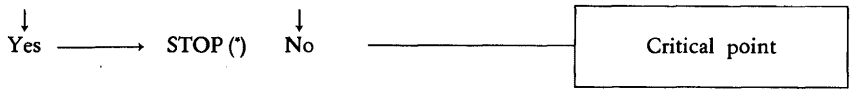
Question 3

Could contamination occur at, or hazard increase to, an unacceptable level?



Question 4

Will a subsequent step eliminate or reduce the hazard to an acceptable level?



(*) The step is not a critical point. Proceed to next step.

(1) OJ No L 40, 11. 2. 1989, p. 27.

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.

8. **Action to be taken following identification of a critical point**

The identification of critical points has two consequences for the multidisciplinary 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 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 and checking system at each critical point.

CHAPTER II :

ESTABLISHMENT AND IMPLEMENTATION OF MONITORING AND CHECKING CRITICAL POINTS

An appropriate monitoring and checking system is essential to ensure the effective control of each critical point.

To develop such a system, it is recommended to proceed to the following activities :

1. **Establishment of critical limits for each control measure associated with each critical point**

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, ect.

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 manufactoring practices, the team should ascertain their validity relative to the control of identified hazard and critical points.

2. **Establishment of a monitoring and checking system for each critical point**

An essential part of own-checks is a programme of observations or measurements performed at each critical point to ensure compliance with specified critical limits. The programme 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.

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 programme 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.

3. **Establishment of a corrective action plan**

Observations or measurements may indicate :

— 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 occurence of hazard,

— 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.

CHAPTER III :

VERIFICATION OF OWN-CHECKS SYSTEMS

Own-checks system verification is necessary to ensure that they are working effectively. The multidisciplinary team should specify the methods and procedures to be used.

Usable methods 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.

Verification procedures may include : inspection of operations, validation of critical limits, review of deviations, corrective action and measures taken with regard to the product, audits of the own-check system and its records.

Verification should provide for confirmation of the suitability of the own-checks system established and ensure, afterwards, with an appropriate frequency, that the provisions laid down are still being properly applied.

In addition, it is necessary to review the system, to ensure that it is (or will be) still valid in case of change.

Examples of change include :

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

— change in packaging, storage or distribution conditions,

— change in consumer use,

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

Where necessary, such a review must result in the amendment of the provisions laid down.

Any change to the own-checks system arising should be fully incorporated into the documentation and record-keeping system in order to ensure that accurate up-to-date information is available.

Where criteria are specified in regulations, such criteria are to be used as reference values for the verification process.