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(Acts whose publication is obligatory)

COMMISSION REGULATION (EC) No 2073/2005

of 15 November 2005

on microbiological criteria for foodstuffs

(Text with EEA relevance)

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 of 29 April 2004 on the hygiene of foodstuffs [1], and in particular Articles 4(4) and 12 thereof,

Whereas:

(1) A high level of protection of public health is one of the fundamental objectives of food law, as laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2]. Microbiological hazards in foodstuffs form a major source of food-borne diseases in humans.

(2) Foodstuffs should not contain micro-organisms or their toxins or metabolites in quantities that present an unacceptable risk for human health.

(3) Regulation (EC) No 178/2002 lays down general food safety requirements, according to which food must not be placed on the market if it is unsafe. Food business operators have an obligation to withdraw unsafe food from the market. In order to contribute to the protection of public health and to prevent differing interpretations, it is appropriate to establish harmonised safety criteria on the acceptability of food, in particular as regards the presence of certain pathogenic micro-organisms.

(4) Microbiological criteria also give guidance on the acceptability of foodstuffs and their manufacturing, handling and distribution processes. The use of microbiological criteria should form an integral part of the implementation of HACCP-based procedures and other hygiene control measures.

(5) The safety of foodstuffs is mainly ensured by a preventive approach, such as implementation of good hygiene practice and application of procedures based on hazard analysis and critical control point (HACCP) principles. Microbiological criteria can be used in validation and verification of HACCP procedures and other hygiene control measures. It is therefore appropriate to set microbiological criteria defining the acceptability of the processes, and also food safety microbiological criteria setting a limit above which a foodstuff should be considered unacceptably contaminated with the micro-organisms for which the criteria are set.

(6) According to Article 4 of Regulation (EC) No 852/2004, food business operators are to comply with microbiological criteria. This should include testing against the values set for the criteria through the taking of samples, the conduct of analyses and the implementation of corrective actions, in accordance with food law and the instructions given by the competent authority. It is therefore appropriate to lay down implementing measures concerning the analytical methods, including, where necessary, the measurement uncertainty, the sampling plan, the microbiological limits, the number of analytical units that should comply with these limits. Furthermore, it is appropriate to lay down implementing measures concerning the foodstuff to which the criterion applies, the points of the food chain where the criterion applies, as well as the actions to be taken when the criterion is not met. The measures to be taken by the food business operators in order to ensure compliance with criteria defining the acceptability of a process may include, among other things, controls of raw materials, hygiene, temperature and shelf-life of the product.

[1] OJ L 139, 30.4.2004, p. 1, corrected by OJ L 226, 25.6.2004, p. 3.

[2] OJ L 31, 1.2.2002, p. 1. Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

(7) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules [1] requires the Member States to ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency. Those controls should take place at appropriate stages of the production, processing and distribution of food to ensure that the criteria laid down in this Regulation are complied with by food business operators.

(8) The Communication from the Commission on the Community Strategy for setting microbiological criteria for foodstuffs [2] describes the strategy to lay down and revise the criteria in Community legislation, as well as the principles for the development and application of the criteria. This strategy should be applied when microbiological criteria are laid down.

(9) The Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) issued an opinion on 23 September 1999 on the evaluation of microbiological criteria for food products of animal origin for human consumption. It highlighted the relevance of basing microbiological criteria on formal risk assessment and internationally approved principles. The opinion recommends that microbiological criteria should be relevant and effective in relation to consumer health protection. The SCVPH proposed, while awaiting formal risk assessments, certain revised criteria as interim measures.

(10) The SCVPH issued at the same time a separate opinion on *Listeria monocytogenes*. That opinion recommended that it be an objective to keep the concentration of *Listeria monocytogenes* in food below 100 cfu/g. The Scientific Committee on Food (SCF) agreed with these recommendations in its opinion of 22 June 2000.

(11) The SCVPH adopted an opinion on *Vibrio vulnificus* and *Vibrio parahaemolyticus* on 19 and 20 September 2001. It concluded that currently available scientific data do not support setting specific criteria for pathogenic *V. vulnificus* and *parahaemolyticus* in seafood. However, it recommended that codes of practice should be established to ensure that good hygiene practice has been applied.

(12) The SCVPH issued an opinion on Norwalk-like viruses (NLVs, noroviruses) on 30-31 January 2002. In that opinion it concluded that the conventional faecal indicators are unreliable for demonstrating the presence or absence of NLVs and that the reliance on faecal bacterial indicator removal for determining shellfish purification times is unsafe practice. It also recommended using *E. coli* rather than faecal coliforms to indicate faecal contamination in shellfish harvesting areas, when applying bacterial indicators.

(13) On 27 February 2002 the SCF adopted an opinion on specifications for gelatine in terms of consumer health. It concluded that the microbiological criteria set in Chapter 4 of Annex II to Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A(I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC [3] in terms of consumer health were excessive, and considered it sufficient to apply a mandatory microbiological criterion for salmonella only.

(14) The SCVPH issued an opinion on verotoxigenic *E. coli* (VTEC) in foodstuffs on 21 and 22 January 2003. In its opinion it concluded that applying an end-product microbiological standard for VTEC O157 is unlikely to deliver meaningful reductions in the associated risk for the consumers. However, microbiological guidelines aimed at reducing the faecal contamination along the food chain can contribute to a reduction in public health risks, including VTEC. The SCVPH identified the following food categories where VTEC represents a hazard to public health: raw or undercooked beef and possibly meat from other ruminants, minced meat and fermented beef and products thereof, raw milk and raw milk products, fresh produce, in particular sprouted seeds, and unpasteurised fruit and vegetable juices.

(15) On 26 and 27 March 2003 the SCVPH adopted an opinion on staphylococcal enterotoxins in milk products, particularly in cheeses. It recommended revising the criteria for coagulase-positive staphylococci in cheeses, in raw milk intended for processing and in powdered milk. In addition, criteria for staphylococcal enterotoxins should be laid down for cheeses and powdered milk.

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(1) OJ L 165, 30.4.2004, p. 1, corrected by OJ L 191, 28.5.2004, p. 1.

(2) SANCO/1252/2001 Discussion paper on strategy for setting microbiological criteria for foodstuffs in Community legislation, p. 34.

(3) OJ L 62, 15.3.1993, p. 49. Directive as last amended by Commission Regulation (EC) No 445/2004 (OJ L 72, 11.3.2004, p. 60).

(16) The SCVPH adopted an opinion on salmonellae in foodstuffs on 14 and 15 April 2003. According to the opinion, food categories possibly posing a high risk to public health include raw meat and some products intended to be eaten raw, raw and undercooked products of poultry meat, eggs and products containing raw eggs, unpasteurised milk and some products thereof. Sprouted seeds and unpasteurised fruit juices are also of concern. It recommended that the decision on the need for microbiological criteria should be taken on the basis of its ability to protect the consumers and its feasibility.

(17) The Scientific Panel on Biological Hazards (BIOHAZ Panel) of the European Food Safety Authority (EFSA) issued an opinion on the microbiological risks in infant formulae and follow-on formulae on 9 September 2004. It concluded that *Salmonella* and *Enterobacter sakazakii* are the micro-organisms of greatest concern in infant formulae, formulae for special medical purposes and follow-on formulae. The presence of these pathogens constitutes a considerable risk if conditions after reconstitution permit multiplication. Enterobacteriaceae, which are more often present, could be used as an indicator for risk. Monitoring and testing of Enterobacteriaceae was recommended in both the manufacturing environment and the finished product by the EFSA. However, besides pathogenic species the family Enterobacteriaceae includes also environmental species, which often appear in the food manufacturing environment without posing any health hazard. Therefore, the family Enterobacteriaceae can be used for routine monitoring, and if they are present testing of specific pathogens can be started.

(18) International guidelines for microbiological criteria in respect of many foodstuffs have not yet been established. However, the Commission has followed the Codex Alimentarius guideline 'Principles for the establishment and application of microbiological criteria for foods CAC/GL 21 — 1997' and in addition, the advice of the SCVPH and the SCF in laying down microbiological criteria. Existing Codex specifications in respect of dried milk products, foods for infants and children and the histamine criterion for certain fish and fishery products have been taken account. The adoption of Community criteria should benefit trade by providing harmonised microbiological requirements for foodstuffs and replacing national criteria.

(19) The microbiological criteria set for certain categories of food of animal origin in Directives that were repealed by Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC ([1]) should be revised and certain new criteria set in the light of the scientific advice.

(20) The microbiological criteria laid down in Commission Decision 93/51 EEC of 15 December 1992 on the microbiological criteria applicable to the production of cooked crustaceans and molluscan shellfish ([2]) are incorporated in this Regulation. It is therefore appropriate to repeal that Decision. Since Commission Decision 2001/471/EC of 8 June 2001 laying down rules for the regular checks on the general hygiene carried out by the operators in establishments according to Directive 64/433/EEC on health conditions for the production and marketing of fresh meat and Directive 71/118/EEC on health problems affecting the production and placing on the market of fresh poultrymeat ([3]) is repealed with effect from the 1 January 2006, it is appropriate to incorporate microbiological criteria set for carcases in this Regulation.

(21) The producer or manufacturer of a food product has to decide whether the product is ready to be consumed as such, without the need to cook or otherwise process it in order to ensure its safety and compliance with the microbiological criteria. According to Article 3 of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs ([4]), the instructions for use of a foodstuff are compulsory on the labelling when it would be impossible to make appropriate use of the foodstuff in the absence of such instructions. Such instructions should be taken into account by food business operators when deciding appropriate sampling frequencies for the testing against microbiological criteria.

(22) Sampling of the production and processing environment can be a useful tool to identify and prevent the presence of pathogenic micro-organisms in foodstuffs.

(23) Food business operators should decide themselves the necessary sampling and testing frequencies as part of their procedures based on HACCP principles and other hygiene control procedures. However, it may be necessary in certain cases to set harmonised sampling frequencies at Community level, particularly in order to ensure the same level of controls to be performed throughout the Community.

([1]) OJ L 157, 30.4.2004, p. 33, corrected by OJ L 195, 2.6.2004, p. 12.

([2]) OJ L 13, 21.1.1993, p. 11.

([3]) OJ L 165, 21.6.2001, p. 48. Decision as amended by Decision 2004/379/EC (OJ L 144, 30.4.2004, p. 1).

([4]) OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15).

(24) Test results are dependent on the analytical method used, and therefore a given reference method should be associated with each microbiological criterion. However, food business operators should have the possibility to use analytical methods other than the reference methods, in particular more rapid methods, as long as the use of these alternative methods provides equivalent results. Moreover, a sampling plan needs to be defined for each criterion in order to ensure harmonised implementation. It is nevertheless necessary to allow the use of other sampling and testing schemes, including the use of alternative indicator organisms, on condition that these schemes provide equivalent guarantees of food safety.

(25) Trends in test results should be analysed, as they are able to reveal unwanted developments in the manufacturing process enabling the food business operator to take corrective actions before the process is out of control.

(26) The microbiological criteria set in this Regulation should be open to review and revised or supplemented, if appropriate, in order to take into account developments in the field of food safety and food microbiology. This includes progress in science, technology and methodology, changes in prevalence and contamination levels, changes in the population of vulnerable consumers, as well as the possible outputs from risk assessments.

(27) In particular, criteria for pathogenic viruses in live bivalve molluscs should be established when the analytical methods are developed sufficiently. There is a need for development of reliable methods for other microbial hazards too, e.g. *Vibrio parahaemolyticus*.

(28) It has been demonstrated that the implementation of control programmes can markedly contribute to a reduction of the prevalence of salmonella in production animals and products thereof. The purpose of Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents ([1]) is to ensure that proper and effective measures are taken to control salmonella at relevant stages of the food chain. Criteria for meat and products thereof should take into account the expected improvement in the salmonella situation at the level of primary production.

(29) For certain food safety criteria, it is appropriate to grant the Member States a transitional derogation, enabling them to comply with less stringent criteria but provided that the foodstuffs would only be marketed on the national market. The Member States should notify the Commission and other Member States where this transitional derogation is used.

(30) 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:

Article 1

Subject-matter and scope

This Regulation lays down the microbiological criteria for certain micro-organisms and the implementing rules to be complied with by food business operators when implementing the general and specific hygiene measures referred to in Article 4 of Regulation (EC) No 852/2004. The competent authority shall verify compliance with the rules and criteria laid down in this Regulation in accordance with Regulation (EC) No 882/2004, without prejudice to its right to undertake further sampling and analyses for the purpose of detecting and measuring other micro-organisms, their toxins or metabolites, either as a verification of processes, for food suspected of being unsafe, or in the context of a risk analysis.

This Regulation shall apply without prejudice to other specific rules for the control of micro-organisms laid down in Community legislation and in particular the health standards for foodstuffs laid down in Regulation (EC) No 853/2004 of the European Parliament and of the Council ([2]), the rules on parasites laid down under Regulation (EC) No 854/2004 of the European Parliament and of the Council ([3]) and the microbiological criteria laid down under Council Directive 80/777/EEC ([4]).

Article 2

Definitions

The following definitions shall apply:

(a) 'micro-organisms' means bacteria, viruses, yeasts, moulds, algae, parasitic protozoa, microscopic parasitic helminths, and their toxins and metabolites;

(b) 'microbiological criterion' means a criterion defining the acceptability of a product, a batch of foodstuffs or a process, based on the absence, presence or number of micro-organisms, and/or on the quantity of their toxins/metabolites, per unit(s) of mass, volume, area or batch;

([1]) OJ L 325, 12.12.2003, p. 1.

([2]) OJ L 139, 30.4.2004, p. 55, corrected by OJ L 226, 25.6.2004, p. 22.

([3]) OJ L 139, 30.4.2004, p. 206, corrected by OJ L 226, 25.6.2004, p. 83.

([4]) OJ L 229, 30.8.1980, p. 1.

(c) 'food safety criterion' means a criterion defining the acceptability of a product or a batch of foodstuff applicable to products placed on the market;

(d) 'process hygiene criterion' a criterion indicating the acceptable functioning of the production process. Such a criterion is not applicable to products placed on the market. It sets an indicative contamination value above which corrective actions are required in order to maintain the hygiene of the process in compliance with food law;

(e) 'batch' means a group or set of identifiable products obtained from a given process under practically identical circumstances and produced in a given place within one defined production period;

(f) 'shelf-life' means either the period corresponding to the period preceding the 'use by' or the minimum durability date, as defined respectively in Articles 9 and 10 of Directive 2000/13/EC;

(g) 'ready-to-eat food' means food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing effective to eliminate or reduce to an acceptable level micro-organisms of concern;

(h) 'food intended for infants' means food specifically intended for infants, as defined in Commission Directive 91/321/EEC ([1]);

(i) 'food intended for special medical purposes' means dietary food for special medical purposes, as defined in Commission Directive 1999/21/EC ([2]);

(j) 'sample' means a set composed of one or several units or a portion of matter selected by different means in a population or in an important quantity of matter, which is intended to provide information on a given characteristic of the studied population or matter and to provide a basis for a decision concerning the population or matter in question or concerning the process which has produced it;

(k) 'representative sample' means a sample in which the characteristics of the batch from which it is drawn are maintained. This is in particular the case of a simple random sample where each of the items or increments of the batch has been given the same probability of entering the sample;

(l) 'compliance with microbiological criteria' means obtaining satisfactory or acceptable results set in Annex I when testing against the values set for the criteria through the taking of samples, the conduct of analyses and the implementation of corrective action, in accordance with food law and the instructions given by the competent authority.

Article 3

General requirements

1. Food business operators shall ensure that foodstuffs comply with the relevant microbiological criteria set out in Annex I. To this end the food business operators at each stage of food production, processing and distribution, including retail, shall take measures, as part of their procedures based on HACCP principles together with the implementation of good hygiene practice, to ensure the following:

(a) that the supply, handling and processing of raw materials and foodstuffs under their control are carried out in such a way that the process hygiene criteria are met,

(b) that the food safety criteria applicable throughout the shelf-life of the products can be met under reasonably foreseeable conditions of distribution, storage and use.

2. As necessary, the food business operators responsible for the manufacture of the product shall conduct studies in accordance with Annex II in order to investigate compliance with the criteria throughout the shelf-life. In particular, this applies to ready-to-eat foods that are able to support the growth of *Listeria monocytogenes* and that may pose a *Listeria monocytogenes* risk for public health.

Food businesses may collaborate in conducting those studies.

Guidelines for conducting those studies may be included in the guides to good practice referred to in Article 7 of Regulation (EC) No 852/2004.

Article 4

Testing against criteria

1. Food business operators shall perform testing as appropriate against the microbiological criteria set out in Annex I, when they are validating or verifying the correct functioning of their procedures based on HACCP principles and good hygiene practice.

2. Food business operators shall decide the appropriate sampling frequencies, except where Annex I provides for specific sampling frequencies, in which case the sampling frequency shall be at least that provided for in Annex I. Food business operators shall make this decision in the context of their procedures based on HACCP principles and good

([1]) OJ L 175, 4.7.1991, p. 35.

([2]) OJ L 91, 7.4.1999, p. 29.

hygiene practice, taking into account the instructions for use of the foodstuff.

The frequency of sampling may be adapted to the nature and size of the food businesses, provided that the safety of foodstuffs will not be endangered.

Article 5

Specific rules for testing and sampling

1. The analytical methods and the sampling plans and methods in Annex I shall be applied as reference methods.

2. Samples shall be taken from processing areas and equipment used in food production, when such sampling is necessary for ensuring that the criteria are met. In that sampling the ISO standard 18593 shall be used as a reference method.

Food business operators manufacturing ready-to-eat foods, which may pose a *Listeria monocytogenes* risk for public health, shall sample the processing areas and equipment for *Listeria monocytogenes* as part of their sampling scheme.

Food business operators manufacturing dried infant formulae or dried foods for special medical purposes intended for infants below six months which pose an *Enterobacter sakazakii* risk shall monitor the processing areas and equipment for Enterobacteriaceae as part of their sampling scheme.

3. The number of sample units of the sampling plans set out in Annex I may be reduced if the food business operator can demonstrate by historical documentation that he has effective HACCP-based procedures.

4. If the aim of the testing is to specifically assess the acceptability of a certain batch of foodstuffs or a process, the sampling plans set out in Annex I shall be respected as a minimum.

5. Food business operators may use other sampling and testing procedures, if they can demonstrate to the satisfaction of the competent authority that these procedures provide at least equivalent guarantees. Those procedures may include use of alternative sampling sites and use of trend analyses.

Testing against alternative micro-organisms and related microbiological limits as well as testing of analytes other than microbiological ones shall be allowed only for process hygiene criteria.

The use of alternative analytical methods is acceptable when the methods are validated against the reference method in Annex I and if a proprietary method, certified by a third party in accordance with the protocol set out in EN/ISO standard 16140 or other internationally accepted similar protocols, is used.

If the food business operator wishes to use analytical methods other than those validated and certified as described in paragraph 3 the methods shall be validated according to internationally accepted protocols and their use authorised by the competent authority.

Article 6

Labelling requirements

1. When the requirements for *Salmonella* in minced meat, meat preparations and meat products intended to be eaten cooked of all species set down in Annex I are fulfilled, the batches of those products placed on the market must be clearly labelled by the manufacturer in order to inform the consumer of the need for thorough cooking prior to consumption.

2. As from 1 January 2010 labelling as referred to in paragraph 1 in respect of minced meat, meat preparations and meat products made from poultrymeat will no longer be required.

Article 7

Unsatisfactory results

1. When the results of testing against the criteria set out in Annex I are unsatisfactory, the food business operators shall take the measures laid down in paragraphs 2 to 4 of this Article together with other corrective actions defined in their HACCP-based procedures and other actions necessary to protect the health of consumers.

In addition, they shall take measures to find the cause of the unsatisfactory results in order to prevent the recurrence of the unacceptable microbiological contamination. Those measures may include modifications to the HACCP-based procedures or other food hygiene control measures in place.

2. When testing against food safety criteria set out in Chapter 1 of Annex I provides unsatisfactory results, the product or batch of foodstuffs shall be withdrawn or recalled in accordance with Article 19 of Regulation (EC) No 178/2002. However, products placed on the market, which are not yet at retail level and which do not fulfil the food safety criteria, may be submitted to further processing by a treatment eliminating the hazard in question. This treatment may only be carried out by food business operators other than those at retail level.

The food business operator may use the batch for purposes other than those for which it was originally intended, provided that this use does not pose a risk for public or animal health and provided that this use has been decided within the procedures based on HACCP principles and good hygiene practice and authorised by the competent authority.

3. A batch of mechanically separated meat (MSM) produced with the techniques referred to in Chapter III, paragraph 3, in Section V of Annex III to Regulation (EC) No 853/2004, with unsatisfactory results in respect of the *Salmonella* criterion, may be used in the food chain only to manufacture heat-treated meat products in establishments approved in accordance with Regulation (EC) No 853/2004.

4. In the event of unsatisfactory results as regards process hygiene criteria the actions laid down in Annex I, Chapter 2 shall be taken.

Article 8

Transitional derogation

1. A transitional derogation is granted until 31 December 2009 at the latest pursuant to Article 12 of Regulation (EC) No 852/2004 as regards compliance with the value set in Annex I to this Regulation for *Salmonella* in minced meat, meat preparations and meat products intended to be eaten cooked placed on the national market of a Member State.

2. The Member States using this possibility shall notify the Commission and other Member States thereof. The Member State shall:

(a) guarantee that the appropriate means, including labelling and a special mark, which cannot be confused with the identification mark provided for in Annex II, Section I to Regulation (EC) No 853/2004, are in place to ensure that the derogation applies only to the products concerned when placed on the domestic market, and that products dispatched for intra-Community trade comply with the criteria laid down in Annex I;

(b) provide that the products to which such transitional derogation applies shall be clearly labelled that they must be thoroughly cooked prior to consumption;

(c) undertake that when testing against the *Salmonella* criterion pursuant to Article 4, and for the result to be acceptable as regards such transitional derogation, no more than one out of five sample units shall be found to be positive.

Article 9

Analyses of trends

Food business operators shall analyse trends in the test results. When they observe a trend towards unsatisfactory results, they shall take appropriate actions without undue delay to remedy the situation in order to prevent the occurrence of microbiological risks.

Article 10

Review

This Regulation shall be reviewed taking into account progress in science, technology and methodology, emerging pathogenic micro-organisms in foodstuffs, and information from risk assessments. In particular, the criteria and conditions concerning the presence of salmonella in carcases of cattle, sheep, goats, horses, pigs and poultry shall be revised in the light of the changes observed in salmonella prevalence.

Article 11

Repeal

Decision 93/51/EEC is repealed.

Article 12

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

It shall apply from 1 January 2006.

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

Done at Brussels, 15 November 2005.

For the Commission

Markos KYPRIANOU

Member of the Commission

ANNEX I

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Chapter 1. Food safety criteria

Food category	Micro-organisms/their toxins, metabolites	Sampling-plan (1)		Limits (2)		Analytical reference method (3)	Stage where the criterion applies
		n	c	m	M		
1.1. Ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes (4)	*Listeria monocytogenes*	10	0	Absence in 25 g		EN/ISO 11290-1	Products placed on the market during their shelf-life
1.2. Ready-to-eat foods able to support the growth of *L. monocytogenes,* other than those intended for infants and for special medical purposes	*Listeria monocytogenes*	5	0	100 cfu/g (5)		EN/ISO 11290-2 (6)	Products placed on the market during their shelf-life
		5	0	Absence in 25 g (7)		EN/ISO 11290-1	Before the food has left the immediate control of the food business operator, who has produced it
1.3. Ready-to-eat foods unable to support the growth of *L. monocytogenes,* other than those intended for infants and for special medical purposes (4) (8)	*Listeria monocytogenes*	5	0	100 cfu/g		EN/ISO 11290-2 (6)	Products placed on the market during their shelf-life
1.4. Minced meat and meat preparations intended to be eaten raw	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.5. Minced meat and meat preparations made from poultry meat intended to be eaten cooked	*Salmonella*	5	0	From 1.1.2006 Absence in 10 g From 1.1.2010 Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.6. Minced meat and meat preparations made from other species than poultry intended to be eaten cooked	*Salmonella*	5	0	Absence in 10 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.7. Mechanically separated meat (MSM) (9)	*Salmonella*	5	0	Absence in 10 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.8. Meat products intended to be eaten raw, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life

Food category	Micro-organisms/their toxins, metabolites	Sampling-plan (1)		Limits (2)		Analytical reference method (3)	Stage where the criterion applies
		n	c	m	M		
1.9. Meat products made from poultry meat intended to be eaten cooked	*Salmonella*	5	0	From 1.1.2006 Absence in 10 g From 1.1.2010 Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.10. Gelatine and collagen	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.11. Cheeses, butter and cream made from raw milk or milk that has undergone a lower heat treatment than pasteurisation (10)	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.12. Milk powder and whey powder (10)	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.13. Ice cream (11), excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.14. Egg products, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	*Salmonella*	5	0	Absence in 25g		EN/ISO 6579	Products placed on the market during their shelf-life
1.15. Ready-to-eat foods containing raw egg, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	*Salmonella*	5	0	Absence in 25 g or ml		EN/ISO 6579	Products placed on the market during their shelf-life
1.16. Cooked crustaceans and molluscan shellfish	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.17. Live bivalve molluscs and live echinoderms, tunicates and gastropods	*Salmonella*	5	0	Absence in 25g		EN/ISO 6579	Products placed on the market during their shelf-life

Food category	Micro-organisms/their toxins, metabolites	Sampling-plan (1)		Limits (2)		Analytical reference method (3)	Stage where the criterion applies
		n	c	m	M		
1.18. Sprouted seeds (ready-to-eat) (12)	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.19. Pre-cut fruit and vegetables (ready-to-eat)	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.20. Unpasteurised fruit and vegetable juices (ready-to-eat)	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.21. Cheeses, milk powder and whey powder, as referred to in the coagulase-positive staphylococci criteria in Chapter 2.2 of this Annex	Staphylococcal entero-toxins	5	0	Not detected in 25g		European screening method of the CRL for Milk (13)	Products placed on the market during their shelf-life
1.22. Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age, as referred to in the Enterobacter-iaceae criterion in Chapter 2.2 of this Annex	*Salmonella*	30	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.23. Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age, as referred to in the Enterobacter-iaceae criterion in Chapter 2.2 of this Annex	*Enterobacter sakazakii*	30	0	Absence in 10 g		ISO/DTS 22964	Products placed on the market during their shelf-life
1.24. Live bivalve molluscs and live echino-derms, tunicates and gastropods	*E.coli* (14)	1 (15)	0	230 MPN/100g of flesh and intra-valvular liquid		ISO TS 16649-3	Products placed on the market during their shelf-life
1.25. Fishery products from fish species asso-ciated with a high amount of histidine (16)	Histamine	9 (17)	2	100 mg/kg	200 mg/kg	HPLC (18)	Products placed on the market during their shelf-life

Food category	Micro-organisms/their toxins, metabolites	Sampling-plan (1)		Limits (2)		Analytical reference method (3)	Stage where the criterion applies
		n	c	m	M		
1.26. Fishery products which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with a high amount of histidine (16)	Histamine	9	2	200 mg/kg	400 mg/kg	HPLC (18)	Products placed on the market during their shelf-life

(1) n = number of units comprising the sample; c = number of sample units giving values over m or between m and M.
(2) For points 1.1-1.24 m=M.
(3) The most recent edition of the standard shall be used.
(4) Regular testing against the criterion is not useful in normal circumstances for the following ready-to-eat foods:
— those which have received heat treatment or other processing effective to eliminate *L. monocytogenes*, when recontamination is not possible after this treatment (e.g. products heat treated in their final package),
— fresh, uncut and unprocessed vegetables and fruits, excluding sprouted seeds,
— bread, biscuits and similar products,
— bottled or packed waters, soft drinks, beer, cider, wine, spirits and similar products,
— sugar, honey and confectionery, including cocoa and chocolate products,
— live bivalve molluscs.
(5) This criterion applies if the manufacturer is able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit 100 cfu/g throughout the shelf-life. The operator may fix intermediate limits during the process that should be low enough to guarantee that the limit of 100 cfu/g is not exceeded at the end of the shelf-life.
(6) 1 ml of inoculum is plated on a Petri dish of 140 mm diameter or on three Petri dishes of 90 mm diameter.
(7) This criterion applies to products before they have left the immediate control of the producing food business operator, when he is not able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit of 100 cfu/g throughout the shelf-life.
(8) Products with pH ≤ 4,4 or a_w ≤ 0,92, products with pH ≤ 5,0 and a_w ≤ 0,94, products with a shelf-life of less than five days are automatically considered to belong to this category. Other categories of products can also belong to this category, subject to scientific justification.
(9) This criterion applies to mechanically separated meat (MSM) produced with the techniques referred to in Chapter III, paragraph 3, in section V of Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin.
(10) Excluding products when the manufacturer can demonstrate to the satisfaction of the competent authorities that, due to the ripening time and a_w of the product where appropriate, there is no salmonella risk.
(11) Only ice creams containing milk ingredients.
(12) Preliminary testing of the batch of seeds before starting the sprouting process or the sampling to be carried out at the stage where the highest probability of finding *Salmonella* is expected.
(13) Reference: Hennekinne et al., J. AOAC Internat. Vol. 86, No 2, 2003.
(14) *E. coli* is used here as an indicator of faecal contamination.
(15) A pooled sample comprising a minimum of 10 individual animals.
(16) Particularly fish species of the families: *Scombridae, Clupeidae, Engraulidae, Coryfenidae, Pomatomidae, Scombresosidae*.
(17) Single samples may be taken at retail level. In such a case the presumption laid down in Article 14(6) of Regulation (EC) No 178/2002, according to which the whole batch should be deemed unsafe, shall not apply.
(18) References: 1. Malle P., Valle M., Bouquelet S. Assay of biogenic amines involved in fish decomposition. J. AOAC Internat. 1996, 79, 43-49.
2. Duflos G., Dervin C., Malle P., Bouquelet S. Relevance of matrix effect in determination of biogenic amines in plaice (*Pleuronectes platessa*) and whiting (*Merlangus merlangus*). J. AOAC Internat. 1999, 82, 1097-1101.

Interpretation of the test results

The limits given refer to each sample unit tested, excluding live bivalve molluscs and live echinoderms, tunicates and gastropods in relation to testing *E. coli*, where the limit refers to a pooled sample.

The test results demonstrate the microbiological quality of the batch tested ([1]).

L. monocytogenes in ready-to-eat foods intended for infants and for special medical purposes:

— satisfactory, if all the values observed indicate the absence of the bacterium,

— unsatisfactory, if the presence of the bacterium is detected in any of the sample units.

L. monocytogenes in ready-to-eat foods able to support the growth of *L. monocytogenes* before the food has left the immediate control of the producing food business operator when he is not able to demonstrate that the product will not exceed the limit of 100 cfu/g throughout the shelf-life:

— satisfactory, if all the values observed indicate the absence of the bacterium,

— unsatisfactory, if the presence of the bacterium is detected in any of the sample units.

L. monocytogenes in other ready-to-eat foods and *E. coli* in live bivalve molluscs:

— satisfactory, if all the values observed are ≤ the limit,

— unsatisfactory, if any of the values are > the limit.

Salmonella in different food categories:

— satisfactory, if all the values observed indicate the absence of the bacterium,

— unsatisfactory, if the presence of the bacterium is detected in any of the sample units.

([1]) The test results can be used also for demonstrating the effectiveness of the HACCP or good hygiene procedure of the process.

Staphylococcal enterotoxins in dairy products:

— satisfactory, if in all the sample units the enterotoxins are not detected,

— unsatisfactory, if the enterotoxins are detected in any of the sample units.

Enterobacter sakazakii in dried infant formulae and dried dietary foods for special medical purposes intended for infants below 6 months of age:

— satisfactory, if all the values observed indicate the absence of the bacterium,

— unsatisfactory, if the presence of the bacterium is detected in any of the sample units.

Histamine in fishery products from fish species associated with a high amount of histidine:

— satisfactory, if the following requirements are fulfilled:

1. the mean value observed is ≤ m
2. a maximum of c/n values observed are between m and M
3. no values observed exceed the limit of M,

— unsatisfactory, if the mean value observed exceeds m or more than c/n values are between m and M or one or more of the values observed are >M.

Chapter 2. Process hygiene criteria

2.1. Meat and products thereof

Food category	Micro-organisms	Sampling plan (1)		Limits (2)		Analytical reference method (3)	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.1.1. Carcases of cattle, sheep, goats and horses (4)	Aerobic colony count			3,5 log cfu/cm^2 daily mean log	5,0 log cfu/cm^2 daily mean log	ISO 4833	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
	Enterobacteriaceae			1,5 log cfu/cm^2 daily mean log	2,5 log cfu/cm^2 daily mean log	ISO 21528-2	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
2.1.2. Carcases of pigs (4)	Aerobic colony count			4,0 log cfu/cm^2 daily mean log	5,0 log cfu/cm^2 daily mean log	ISO 4833	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
	Enterobacteriaceae			2,0 log cfu/cm^2 daily mean log	3,0 log cfu/cm^2 daily mean log	ISO 21528-2	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
2.1.3. Carcases of cattle, sheep, goats and horses	*Salmonella*	50 (5)	2 (6)	Absence in the area tested per carcase		EN/ISO 6579	Carcases after dressing but before chilling	Improvements in slaughter hygiene, review of process controls and of origin of animals
2.1.4. Carcases of pig	*Salmonella*	50 (5)	5 (6)	Absence in the area tested per carcase		EN/ISO 6579	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls, origin of animals and of the biosecurity measures in the farms of origin
2.1.5. Poultry carcases of broilers and turkeys	*Salmonella*	50 (5)	7 (6)	Absence in 25 g of a pooled sample of neck skin		EN/ISO 6579	Carcases after chilling	Improvements in slaughter hygiene and review of process controls, origin of animals and biosecurity measures in the farms of origin

Food category	Micro-organisms	Sampling plan (1)		Limits (2)		Analytical reference method (3)	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.1.6. Minced meat	Aerobic colony count (7)	5	2	$5x10^5$ cfu/g	$5x10^6$ cfu/g	ISO 4833	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
	E.coli (8)	5	2	50 cfu/g	500 cfu/g	ISO 16649-1 or 2	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
2.1.7. Mechanically separated meat (MSM) (9)	Aerobic colony count	5	2	$5x10^5$ cfu/g	$5x10^6$ cfu/g	ISO 4833	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
	E.coli (8)	5	2	50 cfu/g	500 cfu/g	ISO 16649-1 or 2	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
2.1.8. Meat preparations	*E.coli* (8)	5	2	500 cfu/g or cm^2	5 000 cfu/g or cm^2	ISO 16649-1 or 2	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials

(1) n = number of units comprising the sample; c = number of sample units giving values between m and M.
(2) For points 2.1.3 — 2.1.5 m=M.
(3) The most recent edition of the standard shall be used.
(4) The limits (m and M) apply only to samples taken by the destructive method. The daily mean log is calculated by first taking a log value of each individual test result and then calculating the mean of these log values.
(5) The 50 samples are derived from 10 consecutive sampling sessions in accordance with the sampling rules and frequencies laid down in this Regulation.
(6) The number of samples where the presence of salmonella is detected. The c value is subject to review in order to take into account the progress made in reducing the salmonella prevalence. Member States or regions having low salmonella prevalence may use lower c values even before the review.
(7) This criterion does not apply to minced meat produced at retail level when the shelf-life of the product is less then 24 hours.
(8) *E. coli* is used here as an indicator of faecal contamination.
(9) These criteria apply to mechanically separated meat (MSM) produced with the techniques referred to in Chapter III, paragraph 3, in section V of Annex III of Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin.

Interpretation of the test results

The limits given refer to each sample unit tested, excluding testing of carcases where the limits refer to pooled samples.

The test results demonstrate the microbiological quality of the process tested.

Enterobacteriaceae and aerobic colony count in carcases of cattle, sheep, goats, horses and pigs:

— satisfactory, if the daily mean log is < m,

— acceptable, if the daily mean log is between m and M,

— unsatisfactory, if the daily mean log is >M.

Salmonella in carcases:

— satisfactory, if the presence of *Salmonella* is detected in a maximum of c/n samples,

— unsatisfactory, if the presence of *Salmonella* is detected in more than c/n samples.

After each sampling session, the results of the last ten sampling sessions are assessed in order to obtain the n number of samples.

E. coli and aerobic colony count in minced meat, meat preparations and mechanically separated meat (MSM):

— satisfactory, if all the values observed are < m,

— acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are < m,

— unsatisfactory, if one or more of the values observed are >M or more than c/n values are between m and M.

2.2. Milk and dairy products

Food category	Micro-organisms	Sampling plan (1)		Limits (2)		Analytical reference method (3)	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.2.1. Pasteurised milk and other pasteurised liquid dairy products (4)	Enterobacteriaceae	5	2	<1 cfu/ml	5 cfu/ml	ISO 21528-1	End of the manufacturing process	Check on the efficiency of heat- treatment and prevention of recontamination as well as the quality of raw materials
2.2.2. Cheeses made from milk or whey that has undergone heat treatment	*E.coli* (5)	5	2	100 cfu/g	1 000 cfu/g	ISO 16649- 1 or 2	At the time during the manufacturing process when the *E. coli* count is expected to be highest (6)	Improvements in production hygiene and selection of raw materials
2.2.3. Cheeses made from raw milk	Coagulase-positive staphylococci	5	2	10^4 cfu/g	10^5 cfu/g	EN/ISO 6888-2	At the time during the manufacturing process when the number of staphylococci is expected to be highest	Improvements in production hygiene and selection of raw materials. If values >10^5 cfu/g are detected, the cheese batch has to be tested for staphylococcal enterotoxins.
2.2.4. Cheeses made from milk that has undergone a lower heat treatment than pasteurisation (7) and ripened cheeses made from milk or whey that has undergone pasteurisation or a stronger heat treatment (7)	Coagulase-positive staphylococci	5	2	100 cfu/g	1 000 cfu/g	EN/ISO 6888-1 or 2		
2.2.5. Unripened soft cheeses (fresh cheeses) made from milk or whey that has undergone pasteurisation or a stronger heat treatment (7)	Coagulase-positive staphylococci	5	2	10 cfu/g	100 cfu/g	EN/ISO 6888-1 or 2	End of the manufacturing process	Improvements in production hygiene. If values > 10^5 cfu/g are detected, the cheese batch has to be tested for staphylococcal enterotoxins.
2.2.6. Butter and cream made from raw milk or milk that has undergone a lower heat treatment than pasteurisation	*E.coli* (5)	5	2	10 cfu/g	100 cfu/g	ISO 16649- 1 or 2	End of the manufacturing process	Improvements in production hygiene and selection of raw materials

Food category	Micro-organisms	Sampling plan (1)		Limits (2)		Analytical reference method (3)	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.2.7. Milk powder and whey powder (4)	Enterobacteriaceae	5	0	10 cfu/g		ISO 21528- 1	End of the manufacturing process	Check on the efficiency of heat treatment and prevention of recontamination
	Coagulase-positive staphylococci	5	2	10 cfu/g	100 cfu/g	EN/ISO 6888-1 or 2	End of the manufacturing process	Improvements in production hygiene. If values > 10^5 cfu/g are detected, the batch has to be tested for staphylococcal enterotoxins.
2.2.8. Ice cream (8) and frozen dairy desserts	Enterobacteriaceae	5	2	10 cfu/g	100 cfu/g	ISO 21528- 2	End of the manufacturing process	Improvements in production hygiene
2.2.9. Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age	Enterobacteriaceae	10	0	Absence in 10 g		ISO 21528- 1	End of the manufacturing process	Improvements in production hygiene to minimise contamination. If Enterobacteriaceae are detected in any of the sample units, the batch has to be tested for *E. sakazakii* and *Salmonella*

(1) n = number of units comprising the sample; c = number of sample units giving values between m and M.
(2) For point 2.2.7 m=M.
(3) The most recent edition of the standard shall be used.
(4) The criterion does not apply to products intended for further processing in the food industry.
(5) *E. coli* is used here as an indicator for the level of hygiene.
(6) For cheeses which are not able to support the growth of *E. coli*, the *E. coli* count is usually the highest at the beginning of the ripening period, and for cheeses which are able to support the growth of *E. coli*, it is normally at the end of the ripening period.
(7) Excluding cheeses where the manufacturer can demonstrate, to the satisfaction of the competent authorities, that the product does not pose a risk of staphylococcal enterotoxins.
(8) Only ice creams containing milk ingredients.

Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.

Enterobacteriaceae in dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age:

— satisfactory, if all the values observed indicate the absence of the bacterium,

— unsatisfactory, if the presence of the bacterium is detected in any of the sample units

E. coli, enterobacteriaceae (other food categories) and coagulase-positive staphylococci:

— satisfactory, if all the values observed are < m,

— acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are < m,

— unsatisfactory, if one or more of the values observed are >M or more than c/n values are between m and M.

2.3. Egg products

Food category	Micro-organisms	Sampling plan (1)		Limits		Analytical reference method (2)	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.3.1. Egg products	Enterobacteriaceae	5	2	10 cfu/g or ml	100 cfu/g or ml	ISO 21528-2	End of the manufacturing process	Checks on the efficiency of the heat treatment and prevention of recontamination

(1) n = number of units comprising the sample; c = number of sample units giving values between m and M.
(2) The most recent edition of the standard shall be used.

Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.

Enterobacteriaceae in egg products:

— satisfactory, if all the values observed are < m,

— acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m,

— unsatisfactory, if one or more of the values observed are >M or more than c/n values are between m and M.

2.4. Fishery products

Food category	Micro-organisms	Sampling plan (1)		Limits		Analytical reference method (2)	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.4.1. Shelled and shucked products of cooked crustaceans and molluscan shellfish	*E.coli*	5	2	1 cfu/g	10 cfu/g	ISO TS 16649-3	End of the manufacturing process	Improvements in production hygiene
	Coagulase-positive staphylococci	5	2	100 cfu/g	1 000 cfu/g	EN/ISO 6888-1 or 2	End of the manufacturing process	Improvements in production hygiene

(1) n = number of units comprising the sample; c = number of sample units giving values between m and M.
(2) The most recent edition of the standard shall be used.

Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.

E. coli in shelled and shucked products of cooked crustaceans and molluscan shellfish:

— satisfactory, if all the values observed are ≤ m,

— acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m,

— unsatisfactory, if one or more of the values observed are >M or more than c/n values are between m and M.

Coagulase-positive staphylococci in shelled and cooked crustaceans and molluscan shellfish:

— satisfactory, if all the values observed are < m,

— acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are < m,

— unsatisfactory, if one or more of the values observed are >M or more than c/n values are between m and M.

2.5. Vegetables, fruits and products thereof

Food category	Micro-organisms	Sampling plan (1)		Limits		Analytical reference method (2)	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.5.1. Pre-cut fruit and vegetables (ready-to-eat)	*E.coli*	5	2	100 cfu/g	1 000 cfu/g	ISO 16649- 1 or 2	Manufacturing process	Improvements in production hygiene, selection of raw materials
2.5.2. Unpasteurised fruit and vegetable juices (ready-to-eat)	*E.coli*	5	2	100 cfu/g	1 000 cfu/g	ISO 16649- 1 or 2	Manufacturing process	Improvements in production hygiene, selection of raw materials

(1) n = number of units comprising the sample; c = number of sample units giving values between m and M.
(2) The most recent edition of the standard shall be used.

Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.

E. coli in pre-cut fruit and vegetables (ready-to-eat) and in unpasteurised fruit and vegetable juices (ready-to-eat):

— satisfactory, if all the values observed are ≤ m,

— acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m,

— unsatisfactory, if one or more of the values observed are >M or more than c/n values are between m and M.

Chapter 3. Rules for sampling and preparation of test samples

3.1. General rules for sampling and preparation of test samples

In the absence of more specific rules on sampling and preparation of test samples, the relevant standards of the ISO (International Organisation for Standardisation) and the guidelines of the Codex Alimentarius shall be used as reference methods.

3.2. Bacteriological sampling in slaughterhouses and at premises producing minced meat and meat preparations

Sampling rules for carcases of cattle, pigs, sheep, goats and horses

The destructive and non-destructive sampling methods, the selection of the sampling sites and the rules for storage and transport of samples are described in standard ISO 17604.

Five carcases shall be sampled at random during each sampling session. Sample sites should be selected taking into account the slaughter technology used in each plant.

When sampling for analyses of enterobacteriaceae and aerobic colony counts, four sites of each carcase shall be sampled. Four tissue samples representing a total of 20 cm^2 shall be obtained by the destructive method. When using the non-destructive method for this purpose, the sampling area shall cover a minimum of 100 cm^2 (50 cm^2 for small ruminant carcases) per sampling site.

When sampling for *Salmonella* analyses, an abrasive sponge sampling method shall be used. The sampling area shall cover a minimum of 100 cm^2 per site selected.

When samples are taken from the different sampling sites on the carcase, they shall be pooled before examination.

Sampling rules for poultry carcases

For the *Salmonella* analyses, a minimum of 15 carcases shall be sampled at random during each sampling session and after chilling. A piece of approximately 10 g from neck skin shall be obtained from each carcase. On each occasion the neck skin samples from three carcases shall be pooled before examination in order to form 5 x 25 g final samples.

Guidelines for sampling

More detailed guidelines on the sampling of carcases, in particular concerning the sampling sites, may be included in the guides to good practice referred to in Article 7 of Regulation (EC) No 852/2004.

Sampling frequencies for carcases, minced meat, meat preparations and mechanically separated meat

However, when justified on the basis of a risk analysis and consequently authorised by the competent authority, small slaughterhouses and establishments producing minced meat and meat preparations in small quantities may be exempted from these sampling frequencies.

In the case of sampling for *Salmonella* analyses of minced meat, meat preparations and carcases, the frequency can be reduced to fortnightly if satisfactory results have been obtained for 30 consecutive weeks. The salmonella sampling frequency may also be reduced if there is a national or regional salmonella control programme in place and if this programme includes testing that replaces the described sampling. The sampling frequency may be further reduced if the national or regional salmonella control programme demonstrates that the salmonella prevalence is low in animals purchased by the slaughterhouse.

As regards the sampling of minced meat and meat preparations for *E. coli* and aerobic colony count analyses and the sampling of carcases for enterobacteriaceae and aerobic colony count analyses, the frequency may be reduced to fortnightly testing if satisfactory results are obtained for six consecutive weeks.

The food business operators of slaughterhouses or establishments producing minced meat, meat preparations or mechanically separated meat shall take samples for microbiological analysis at least once a week. The day of sampling shall be changed each week to ensure that each day of the week is covered.

ANNEX II

The studies referred to in Article 3(2) shall include:

— specifications for physico-chemical characteristics of the product, such as pH, a_w, salt content, concentration of preservatives and the type of packaging system, taking into account the storage and processing conditions, the possibilities for contamination and the foreseen shelf-life, and

— consultation of available scientific literature and research data regarding the growth and survival characteristics of the micro-organisms of concern.

When necessary on the basis of the abovementioned studies, the food business operator shall conduct additional studies, which may include:

— predictive mathematical modelling established for the food in question, using critical growth or survival factors for the micro-organisms of concern in the product,

— tests to investigate the ability of the appropriately inoculated micro-organism of concern to grow or survive in the product under different reasonably foreseeable storage conditions,

— studies to evaluate the growth or survival of the micro-organisms of concern that may be present in the product during the shelf-life under reasonably foreseeable conditions of distribution, storage and use.

The above mentioned studies shall take into account the inherent variability linked to the product, the micro-organisms in question and the processing and storage conditions.