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<sup>(1)</sup> Text with EEA relevance.

# EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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## I

(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 <sup>(1)</sup>, 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 <sup>(2)</sup>. 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.

<sup>(1)</sup> OJ L 139, 30.4.2004, p. 1, corrected by OJ L 226, 25.6.2004, p. 3.

<sup>(2)</sup> 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 <sup>(1)</sup> 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 <sup>(2)</sup> 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 <sup>(3)</sup> 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.

<sup>(1)</sup> OJ L 165, 30.4.2004, p. 1, corrected by OJ L 191, 28.5.2004, p. 1.

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

<sup>(3)</sup> 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<sup>(1)</sup> 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<sup>(2)</sup> 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<sup>(3)</sup> is repealed with effect from the 1 January 2006, it is appropriate to incorporate microbiological criteria set for carcasses 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<sup>(4)</sup>, 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 <sup>(1)</sup> 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 <sup>(2)</sup>, the rules on parasites laid down under Regulation (EC) No 854/2004 of the European Parliament and of the Council <sup>(3)</sup> and the microbiological criteria laid down under Council Directive 80/777/EEC <sup>(4)</sup>.

#### 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;

<sup>(2)</sup> OJ L 139, 30.4.2004, p. 55, corrected by OJ L 226, 25.6.2004, p. 22.

<sup>(3)</sup> OJ L 139, 30.4.2004, p. 206, corrected by OJ L 226, 25.6.2004, p. 83.

<sup>(4)</sup> OJ L 229, 30.8.1980, p. 1.

<sup>(1)</sup> OJ L 325, 12.12.2003, 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 <sup>(1)</sup>;
- (i) 'food intended for special medical purposes' means dietary food for special medical purposes, as defined in Commission Directive 1999/21/EC <sup>(2)</sup>;
- (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

<sup>(1)</sup> OJ L 175, 4.7.1991, p. 35.

<sup>(2)</sup> 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;

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

Done at Brussels, 15 November 2005.

- (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 carcasses 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.

*For the Commission*

Markos KYPRIANOU

*Member of the Commission*



## ANNEX I

**Microbiological criteria for foodstuffs**

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## Chapter 1. Food safety criteria

Food category	Micro-organisms/their toxins, metabolites	Sampling-plan <sup>(1)</sup>		Limits <sup>(2)</sup>		Analytical reference method <sup>(3)</sup>	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 <sup>(4)</sup>	<i>Listeria monocytogenes</i>	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 <i>L. monocytogenes</i> , other than those intended for infants and for special medical purposes	<i>Listeria monocytogenes</i>	5	0	100 cfu/g <sup>(5)</sup>		EN/ISO 11290-2 <sup>(6)</sup>	Products placed on the market during their shelf-life
		5	0	Absence in 25 g <sup>(7)</sup>		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 <i>L. monocytogenes</i> , other than those intended for infants and for special medical purposes <sup>(4)</sup> <sup>(8)</sup>	<i>Listeria monocytogenes</i>	5	0	100 cfu/g		EN/ISO 11290-2 <sup>(6)</sup>	Products placed on the market during their shelf-life
1.4. Minced meat and meat preparations intended to be eaten raw	<i>Salmonella</i>	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	<i>Salmonella</i>	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	<i>Salmonella</i>	5	0	Absence in 10 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.7. Mechanically separated meat (MSM) <sup>(9)</sup>	<i>Salmonella</i>	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	<i>Salmonella</i>	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 <sup>(1)</sup>		Limits <sup>(2)</sup>		Analytical reference method <sup>(3)</sup>	Stage where the criterion applies
		n	c	m	M		
1.9. Meat products made from poultry meat intended to be eaten cooked	<i>Salmonella</i>	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	<i>Salmonella</i>	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 <sup>(10)</sup>	<i>Salmonella</i>	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 <sup>(10)</sup>	<i>Salmonella</i>	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.13. Ice cream <sup>(11)</sup> , excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	<i>Salmonella</i>	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	<i>Salmonella</i>	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	<i>Salmonella</i>	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	<i>Salmonella</i>	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	<i>Salmonella</i>	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 <sup>(1)</sup>		Limits <sup>(2)</sup>	Analytical reference method <sup>(3)</sup>	Stage where the criterion applies
		n	c			
1.18. Sprouted seeds (ready-to-eat) <sup>(12)</sup>	<i>Salmonella</i>	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)	<i>Salmonella</i>	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)	<i>Salmonella</i>	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 enterotoxins	5	0	Not detected in 25g	European screening method of the CRL for Milk <sup>(13)</sup>	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 Enterobacteriaceae criterion in Chapter 2.2 of this Annex	<i>Salmonella</i>	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 Enterobacteriaceae criterion in Chapter 2.2 of this Annex	<i>Enterobacter sakazakii</i>	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 echinoderms, tunicates and gastropods	<i>E.coli</i> <sup>(14)</sup>	1 <sup>(15)</sup>	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 associated with a high amount of histidine <sup>(16)</sup>	Histamine	9 <sup>(17)</sup>	2	100 mg/kg	HPLC <sup>(18)</sup>	Products placed on the market during their shelf-life
				200 mg/kg		

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

<sup>(1)</sup> n = number of units comprising the sample; c = number of sample units giving values over m or between m and M.

<sup>(2)</sup> For points 1.1-1.24 m=M.

<sup>(3)</sup> The most recent edition of the standard shall be used.

<sup>(4)</sup> 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.

<sup>(5)</sup> 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.

<sup>(6)</sup> 1 ml of inoculum is plated on a Petri dish of 140 mm diameter or on three Petri dishes of 90 mm diameter.

<sup>(7)</sup> 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.

<sup>(8)</sup> Products with pH  $\leq 4,4$  or  $a_w \leq 0,92$ , products with pH  $\leq 5,0$  and  $a_w \leq 0,94$ , 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.

<sup>(9)</sup> 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.

<sup>(10)</sup> 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.

<sup>(11)</sup> Only ice creams containing milk ingredients.

<sup>(12)</sup> 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.

<sup>(13)</sup> Reference: Hennekine et al., J. AOAC Internat. Vol. 86, No 2, 2003.

<sup>(14)</sup> *E. coli* is used here as an indicator of faecal contamination.

<sup>(15)</sup> A pooled sample comprising a minimum of 10 individual animals.

<sup>(16)</sup> Particularly fish species of the families: *Scombridae*, *Clupeidae*, *Engraulidae*, *Coryphenidae*, *Pomatomidae*, *Scombrosidae*.

<sup>(17)</sup> 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.

<sup>(18)</sup> References: 1. Malle P., Valle M., Bouquelet S. Assay of biogenic amines involved in fish decomposition. J. AOAC Internat. 1996, 79, 43-49.

2. Duffos G., Dervin C., Malle P., Bouquelet S. Relevance of matrix effect in determination of biogenic amines in plaice (*Pleuronectes platessa*) and whiting (*Merlangius 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 <sup>(1)</sup>.

*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  $\leq$  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.

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<sup>(1)</sup> 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  $\leq m$
  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 <sup>(1)</sup>		Limits <sup>(2)</sup>		Analytical reference method <sup>(3)</sup>	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.1.1. Carcasses of cattle, sheep, goats and horses <sup>(4)</sup>	Aerobic colony count			3,5 log cfu/cm <sup>2</sup> daily mean log	5,0 log cfu/cm <sup>2</sup> daily mean log	ISO 4833	Carcasses after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
	Enterobacteriaceae			1,5 log cfu/cm <sup>2</sup> daily mean log	2,5 log cfu/cm <sup>2</sup> daily mean log	ISO 21528-2	Carcasses after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
2.1.2. Carcasses of pigs <sup>(4)</sup>	Aerobic colony count			4,0 log cfu/cm <sup>2</sup> daily mean log	5,0 log cfu/cm <sup>2</sup> daily mean log	ISO 4833	Carcasses after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
	Enterobacteriaceae			2,0 log cfu/cm <sup>2</sup> daily mean log	3,0 log cfu/cm <sup>2</sup> daily mean log	ISO 21528-2	Carcasses after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
2.1.3. Carcasses of cattle, sheep, goats and horses	<i>Salmonella</i>	50 <sup>(5)</sup>	2 <sup>(6)</sup>	Absence in the area tested per carcass		EN/ISO 6579	Carcasses after dressing but before chilling	Improvements in slaughter hygiene, review of process controls and of origin of animals
2.1.4. Carcasses of pig	<i>Salmonella</i>	50 <sup>(5)</sup>	5 <sup>(6)</sup>	Absence in the area tested per carcass		EN/ISO 6579	Carcasses 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 carcasses of broilers and turkeys	<i>Salmonella</i>	50 <sup>(5)</sup>	7 <sup>(6)</sup>	Absence in 25 g of a pooled sample of neck skin		EN/ISO 6579	Carcasses 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 <sup>(1)</sup>		Limits <sup>(2)</sup>		Analytical reference method <sup>(3)</sup>	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.1.6. Minced meat	Aerobic colony count <sup>(7)</sup>	5	2	5x10 <sup>5</sup> cfu/g	5x10 <sup>6</sup> cfu/g	ISO 4833	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
	<i>E.coli</i> <sup>(8)</sup>	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) <sup>(9)</sup>	Aerobic colony count	5	2	5x10 <sup>5</sup> cfu/g	5x10 <sup>6</sup> cfu/g	ISO 4833	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
	<i>E.coli</i> <sup>(8)</sup>	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	<i>E.coli</i> <sup>(8)</sup>	5	2	500 cfu/g or cm <sup>2</sup>	5 000 cfu/g or cm <sup>2</sup>	ISO 16649-1 or 2	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials

<sup>(1)</sup> n = number of units comprising the sample; c = number of sample units giving values between m and M.

<sup>(2)</sup> For points 2.1.3 — 2.1.5 m=M.

<sup>(3)</sup> The most recent edition of the standard shall be used.

<sup>(4)</sup> 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.

<sup>(5)</sup> The 50 samples are derived from 10 consecutive sampling sessions in accordance with the sampling rules and frequencies laid down in this Regulation.

<sup>(6)</sup> 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.

<sup>(7)</sup> This criterion does not apply to minced meat produced at retail level when the shelf-life of the product is less than 24 hours.

<sup>(8)</sup> *E. coli* is used here as an indicator of faecal contamination.

<sup>(9)</sup> 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 carcasses where the limits refer to pooled samples.

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

Enterobacteriaceae and aerobic colony count in carcasses 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 carcasses:

- 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 <sup>(1)</sup>		Limits <sup>(2)</sup>		Analytical reference method <sup>(3)</sup>	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 <sup>(4)</sup>	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	<i>E.coli</i> <sup>(5)</sup>	5	2	100 cfu/g	1 000 cfu/g	ISO 16649- 1 or 2	At the time during the manufacturing process when the <i>E. coli</i> count is expected to be highest <sup>(6)</sup>	Improvements in production hygiene and selection of raw materials
2.2.3. Cheeses made from raw milk	Coagulase-positive staphylococci	5	2	10 <sup>4</sup> cfu/g	10 <sup>5</sup> 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 <sup>5</sup> 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 <sup>(7)</sup> and ripened cheeses made from milk or whey that has undergone pasteurisation or a stronger heat treatment <sup>(7)</sup>	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 <sup>(7)</sup>	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 <sup>5</sup> 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	<i>E.coli</i> <sup>(5)</sup>	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 <sup>(1)</sup>		Limits <sup>(2)</sup>		Analytical reference method <sup>(3)</sup>	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.2.7. Milk powder and whey powder <sup>(4)</sup>	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 <sup>5</sup> cfu/g are detected, the batch has to be tested for staphylococcal enterotoxins.
2.2.8. Ice cream <sup>(5)</sup> 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 <i>E. sakazakii</i> and <i>Salmonella</i>

<sup>(1)</sup> n = number of units comprising the sample; c = number of sample units giving values between m and M.

<sup>(2)</sup> For point 2.2.7 m=M.

<sup>(3)</sup> The most recent edition of the standard shall be used.

<sup>(4)</sup> The criterion does not apply to products intended for further processing in the food industry.

<sup>(5)</sup> *E. coli* is used here as an indicator for the level of hygiene.

<sup>(6)</sup> 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.

<sup>(7)</sup> 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.

<sup>(8)</sup> 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 <sup>(1)</sup>		Limits		Analytical reference method <sup>(2)</sup>	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

<sup>(1)</sup> n = number of units comprising the sample; c = number of sample units giving values between m and M.

<sup>(2)</sup> 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 <sup>(1)</sup>		Limits		Analytical reference method <sup>(2)</sup>	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	<i>E.coli</i>	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

<sup>(1)</sup> n = number of units comprising the sample; c = number of sample units giving values between m and M.

<sup>(2)</sup> 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  $\leq$  m,
- acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are  $\leq$  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 <sup>(1)</sup>		Limits		Analytical reference method <sup>(2)</sup>	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)	<i>E.coli</i>	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)	<i>E.coli</i>	5	2	100 cfu/g	1 000 cfu/g	ISO 16649- 1 or 2	Manufacturing process	Improvements in production hygiene, selection of raw materials

<sup>(1)</sup> n = number of units comprising the sample; c = number of sample units giving values between m and M.

<sup>(2)</sup> 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  $\leq$  m,
- acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are  $\leq$  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 carcasses 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 carcasses 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 carcass shall be sampled. Four tissue samples representing a total of 20 cm<sup>2</sup> 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<sup>2</sup> (50 cm<sup>2</sup> for small ruminant carcasses) 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<sup>2</sup> per site selected.

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

##### *Sampling rules for poultry carcasses*

For the *Salmonella* analyses, a minimum of 15 carcasses 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 carcass. On each occasion the neck skin samples from three carcasses 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 carcasses, 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 carcasses, 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 carcasses, 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 carcasses 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.

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## 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.

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**COMMISSION REGULATION (EC) No 2074/2005**  
**of 5 December 2005**

**laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004**

(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 <sup>(1)</sup>, and in particular Article 13(2) thereof,

Having regard 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 <sup>(2)</sup>, and in particular Articles 9, 10 and 11 thereof,

Having regard to Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption <sup>(3)</sup>, and in particular Articles 16, 17 and 18 thereof,

Having regard to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the compliance with feed and food law, animal health and animal welfare rules <sup>(4)</sup>, and in particular Article 63 thereof,

Whereas:

- (1) Regulation (EC) No 853/2004 lays down specific requirements concerning hygiene rules for food of animal origin. It is necessary to lay down certain implementing measures for meat, live bivalve molluscs, fishery products, milk, eggs, frogs' legs and snails, and processed products thereof.
- (2) Regulation (EC) No 854/2004 lays down specific rules for the organisation of official controls on products of animal origin intended for human consumption. It is necessary to develop certain rules and further specify other requirements.

- (3) Regulation (EC) No 882/2004 establishes at Community level a harmonised framework of general rules for the organisation of official controls. It is necessary to develop certain rules and further specify other requirements.

- (4) Commission Decision 20XX/2005/EC <sup>(5)</sup> repeals certain Decisions implementing measures provided for in the Directives 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 <sup>(6)</sup>. Certain parts of the relevant Decisions should therefore be retained in this Regulation.

- (5) Regulation (EC) No 852/2004 requires the food business operator to keep and retain records and on request to make relevant information in these records available to the competent authority and receiving food business operator.

- (6) Regulation (EC) No 853/2004 also requires the slaughterhouse operator to request, receive, check and act upon the food chain information for all animals, other than wild game, sent or intended to be sent to the slaughterhouse. In addition, he should make sure the food chain information provides all the details required under Regulation (EC) No 853/2004.

- (7) The food chain information assists the slaughterhouse operator to organise slaughter operations and assists the official veterinarian to determine the required inspection procedures. The food chain information should be

<sup>(1)</sup> OJ L 139, 30.4.2004, p. 1. Corrected by OJ L 226, 25.6.2004, p. 3.

<sup>(2)</sup> OJ L 139, 30.4.2004, p. 55. Corrected by OJ L 226, 25.6.2004, p. 22.

<sup>(3)</sup> OJ L 139, 30.4.2004, p. 206. Corrected by OJ L 226, 25.6.2004, p. 83.

<sup>(4)</sup> OJ L 165, 30.4.2004, p. 1. Corrected by OJ L 191, 28.5.2004, p. 1.

<sup>(5)</sup> Not yet published in the Official Journal.

<sup>(6)</sup> OJ L 157, 30.4.2004, p. 33. Corrected by OJ L 195, 2.6.2004, p. 12.

analysed by the official veterinarian and used as an integral part of the inspection procedures.

- (8) Existing systems for information flow should be used as much as possible and adapted to comply with the requirements for the food chain information laid down in Regulation (EC) No 854/2004.
- (9) In order to improve animal management at holding level and in accordance with Regulation (EC) No 854/2004, the official veterinarian should record and, if necessary, communicate, to the food business operator of the holding of provenance and to any veterinarian attending the holding of provenance or any competent authority involved, any disease or condition observed at the slaughterhouse in respect of individual animals or the herd/flock and which may affect public or animal health or endanger animal welfare.
- (10) Regulations (EC) Nos 853/2004 and 854/2004 set out the requirements governing parasite checks during handling of fishery products on shore and on board vessels. It is up to food business operators to carry out their own checks at all stages in the production of fishery products in accordance with the rules in Chapter V(D) of Section VIII of Annex III to Regulation (EC) No 853/2004 so that fish which are obviously infested with parasites are not released for human consumption. The adoption of detailed rules relating to visual inspections calls for the concepts of visible parasites and visual inspection to be defined and the type and frequency of the observations to be determined.
- (11) The checks provided for in Regulation (EC) No 853/2004 to prevent fishery products which are unfit for human consumption from being placed on the market may comprise certain chemical checks, including checks of total volatile basic nitrogen (TVB-N). It is necessary to set levels of TVB-N that are not to be exceeded in the case of certain species categories and to specify the analysis methods to be used. The analysis methods that are scientifically recognised for checking TVB-N should continue to be used as a matter of routine, but a reference method should be specified for use where there is doubt regarding the results or in the event of dispute.
- (12) The limits for Paralytic Shellfish Poison (PSP), Amnesic Shellfish Poison (ASP) and lipophilic toxins are laid down in Regulation (EC) No 853/2004. Bioassays are the reference method for detecting certain toxins and preventing toxic shellfish from being harvested. Maximum levels and methods of analysis should be harmonised and implemented by the Member States to protect human health. In addition to biological testing methods, alternative detection methods, such as chemical methods and *in vitro* assays, should be allowed if it is demonstrated that the performance of the chosen methods is at least as effective as the biological method and that their implementation provides an equivalent level of public health protection. The proposed maximum levels for lipophilic toxins are based on provisional data and should be reassessed once new scientific evidence becomes available. A lack of reference material and the sole use of non-bioassay tests currently means that the level of public health protection provided in respect of all toxins specified is not equivalent to that afforded by biological tests. Provision should be made for the replacement of biological tests as soon as possible.
- (13) Mechanically separated meat (MSM) produced using techniques that do not alter the structure of the bones used in the production of MSM should be treated as different from MSM produced using techniques that alter the structure of the bones.
- (14) MSM of the former type produced under specified conditions and of a specified composition should be permitted in meat preparations that are clearly not intended to be consumed without first undergoing heat treatment. These conditions are linked in particular to the calcium content of MSM, which should be specified in accordance with Article 11(2) of Regulation (EC) No 853/2004. An adjustment should be made to the specified maximum calcium content set in this Regulation once detailed information is available on variations occurring where different types of raw material are used.
- (15) Article 31(2)(f) of Regulation (EC) No 882/2004 provides for Member States to maintain up-to-date lists of approved establishments. A common framework should be laid down for the presentation of relevant information to other Member States and to the public.
- (16) Section XI of Annex III to Regulation (EC) No 853/2004 sets out the requirements governing the preparation of frogs' legs and snails intended for human consumption. Specific requirements, including model health certificates, should also be laid down for imports from third countries of frogs' legs and snails intended for human consumption.
- (17) Sections XIV and XV of Annex III to Regulation (EC) No 853/2004 lay down rules on the production and placing on the market of gelatine and collagen intended for human consumption. Specific requirements, including model health certificates, should also be laid down for imports from third countries of gelatine and collagen and raw materials for the production of gelatine and collagen intended for human consumption.
- (18) Flexibility is needed so foods with traditional characteristics can continue to be produced. Member States have already granted derogations for a wide range of such foods under the legislation in force before 1 January 2006. Food business operators should be able to continue without interruption to apply existing practices after that date. A procedure allowing Member States to exercise flexibility is provided for in Regulations (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/

2004. However, in most cases where derogations have already been granted it is only a question of continuing established practices, so applying a full notification procedure, including a complete hazard analysis, may place an unnecessary and disproportionate burden on the Member States. Foods with traditional characteristics should therefore be defined and general conditions applicable to such foods should be laid down, by way of derogation from the structural requirements laid down in Regulation (EC) No 852/2004, with due regard to food health objectives.

- (19) Since Regulations (EC) Nos 853/2004 and 854/2004 were adopted before the accession on 1 May 2004, they did not refer to the new Member States. The ISO codes for those Member States and the abbreviations for the European Community in their languages should therefore be added to the relevant provisions of those Regulations.
- (20) Section I of Annex III to Regulation (EC) No 853/2004 lays down rules on the production and placing on the market of meat from domestic ungulates. Exceptions to the complete skinning of the carcass and other parts of the body intended for human consumption are set out in Chapter IV, point 8 of that Section. Provision should be made to extend these exceptions to feet from adult bovine animals, provided they comply with the same conditions as those applying to feet of calves.
- (21) Certain practices can mislead the consumer regarding the composition of certain products. In particular in order not to disappoint consumer expectations, the sale as fresh meat of poultrymeat treated with water retention agents should be banned.
- (22) The opinion of the European Food Safety Authority adopted on 30 August 2004 has demonstrated that fishery products belonging to the family of *Gempylidae*, in particular *Ruvettus pretiosus* and *Lepidocybium flavobrunneum*, may have adverse gastrointestinal effects if consumed under certain conditions. The fishery products belonging to this family should therefore be subjected to marketing conditions.
- (23) Section IX of Annex III to Regulation (EC) No 853/2004 lays down specific hygiene rules for raw milk and dairy products. According to Part II (B)(1)(e) of Chapter I, teat dips or other udder cleaning products may be used only if they have been approved by the competent authority. However, no detailed authorisation scheme is provided in this Part. It is therefore necessary, in order to ensure a harmonised approach by Member States, to clarify the procedures under which such authorisations should be given.
- (24) Regulation (EC) No 853/2004 requires food business operators to ensure that heat treatments used to process raw milk and dairy products should conform to an internationally recognised standard. However, owing to the specificity of certain heat treatments used in this sector and their impact on food safety and animal health, clearer guidance should be given to food business operators in this regard.
- (25) Regulation (EC) No 853/2004 introduces a new definition to cover products derived from eggs that, after removal of the shell, have not yet been processed. It is, therefore, necessary to clarify the rules applying to those products and amend Section X, Chapter II of Annex III to Regulation (EC) No 853/2004 accordingly.
- (26) Section XIV of Annex III to Regulation (EC) No 853/2004 lays down specific health rules for gelatine. These rules include requirements covering the type of raw materials that may be used to produce gelatine and the transport and storage of such materials. They also lay down specifications applicable to the manufacture of gelatine. However, the rules applying to labelling of gelatine should also be laid down.
- (27) Scientific progress has led to the establishment of ISO 16649-3 as an agreed reference method for analysis of *E. coli* in bivalve molluscs. This reference method is already established for live bivalve molluscs from areas A in accordance with Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs<sup>(1)</sup>. Consequently, ISO 16649-3 should be specified as the reference MPN (most probable number) method for analysis of *E. coli* in bivalve molluscs originating in areas B and C too. The use of alternative methods should be allowed only where they are considered equivalent to the reference method.
- (28) Regulations (EC) Nos 853/2004 and 854/2004 should therefore be amended accordingly.
- (29) 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

#### Requirements concerning food chain information for the purpose of Regulations (EC) Nos 853/2004 and 854/2004

Requirements concerning food chain information as referred to in Section III of Annex II to Regulation (EC) No 853/2004 and in Chapter II (A) of Section I of Annex I to Regulation (EC) No 854/2004 are set out in Annex I to this Regulation.

<sup>(1)</sup> See page 1 of this Official Journal.

*Article 2***Requirements concerning fishery products for the purpose of Regulations (EC) Nos 853/2004 and 854/2004**

Requirements concerning fishery products as referred to in Article 11(9) of Regulation (EC) No 853/2004 and Article 18(14) and (15) of Regulation (EC) No 854/2004 are set out in Annex II to this Regulation.

*Article 3***Recognised testing methods for marine biotoxins for the purpose of Regulations (EC) Nos 853/2004 and 854/2004**

The recognised testing methods for detecting marine biotoxins as referred to in Article 11(4) of Regulation (EC) No 853/2004 and Article 18(13)(a) of Regulation (EC) No 854/2004 are as set out in Annex III to this Regulation.

*Article 4***Calcium content of mechanically separated meat for the purpose of Regulation (EC) No 853/2004**

The calcium content of mechanically separated meat as referred to in Article 11(2) of Regulation (EC) No 853/2004 is as set out in Annex IV to this Regulation.

*Article 5***Lists of establishments for the purpose of Regulation (EC) No 882/2004**

Requirements concerning the lists of establishments as referred to in Article 31(2)(f) of Regulation (EC) No 882/2004 are set out in Annex V to this Regulation.

*Article 6***Model health certificates for frogs' legs, snails, gelatine and collagen for the purpose of Regulation (EC) No 853/2004**

The model health certificates for imports of frogs' legs, snails, gelatine and collagen as referred to in Article 6(1)(d) of Regulation (EC) No 853/2004 and of raw materials for the production of gelatine and collagen are as set out in Annex VI to this Regulation.

*Article 7***Derogation from Regulation (EC) No 852/2004 for foods with traditional characteristics**

1. For the purposes of this Regulation, 'foods with traditional characteristics' means foods that, in the Member State in which they are traditionally manufactured, are:

(a) recognised historically as traditional products, or

(b) manufactured according to codified or registered technical references to the traditional process, or according to traditional production methods, or

(c) protected as traditional food products by a Community, national, regional or local law.

2. Member States may grant establishments manufacturing foods with traditional characteristics individual or general derogations from the requirements set out in:

(a) Chapter II(1) of Annex II to Regulation (EC) No 852/2004 as regards the premises where such products are exposed to an environment necessary for the part-development of their characteristics. Such premises may in particular comprise walls, ceilings and doors that are not smooth, impervious, non-absorbent or of corrosion-resistant material and natural geological walls, ceilings and floors;

(b) Chapter II(1)(f) and Chapter V(1) of Annex II to Regulation (EC) No 852/2004 as regards the type of materials of which the instruments and the equipment used specifically for the preparation, packaging and wrapping of these products are made.

The cleaning and disinfecting measures for the premises referred in (a) and the frequency with which they are carried out shall be adapted to the activity in order to take account of their specific ambient flora.

The instruments and equipment referred to in (b) shall be maintained at all times in a satisfactory state of hygiene and be regularly cleaned and disinfected.

3. Member States granting the derogations provided for in paragraph 2 shall notify the Commission and the other Member States of this no later than 12 months after granting individual or general derogations. Each notification shall:

(a) provide a short description of the requirements that have been adapted;

(b) describe the foodstuffs and establishments concerned; and

(c) give any other relevant information.

*Article 8***Amendments to Regulation (EC) No 853/2004**

Annexes II and III to Regulation (EC) No 853/2004 are amended in accordance with Annex VII to this Regulation.

*Article 9***Amendments to Regulation (EC) No 854/2004**

Annexes I, II and III to Regulation (EC) No 854/2004 are amended in accordance with Annex VIII to this Regulation.

*Article 10***Entry into force and applicability**

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

It shall apply from 1 January 2006, except for Chapters II and III of Annex V, which shall apply from 1 January 2007.

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

Done at Brussels, 5 December 2005.

*For the Commission*

Markos KYPRIANOU

*Member of the Commission*

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## ANNEX I

**FOOD CHAIN INFORMATION**

## SECTION I

**OBLIGATIONS ON FOOD BUSINESS OPERATORS**

Food business operators raising animals dispatched for slaughter shall ensure that the food chain information referred to in Regulation (EC) No 853/2004 is included as appropriate in the documentation relating to the animals dispatched in such a way as to be accessible to the slaughterhouse operator concerned.

## SECTION II

**OBLIGATIONS ON COMPETENT AUTHORITIES**

## CHAPTER I

**PROVISION OF FOOD CHAIN INFORMATION**

1. The competent authority at the place of dispatch shall inform the dispatching food business operator of the minimum elements of food chain information to be supplied to the slaughterhouse in accordance with Section III of Annex II to Regulation (EC) No 853/2004.
2. The competent authority at the place of slaughter shall verify that:
  - (a) the food chain information is consistently and effectively communicated between the food business operator who raised or kept the animals before dispatch and the slaughterhouse operator;
  - (b) the food chain information is valid and reliable;
  - (c) feedback of relevant information to the holding, if applicable, is provided.
3. Where animals are dispatched for slaughter to another Member State, the competent authorities at the place of dispatch and the place of slaughter shall cooperate to ensure that the information provided by the dispatching food business operator is easily accessible to the slaughterhouse operator receiving it.

## CHAPTER II

**FEEDBACK TO HOLDING OF PROVENANCE**

1. The official veterinarian may use the model document laid down in Appendix I for the relevant inspection results that must be communicated to the holding where the animals were raised before slaughter in the same Member State in accordance with Chapter I of Section II of Annex I to Regulation (EC) No 854/2004.
  2. The competent authority is responsible for communicating the relevant inspection results in cases where the animals are raised on a holding in another Member State and must use a version of the model document laid down in the Appendix in both the language of the dispatching country and the language of the recipient country.
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*Appendix to Annex I***MODEL DOCUMENT**

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**1. Identification details**

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- 1.1. holding of provenance (e.g. owner or manager)

name/number

full address

telephone number

- 1.2. identification numbers (attach separate list)

total number of animals (by species)

identification problems (if any)

- 1.3. herd/flock/cage identification (if applicable)

- 1.4. animal species

- 1.5. reference number of health certificate
- 

**2. Ante-mortem findings**

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- 2.1. welfare

number of animals affected

type/class/age

observations (e.g. tail-biting)

- 2.2. animals were delivered dirty

- 2.3. clinical findings (disease)

number of animals affected

type/class/age

observations

date of inspection

- 2.4. laboratory results <sup>(1)</sup>
- 

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<sup>(1)</sup> Microbiological, chemical, serological, etc. (include results as attached).

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**3. Post-mortem findings**

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- 3.1. (macroscopic) findings  
    number of animals affected  
        type/class/age  
    organ or site of animal(s) affected  
    date of slaughter
- 3.2. disease (codes can be used <sup>(1)</sup>)  
    number of animals affected  
        type/class/age  
    organ or site of the animal(s) affected  
    partially or totally condemned carcase (give reason)  
        date of slaughter
- 3.3. laboratory results <sup>(2)</sup>
- 3.4. other results (e.g. parasites, foreign objects, etc)
- 3.5. welfare findings (e.g. broken legs)
- 

**4. Additional information**

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**5. Contact details**

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- 5.1. slaughterhouse (approval number)  
    name  
    full address  
    telephone number
- 5.2. electronic address if available
- 

**6. Official veterinarian (print name)**

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signature and stamp

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**7. Date**

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**8. Number of pages attached to this form:**

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<sup>(1)</sup> The competent authorities may introduce the following codes: Code A for OIE-listed diseases; codes B100 and B200 for welfare issues (Chapter II(C) of Section I of Annex I to Regulation (EC) No 854/2004) and C100 to C290 for decisions concerning meat (Chapter V(1)(a) to (u) of Section II of Annex I to Regulation (EC) No 854/2004). The coding system can, if necessary, include further subdivisions (e.g. C141 for a mild generalised disease, C142 for a more severe disease, etc.). If codes are used, they should be readily available to the food business operator with a suitable explanation of their meaning.

<sup>(2)</sup> Microbiological, chemical, serological, etc. (include results as attached).

## ANNEX II

**FISHERY PRODUCTS**

## SECTION I

**OBLIGATIONS ON FOOD BUSINESS OPERATORS**

This Section lays down detailed rules relating to visual inspections to detect parasites in fishery products.

## CHAPTER I

**DEFINITIONS**

1. 'Visible parasite' means a parasite or a group of parasites which has a dimension, colour or texture which is clearly distinguishable from fish tissues.
2. 'Visual inspection' means non-destructive examination of fish or fishery products with or without optical means of magnifying and under good light conditions for human vision, including, if necessary, candling.
3. 'Candling' means, in respect of flat fish or fish fillets, holding up fish to a light in a darkened room to detect parasites.

## CHAPTER II

**VISUAL INSPECTION**

1. Visual inspection shall be performed on a representative number of samples. The persons in charge of establishments on land and qualified persons on board factory vessels shall determine the scale and frequency of the inspections by reference to the type of fishery products, their geographical origin and their use. During production, visual inspection of eviscerated fish must be carried out by qualified persons on the abdominal cavity and livers and roes intended for human consumption. Depending on the system of gutting used, the visual inspection must be carried out:
  - (a) in the case of manual evisceration, in a continuous manner by the handler at the time of evisceration and washing;
  - (b) in the case of mechanical evisceration, by sampling carried out on a representative number of samples being not less than 10 fish per batch.
2. The visual inspection of fish fillets or fish slices must be carried out by qualified persons during trimming and after filleting or slicing. Where an individual examination is not possible because of the size of the fillets or the filleting operations, a sampling plan must be drawn up and kept available for the competent authority in accordance with Chapter II(4) of Section VIII of Annex III to Regulation (EC) No 853/2004. Where candling of fillets is necessary from a technical viewpoint, it must be included in the sampling plan.

## SECTION II

**OBLIGATIONS ON THE COMPETENT AUTHORITIES**

## CHAPTER I

**TOTAL VOLATILE BASIC NITROGEN (TVB-N) LIMIT VALUES FOR CERTAIN CATEGORIES OF FISHERY PRODUCTS AND ANALYSIS METHODS TO BE USED**

1. Unprocessed fishery products belonging to the species categories listed in Chapter II shall be regarded as unfit for human consumption where organoleptic assessment has raised doubts as to their freshness and chemical checks reveal that the following TVB-N limits are exceeded:
  - (a) 25 mg of nitrogen/100 g of flesh for the species referred to in point 1 of Chapter II;
  - (b) 30 mg of nitrogen/100 g of flesh for the species referred to in point 2 of Chapter II
  - (c) 35 mg of nitrogen/100 g of flesh for the species referred to in point 3 of Chapter II.

The reference method to be used for checking the TVB-N limit involves distilling an extract deproteinised by perchloric acid as set out in Chapter III.

2. Distillation as referred to in point 1 must be performed using apparatus which complies with the diagram in Chapter IV.
3. The routine methods which may be used to check the TVB-N limit are as follows:
  - microdiffusion method described by Conway and Byrne (1933),
  - direct distillation method described by Antonacopoulos (1968),
  - distillation of an extract deproteinised by trichloroacetic acid (Codex Alimentarius Committee on Fish and Fishery Products (1968).
4. The sample must consist of about 100 g of flesh, taken from at least three different points and mixed together by grinding.

Member States shall recommend that official laboratories use, as a matter of routine, the reference method referred to above. Where the results are dubious or in the event of dispute regarding the results of analysis performed by one of the routine methods, only the reference method may be used to check the results.

## CHAPTER II

**SPECIES CATEGORIES FOR WHICH TVB-N LIMIT VALUES ARE FIXED**

1. *Sebastes* spp., *Helicolenus dactylopterus*, *Sebastichthys capensis*.
2. Species belonging to the *Pleuronectidae* family (with the exception of halibut: *Hippoglossus* spp.).
3. *Salmo salar*, species belonging to the *Merlucciidae* family, species belonging to the *Gadidae* family.

## CHAPTER III

**DETERMINATION OF THE CONCENTRATION OF TVB-N IN FISH AND FISHERY PRODUCTS****Reference procedure**1. *Purpose and area of application*

This method describes a reference procedure for identifying the nitrogen concentration of TVB-N in fish and fishery products. This procedure is applicable at TVB-N concentrations of 5 mg/100 g to at least 100 mg/100 g.

2. *Definition*

'TVB-N concentration' means the nitrogen content of volatile nitrogenous bases as determined by the procedure described.

The concentration shall be expressed in mg/100 g.

3. *Brief description*

The volatile nitrogenous bases are extracted from a sample using a solution of 0,6 mol perchloric acid. After alkalisation the extract undergoes steam distillation and the volatile base components are absorbed by an acid receiver. The TVB-N concentration is determined by titration of the absorbed bases.

4. *Chemicals*

Unless otherwise indicated, reagent-grade chemicals should be used. The water used must be either distilled or demineralised and of at least the same purity. Unless otherwise indicated, 'solution' means an aqueous solution as follows:

- (a) perchloric acid solution = 6 g/100 ml;
- (b) sodium hydroxide solution = 20 g/100 ml;
- (c) hydrochloric acid standard solution 0,05 mol/l ((0,05 N),

*Note:* When using an automatic distillation apparatus, titration should take place with a hydrochloric acid standard solution of 0,01 mol/l ((0,01 N);

- (d) boric acid solution = 3 g/100 ml;
- (e) silicone anti-foaming agent;
- (f) phenolphthalein solution = 1 g/100 ml 95 % ethanol;
- (g) indicator solution (Tashiro Mixed Indicator) 2 g methyl-red and 1 g methylene-blue are dissolved in 1 000 ml 95 % ethanol.

5. *Instruments and accessories*

- (a) A meat grinder to produce a sufficiently homogenous fish mince.
- (b) High-speed blender with a speed of between 8 000 and 45 000 revolutions/min.
- (c) Fluted filter, diameter 150 mm, quick-filtering.
- (d) Burette, 5 ml, graduated to 0,01 ml.

- (e) Apparatus for steam distillation. The apparatus must be able to regulate various amounts of steam and produce a constant amount of steam over a given period of time. It must ensure that during the addition of alkalisng substances the resulting free bases cannot escape.

#### 6. Execution

Warning: When working with perchloric acid, which is strongly corrosive, necessary caution and preventive measures should be taken. The samples should, if at all possible, be prepared as soon as possible after their arrival, in accordance with the following instructions:

##### (a) Preparing the sample

The sample to be analysed should be ground carefully using a meat grinder as described in point 5(a). Exactly  $10 \text{ g} \pm 0,1 \text{ g}$  of the ground sample is weighed out into a suitable container. This is mixed with 90,0 ml perchloric acid solution as specified in point 4(a), homogenised for two minutes with a blender as described in point 5(b), and then filtered.

The extract thereby obtained can be kept for at least seven days at a temperature of between approximately  $2 \text{ }^\circ\text{C}$  and  $6 \text{ }^\circ\text{C}$ ;

##### (b) Steam distillation

50,0 ml of the extract obtained in accordance with point (a) is put into an apparatus for steam distillation as described in point 5(e). For a later check on the extract's alkalisation, several drops of phenolphthalein as specified in point 4(f) are added. After adding a few drops of silicone anti-foaming agent, 6,5 ml of sodium hydroxide solution as specified in point 4(b) is added to the extract and steam distillation begins immediately.

The steam distillation is regulated so that around 100 ml of distillate is produced in 10 minutes. The distillation outflow tube is submerged in a receiver with 100 ml boric acid solution as specified in point 4 (d), to which three to five drops of the indicator solution as described in point 4(g) have been added. After exactly 10 minutes, distillation is ended. The distillation outflow tube is removed from the receiver and washed out with water. The volatile bases contained in the receiver solution are determined by titration with standard hydrochloric solution as specified in point 4(c).

The pH of the end point should be  $5,0 \pm 0,1$ .

##### (c) Titration

Duplicate analyses are required. The applied method is correct if the difference between the duplicates is not greater than 2 mg/100 g.

##### (d) Blank

A blind test is carried out as described in point (b). Instead of the extract, 50,0 ml perchloric acid solution as specified in point 4(a) is used.

#### 7. Calculation of TVB-N

By titration of the receiver solution with hydrochloric acid as in point 4(c), the TVB-N concentration is calculated using the following equation:

$$\text{TVB - N (expressed in mg/100 g sample)} = \frac{(V_1 - V_0) \times 0,14 \times 2 \times 100}{M}$$

$V_1$  = Volume of 0,01 mol hydrochloric acid solution in ml for sample

$V_0$  = Volume of 0,01 mol hydrochloric acid solution in ml for blank

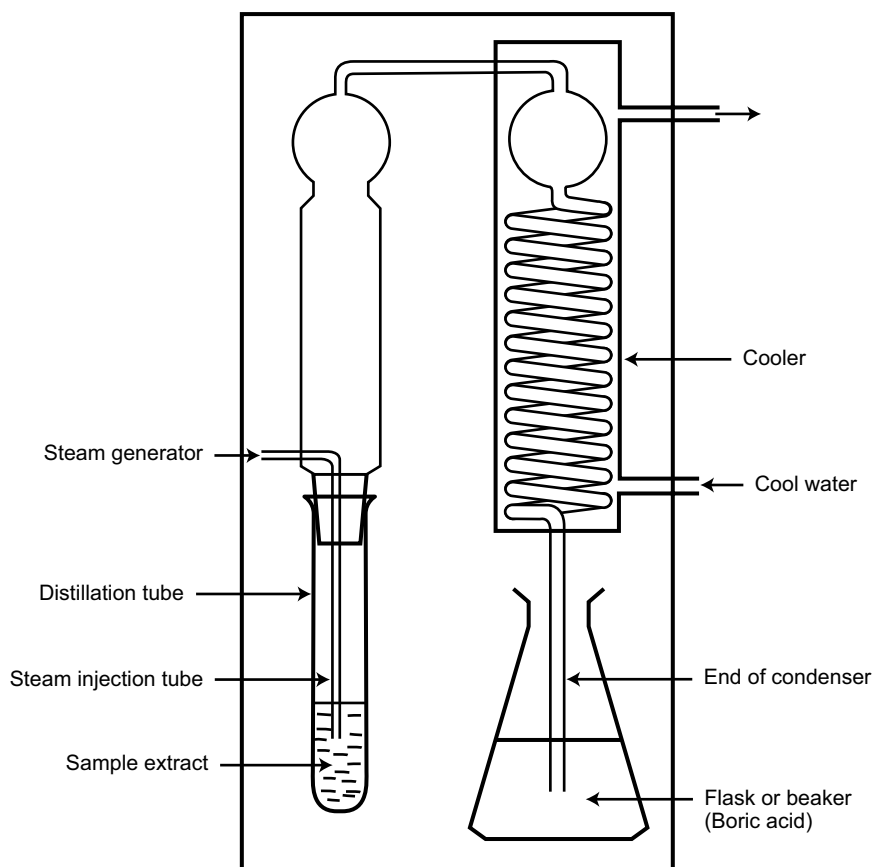
M = Weight of sample in g.

**Remarks**

1. Duplicate analyses are required. The applied method is correct if the difference between duplicates is not greater than 2 mg/100 g.
2. Check the equipment by distilling solutions of  $\text{NH}_4\text{Cl}$  equivalent to 50 mg TVB-N/100 g.
3. Standard deviation of reproducibility  $S_r = 1,20$  mg/100 g. Standard deviation of comparability  $S_R = 2,50$ mg/100 g.

## CHAPTER IV

## TVB-N STEAM DISTILLATION APPARATUS





## ANNEX III

**RECOGNISED TESTING METHODS FOR DETECTING MARINE BIOTOXINS**

The following analytical methods shall be used by the competent authorities to check compliance with the limits laid down in Chapter V(2) of Section VII of Annex III to Regulation (EC) No 853/2004 and, where appropriate, by food business operators.

In accordance with Article 7(2) and (3) of Council Directive 86/609/EEC <sup>(1)</sup>, elements of replacement, refinement and reduction must be taken into account when biological methods are used.

## CHAPTER I

**PARALYTIC SHELLFISH POISON (PSP) DETECTION METHOD**

1. The paralytic shellfish poison (PSP) content of edible parts of molluscs (the whole body or any part edible separately) must be detected in accordance with the biological testing method or any other internationally recognised method. The biological testing method may be carried out in association, if necessary, with another method for detecting Saxitoxin and any of its analogues for which standards are available.
2. If the results are challenged, the reference method shall be the biological method.

## CHAPTER II

**AMNESIC SHELLFISH POISON (ASP) DETECTION METHOD**

The total content of amnesic shellfish poison (ASP) of edible parts of molluscs (the entire body or any part edible separately) must be detected using the high-performance liquid chromatography (HPLC) method or any other recognised method.

If the results are challenged, the reference method shall be the HPLC method.

## CHAPTER III

**LIPHILIC TOXIN DETECTION METHODS****A. Biological methods**

1. A series of mouse bioassay procedures, differing in the test portion (hepatopancreas or whole body) and in the solvents used for extraction and purification, may be used for detecting marine toxins as referred to in Chapter V(2)(c), (d) and (e) of Section VII of Annex III, to Regulation (EC) No 853/2004. Sensitivity and selectivity depend on the choice of solvents used for extraction and purification and this should be taken into account when a decision is made on the method to be used in order to cover the full range of toxins.
2. A single mouse bioassay involving acetone extraction may be used to detect okadaic acid, dinophysistoxins, pectenotoxins and yessotoxins. This assay may be supplemented, if necessary, with liquid/liquid partition steps with ethyl acetate/water or dichloromethane/water to remove potential interferences. Azaspiracid detection at regulatory levels by means of this procedure shall involve the use of the whole body as the test portion.

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<sup>(1)</sup> OJ L 358, 18.12.1986, p. 1.

3. Three mice shall be used for each test. Where two out of three mice die within 24 hours of inoculation with an extract equivalent to 5 g hepatopancreas or 25 g whole body, this shall be considered a positive result for the presence of one or more toxins as referred to in Chapter V(2)(c), (d) and (e) of Section VII of Annex III to Regulation (EC) No 853/2004 at levels above those laid down.
4. A mouse bioassay with acetone extraction followed by liquid/liquid partition with diethylether may be used to detect okadaic acid, dinophysistoxins, pectenotoxins and azaspiracids but it cannot be used to detect yessotoxins as losses of these toxins may take place during the partition step. Three mice shall be used for each test. Where two out of three mice die within 24 hours of inoculation with an extract equivalent to 5 g hepatopancreas or 25 g whole body, this shall be considered a positive result for the presence of okadaic acid, dinophysistoxins, pectenotoxins and azaspiracids at levels above those laid down in Chapter V(2)(c) and (e) of Section VII of Annex III to Regulation (EC) No 853/2004.
5. A rat bioassay may be used to detect okadaic acid, dinophysistoxins and azaspiracids. Three rats shall be used for each test. A diarrhetic response in any of the three rats shall be considered a positive result for the presence of okadaic acid, dinophysistoxins and azaspiracids at levels above those laid down in Chapter V(2)(c) and (e) of Section VII of Annex III to Regulation (EC) No 853/2004.

#### B. Alternative detection methods

1. A series of methods, such as high-performance liquid chromatography (HPLC) with fluorimetric detection, liquid chromatography (LC), mass spectrometry (MS), immunoassays and functional assays, such as the phosphatase inhibition assay, shall be used as alternatives or supplementary to the biological testing methods, provided that either alone or combined they can detect at least the following analogues, that they are not less effective than the biological methods and that their implementation provides an equivalent level of public health protection:
    - okadaic acid and dinophysistoxins: a hydrolysis step may be required to detect the presence of DTX3,
    - pectenotoxins: PTX1 and PTX2,
    - yessotoxins: YTX, 45 OH YTX, homo YTX, and 45 OH homo YTX,
    - azaspiracids: AZA1, AZA2 and AZA3.
  2. If new analogues of public health significance are discovered, they should be included in the analysis. Standards must be available before chemical analysis is possible. Total toxicity shall be calculated using conversion factors based on the toxicity data available for each toxin.
  3. The performance characteristics of these methods shall be defined after validation following an internationally agreed protocol.
  4. Biological methods shall be replaced by alternative detection methods as soon as reference materials for detecting the toxins prescribed in Chapter V of Section VI of Annex III to Regulation (EC) No 853/2004 are readily available, the methods have been validated and this Chapter has been amended accordingly.
-

## ANNEX IV

**CALCIUM CONTENT OF MECHANICALLY SEPARATED MEAT**

The calcium content of MSM as referred to in Regulation (EC) No 853/2004 shall:

1. not exceed 0,1 % (=100 mg/100 g or 1 000 ppm) of fresh product;
  2. be determined by a standardised international method.
-

## ANNEX V

**LISTS OF APPROVED FOOD ESTABLISHMENTS**

## CHAPTER I

**ACCESS TO LISTS OF APPROVED FOOD ESTABLISHMENTS**

In order to assist Member States in making up-to-date lists of approved food establishments available to other Member States and to the public, the Commission shall provide a website to which each Member State shall provide a link to its national website.

## CHAPTER II

**FORMAT FOR NATIONAL WEBSITES****A. Masterlist**

1. Each Member State shall provide the Commission with a linking address to a single national website containing the masterlist of lists of approved food establishments for products of animal origin as defined in point 8(1) of Annex I to Regulation (EC) No 853/2004.
2. The masterlist referred to in point 1 shall consist of one sheet and shall be completed in one or more official languages of the Community.

**B. Operational chart**

1. The website containing the masterlist shall be developed by the competent authority or, where appropriate, one of the competent authorities referred to in Article 4 of Regulation (EC) No 882/2004.
2. The masterlist shall include links to:
  - (a) other web pages located on the same website;
  - (b) where certain lists of approved food establishments are not maintained by the competent authority referred to in point 1, websites managed by other competent authorities, units or where appropriate, bodies.

## CHAPTER III

**LAYOUT AND CODES FOR LISTS OF APPROVED ESTABLISHMENTS**

Layouts, including relevant information and codes, shall be established to ensure wide availability of the information concerning approved food establishments and to improve the readability of the lists.

## CHAPTER IV

**TECHNICAL SPECIFICATIONS**

The tasks and activities referred to in Chapters II and III shall be performed in accordance with the technical specifications published by the Commission.

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## ANNEX VI

**MODEL HEALTH CERTIFICATES FOR IMPORTS FOR FROGS' LEGS, SNAILS, GELATINE AND COLLAGEN**

## SECTION I

**FROGS' LEGS AND SNAILS**

Health certificates as referred to in Article 6(1)(d) of Regulation (EC) No 853/2004 for imports of frogs' legs and snails shall comply with the models laid down respectively in Part A and Part B of Appendix I to this Annex.

## SECTION II

**GELATINE**

Without prejudice to other specific Community legislation, at least including but not limited to legislation on transmissible spongiform encephalopathies and hormones, health certificates as referred to in Article 6(1)(d) of Regulation (EC) No 853/2004 for imports of gelatine and raw materials for the production of gelatine shall comply with the models laid down respectively in Part A and Part B of Appendix II to this Annex.

## SECTION III

**COLLAGEN**

Without prejudice to other specific Community legislation, at least including but not limited to legislation on transmissible spongiform encephalopathies and hormones, health certificates as referred to in Article 6(1)(d) of Regulation (EC) No 853/2004 for imports of collagen and raw materials for the production of collagen shall comply with the models laid down respectively in Part A and Part B of Appendix III to this Annex.

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Appendix I to Annex VI

PART A

**MODEL HEALTH CERTIFICATE FOR IMPORTS OF CHILLED, FROZEN OR PREPARED FROGS' LEGS INTENDED FOR HUMAN CONSUMPTION**

**COUNTRY**

**Veterinary certificate to EU**

<b>Part I: Details of dispatched consignment</b>	I.1. Consignor <input type="checkbox"/> Name  Address  Postal code		I.2.		I.2.a. Local reference number:			
			I.3. Central Competent Authority					
			I.4. Local Competent Authority					
	I.5. Consignee Name  Address  Postal code		I.6.					
	I.7. Country of origin	ISO code	I.8. Region of origin	Code	I.9. Country of destination	ISO code	I.10. Region of destination	Code
	I.11. Place of origin  Establishment/vessel <input type="checkbox"/> Name Address Name Address Name Address			I.12. Place of destination  Establishment/vessel <input type="checkbox"/> Custom warehouse <input type="checkbox"/>  Name Address Name Address Postal code				
	I.13.			I.14. Estimated date and time of arrival				
	I.15. Means of transport <sup>(2)</sup> Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> Identification: Documentary references:			I.16.  I.17.				
	I.18. Animal species/Product				I.19. Commodity code (HS code)		I.20. Quantity	
	I.21. Temperature of product Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>				I.22. Number of packages			
I.23. Identification of container / Seal number				I.24. Type of packaging				
I.25. Animals certified as / products certified for:  Human consumption <input type="checkbox"/>								
I.26.			I.27. For import or admission into EU <input type="checkbox"/> Definitive import <input type="checkbox"/>					
I.28. Identification of the animals/products <sup>(1)</sup>  Approval number of establishments/vessel Species Nature of cuts/ Factory vessel Cutting plant/ Freezer vessel Quantity Net weight (Scientific name) treatment type manufacturing plant								

## COUNTRY

## Frogs' legs

<b>Part II: Certification</b>	II.	Health information	II.a. Certificate reference number	II.b. Local reference number		
	1.	<p><b>Health attestation</b></p> <p>I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004 and (EC) No 853/2004 and certify that the frogs' legs described above were produced in accordance with those requirements, in particular that they:</p> <ul style="list-style-type: none"> <li>— come from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004</li> <li>and</li> <li>— originate from frogs that have been bled, prepared and, where appropriate, chilled frozen or processed, packaged and stored in a hygienic manner in accordance with the requirements of Annex III, Section XI to Regulation (EC) No 853/2004</li> </ul>				
	<p><b>Notes</b></p> <p>(1) Box reference I.28: Treatment type: Chilled, frozen, processed.</p> <p>(2) Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship). This information is to be updated in the event of unloading and reloading.</p> <p>(3) The colour of the stamp and signature must be different from that of the other particulars in the certificate.</p>					
	<p>Official veterinarian or official inspector</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 60%; border: none;"> Name (in capitals):  Local veterinary unit:  Date:  Stamp <sup>(3)</sup> </td> <td style="width: 40%; border: none;"> Qualification and title  No of relevant LVU:  Signature <sup>(3)</sup>: </td> </tr> </table>				Name (in capitals): Local veterinary unit: Date: Stamp <sup>(3)</sup>	Qualification and title No of relevant LVU: Signature <sup>(3)</sup> :
Name (in capitals): Local veterinary unit: Date: Stamp <sup>(3)</sup>	Qualification and title No of relevant LVU: Signature <sup>(3)</sup> :					

PART B

MODEL HEALTH CERTIFICATE FOR IMPORTS OF SHELLED, COOKED, PREPARED OR PRESERVED SNAILS INTENDED FOR HUMAN CONSUMPTION

COUNTRY

Veterinary certificate to EU

<b>Part I: Details of dispatched consignment</b>	I.1. Consignor <input type="checkbox"/> Name Address Postal code		I.2.		I.2.a. Local reference number:			
			I.3. Central Competent Authority					
			I.4. Local Competent Authority					
	I.5. Consignee Name Address Postal code		I.6.					
	I.7. Country of origin	ISO code	I.8. Region of origin	Code	I.9. Country of destination	ISO code	I.10. Region of destination	Code
	I.11. Place of origin Establishment/vessel <input type="checkbox"/> Name Approval number Address Name Approval number Address Name Approval number Address				I.12. Place of destination Establishment/vessel <input type="checkbox"/> Custom warehouse <input type="checkbox"/> Name Approval number Address Postal code			
	I.13.				I.14. Estimated date and time of arrival			
	I.15. Means of transport (?) Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> Identification: Documentary references:				I.16.			
					I.17.			
	I.18. Animal species/Product				I.19. Commodity code (HS code)		I.20. Quantity	
I.21. Temperature of product Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>				I.22. Number of packages				
I.23. Identification of container/Seal number				I.24. Type of packaging				
I.25. Animals certified as/products certified for: Human consumption <input type="checkbox"/>								
I.26.		I.27. For import or admission into EU		<input type="checkbox"/> Definitive import <input type="checkbox"/>				
I.28. Identification of the animals/products (1)								
Approval number of establishments/vessel Species Nature of cuts/ Factory vessel Cutting plant/ Freezer vessel Quantity Net weight (Scientific name) treatment type manufacturing plant								



## COUNTRY

## Snails

<b>Part II: Certification</b>	II. Health information	II.a. Certificate reference number	II.b. Local reference number		
	<p><b>1. Health attestation</b></p> <p>I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004 and (EC) No 853/2004 and certify that the snails described above were produced in accordance with those requirements, in particular that they:</p> <ul style="list-style-type: none"> <li>— come from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004</li> <li>and</li> <li>— have been handled and, where appropriate, shelled, cooked, prepared, preserved, frozen, packaged and stored in a hygienic manner in accordance with the requirements of Annex III, Section XI of Regulation (EC) No 853/2004</li> </ul>				
<p><b>Notes</b></p> <p>(1) Box reference I.28: Treatment type: Chilled, frozen, shelled, cooked, prepared, preserved.</p> <p>(2) Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship). This information is to be updated in the event of unloading and reloading.</p> <p>(3) The colour of the stamp and signature must be different from that of the other particulars in the certificate.</p>					
<p>Official veterinarian or official inspector</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 60%; border: none;"> <p>Name (in capitals):</p> <p>Local veterinary unit:</p> <p>Date:</p> <p>Stamp <sup>(3)</sup></p> </td> <td style="width: 40%; border: none;"> <p>Qualification and title</p> <p>No of relevant LVU:</p> <p>Signature <sup>(3)</sup>:</p> </td> </tr> </table>				<p>Name (in capitals):</p> <p>Local veterinary unit:</p> <p>Date:</p> <p>Stamp <sup>(3)</sup></p>	<p>Qualification and title</p> <p>No of relevant LVU:</p> <p>Signature <sup>(3)</sup>:</p>
<p>Name (in capitals):</p> <p>Local veterinary unit:</p> <p>Date:</p> <p>Stamp <sup>(3)</sup></p>	<p>Qualification and title</p> <p>No of relevant LVU:</p> <p>Signature <sup>(3)</sup>:</p>				

Appendix II to Annex VI

PART A

MODEL HEALTH CERTIFICATE FOR IMPORTS OF GELATINE INTENDED FOR HUMAN CONSUMPTION

COUNTRY

Veterinary certificate to EU

<b>Part I: Details of dispatched consignment</b>	I.1. Consignor <input type="checkbox"/> Name  Address  Postal code				I.2.		I.2.a. Local reference number:				
					I.3. Central Competent Authority						
					I.4. Local Competent Authority						
	I.5. Consignee Name  Address  Postal code				I.6.						
	I.7. Country of origin		ISO code	I.8. Region of origin		Code	I.9. Country of destination		ISO code	I.10. Region of destination	Code
	I.11. Place of origin  Establishment/vessel <input type="checkbox"/> Name Address Name Address Name Address Approval number Approval number Approval number					I.12. Place of destination  Establishment/vessel <input type="checkbox"/> Custom warehouse <input type="checkbox"/>  Name Address Approval number  Postal code					
	I.13.					I.14. Estimated date and time of arrival					
	I.15. Means of transport (*) Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> Identification: Documentary references:					I.16.					
						I.17.					
	I.18. Animal species/Product						I.19. Commodity code (HS code)			I.20. Quantity	
I.21. Temperature of product Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>							I.22. Number of packages				
I.23. Identification of container/Seal number							I.24. Type of packaging				
I.25. Animals certified as/products certified for:  Human consumption <input type="checkbox"/>											
I.26.					I.27. For import or admission into EU <input type="checkbox"/> Definitive import <input type="checkbox"/>						
I.28. Identification of the animals/products  Approval number of establishments/vessel  Species Nature of cuts/ Factory vessel Cutting plant/ Freezer vessel Quantity Net weight (Scientific name) treatment type manufacturing plant											

## COUNTRY

## Gelatine intended for human consumption

<b>Part II: Certification</b>	II.	Health information	II.a. Certificate reference number	II.b. Local reference number		
	1.	<p><b>Health attestation</b></p> <p>I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004 and (EC) No 853/2004 and certify that the gelatine described above was produced in accordance with those requirements, in particular that it:</p> <ul style="list-style-type: none"> <li>— comes from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004,</li> <li>— has been produced from raw material which met the requirements of Section XIV, Chapters I and II of Annex III to Regulation (EC) No 853/2004,</li> <li>— has been manufactured in compliance with the conditions set out in Section XIV, Chapter III of Annex III to Regulation (EC) No 853/2004,</li> <li>— satisfies the criteria of Section XIV, Chapter IV of Annex III to Regulation (EC) No 853/2004 and to Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs.</li> </ul> <p>and</p> <ul style="list-style-type: none"> <li>— if from ruminant origin, does not contain and is not derived from: <ul style="list-style-type: none"> <li>either <sup>(2)</sup></li> </ul> </li> </ul> <p>specified risk material as defined in Annex XI, section A, to Regulation (EC) No 999/2001 produced after 31 March 2001, or mechanically recovered meat obtained from bones of bovine, ovine or caprine animals produced after 31 March 2001. After 31 March 2001 the bovine, ovine and caprine animals, from which this product is derived, have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity.</p> <p>or</p> <p>bovine, ovine and caprine materials other than those derived from animals born, continuously reared and slaughtered in .....<sup>(3)(4)</sup>.</p>				
<p><b>Notes</b></p> <p>(1) Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship). This information is to be updated in case of unloading and reloading.</p> <p>(2) Delete one of these as appropriate.</p> <p>(3) Insert the name of the country.</p> <p>(4) As listed in point 15(b) of Annex XI to Regulation (EC) No 999/2001 as amended.</p> <p>(5) The colour of the stamp and signature must be different from that of the other particulars in the certificate.</p>						
<p>Official veterinarian or official inspector</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 60%; border: none;"> <p>Name (in capitals):</p> <p>Local veterinary unit:</p> <p>Date:</p> <p>Stamp <sup>(5)</sup></p> </td> <td style="width: 40%; border: none;"> <p>Qualification and title</p> <p>No of relevant LVU:</p> <p>Signature <sup>(5)</sup>:</p> </td> </tr> </table>					<p>Name (in capitals):</p> <p>Local veterinary unit:</p> <p>Date:</p> <p>Stamp <sup>(5)</sup></p>	<p>Qualification and title</p> <p>No of relevant LVU:</p> <p>Signature <sup>(5)</sup>:</p>
<p>Name (in capitals):</p> <p>Local veterinary unit:</p> <p>Date:</p> <p>Stamp <sup>(5)</sup></p>	<p>Qualification and title</p> <p>No of relevant LVU:</p> <p>Signature <sup>(5)</sup>:</p>					

PART B

MODEL HEALTH CERTIFICATE FOR IMPORTS OF RAW MATERIALS FOR THE PRODUCTION OF GELATINE INTENDED FOR HUMAN CONSUMPTION

COUNTRY

Veterinary certificate to EU

<b>Part I: Details of dispatched consignment</b>	I.1. Consignor <input type="checkbox"/> Name Address Postal code		I.2.		I.2.a. Local reference number:			
			I.3. Central Competent Authority					
			I.4. Local Competent Authority					
	I.5. Consignee Name Address Postal code		I.6.					
	I.7. Country of origin	ISO code	I.8. Region of origin	Code	I.9. Country of destination	ISO code	I.10. Region of destination	Code
	I.11. Place of origin Establishment <input type="checkbox"/> Name Address Name Address Name Address			I.12. Place of destination Establishment <input type="checkbox"/> Custom warehouse <input type="checkbox"/> Name Address Approval number Approval number Approval number Postal code				
	I.13.			I.14. Estimated date and time of arrival				
	I.15. Means of transport (*) Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> Identification: Documentary references:			I.16. I.17.				
	I.18. Animal species/Product				I.19. Commodity code (HS code)		I.20. Quantity	
	I.21. Temperature of product Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>				I.22. Number of packages			
I.23. Identification of container/Seal number				I.24. Type of packaging				
I.25. Animals certified as/products certified for: Human consumption <input type="checkbox"/>								
I.26.			I.27. For import or admission into EU <input type="checkbox"/> Definitive import <input type="checkbox"/>					
I.28. Identification of the animals/products Approval number of establishments Species (Scientific name) Nature of cuts/treatment type Abattoir/factory vessel Cutting plant/manufacturing plant Freezer vessel Quantity Net weight								

## COUNTRY

## Raw materials for the production of gelatine intended for human consumption

<b>Part II: Certification</b>	II.	Health information	II.a. Certificate reference number	II.b. Local reference number
	<b>1.</b>	<b>Health attestation</b>		
<p>I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004 and 854/2004 and certify that the raw material described above complies with those requirements, in particular that:</p> <ul style="list-style-type: none"> <li>— bones, hides and skins of farmed ruminant animals, pigskins, poultry skin and tendons and sinews described above derive from animals which have been slaughtered in a slaughterhouse and whose carcasses have been found fit for human consumption following ante- and post-mortem inspection <sup>(2)</sup>,</li> </ul> <p>and/or</p> <ul style="list-style-type: none"> <li>— wild game hides and skins described above derive from slaughtered animals whose carcasses have been found fit for human consumption following post-mortem inspection <sup>(2)</sup>,</li> </ul> <p>and/or</p> <ul style="list-style-type: none"> <li>— fish skin and bones described above come from plants manufacturing fish products for human consumption authorised for export <sup>(2)</sup>,</li> </ul> <p>and</p> <ul style="list-style-type: none"> <li>— if from ruminant origin, does not contain and is not derived from:</li> </ul> <p>either <sup>(2)</sup></p> <p>specified risk material as defined in Annex XI, section A, to Regulation (EC) N° 999/2001 produced after 31 March 2001, or mechanically recovered meat obtained from bones of bovine, ovine or caprine animals produced after 31 March 2001. After 31 March 2001 the bovine, ovine and caprine animals, from which this product is derived, have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity</p> <p>or</p> <p>bovine, ovine and caprine materials other than those derived from animals born, continuously reared and slaughtered in .....<sup>(3)(4)</sup>.</p>				
<b>Notes</b>				
(1) Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship). This information is to be updated in case of unloading and reloading.				
(2) Delete as appropriate.				
(3) Insert the name of the country.				
(4) As listed in point 15(b) of Annex XI to Regulation (EC) No 999/2001 as amended.				
(5) The colour of the stamp and signature must be different from that of the other particulars in the certificate.				
Official veterinarian or official inspector				
Name (in capitals):			Qualification and title	
Local veterinary unit:			No of relevant LVU:	
Date:			Signature <sup>(5)</sup> :	
Stamp <sup>(5)</sup>				

Appendix III to Annex VI

PART A

MODEL HEALTH CERTIFICATE FOR IMPORTS OF COLLAGEN INTENDED FOR HUMAN CONSUMPTION

COUNTRY

Veterinary certificate to EU

<b>Part I: Details of dispatched consignment</b>	I.1. Consignor <input type="checkbox"/> Name  Address  Postal code		I.2.		I.2.a. Local reference number:			
			I.3. Central Competent Authority					
			I.4. Local Competent Authority					
	I.5. Consignee Name  Address  Postal code		I.6.					
	I.7. Country of origin	ISO code	I.8. Region of origin	Code	I.9. Country of destination	ISO code	I.10. Region of destination	Code
	I.11. Place of origin  Establishment/vessel <input type="checkbox"/> Name Approval number Address Name Approval number Address Name Approval number Address				I.12. Place of destination  Establishment/vessel <input type="checkbox"/> Custom warehouse <input type="checkbox"/>  Name Approval number Address  Postal code			
	I.13.		I.14. Estimated date and time of arrival					
	I.15. Means of transport (*) Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> Identification: Documentary references:				I.16.			
					I.17.			
	I.18. Animal species/Product				I.19. Commodity code (HS code)		I.20. Quantity	
I.21. Temperature of product Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>				I.22. Number of packages				
I.23. Identification of container/Seal number				I.24. Type of packaging				
I.25. Animals certified as/products certified for:  Human consumption <input type="checkbox"/>								
I.26.		I.27. For import or admission into EU		<input type="checkbox"/>				
		Definitive import		<input type="checkbox"/>				
I.28. Identification of the animals/products  Approval number of establishments/vessel								
Species (Scientific name)	Nature of cuts/ treatment type	Factory vessel	Cutting plant/ manufacturing plant	Freezer vessel	Quantity	Net weight		

## COUNTRY

## Collagen intended for human consumption

<b>Part II: Certification</b>	II. Health information	II.a. Certificate reference number	II.b. Local reference number		
	<p><b>1. Health attestation</b></p> <p>I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004 and (EC) No 853/2004 and certify that the collagen described above was produced in accordance with those requirements, in particular that it:</p> <ul style="list-style-type: none"> <li>— comes from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004,</li> <li>— has been produced from raw material which met the requirements of Section XV, Chapters I and II of Annex III to Regulation (EC) No 853/2004,</li> <li>— has been manufactured in compliance with the conditions set out in Section XV, Chapter III of Annex III to Regulation (EC) No 853/2004,</li> </ul> <p>and</p> <ul style="list-style-type: none"> <li>— satisfies the criteria of Section XV, Chapter IV of Annex III to Regulation (EC) No 853/2004 and to Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs.</li> </ul>				
<p><b>Notes</b></p> <p>(1) Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship). This information is to be updated in case of unloading and reloading.</p> <p>(2) The colour of the stamp and signature must be different from that of the other particulars in the certificate.</p>					
<p>Official veterinarian or official inspector</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"> <p>Name (in capitals):</p> <p>Local veterinary unit:</p> <p>Date:</p> <p>Stamp <sup>(2)</sup></p> </td> <td style="width: 50%; border: none;"> <p>Qualification and title</p> <p>No of relevant LVU:</p> <p>Signature <sup>(2)</sup>:</p> </td> </tr> </table>				<p>Name (in capitals):</p> <p>Local veterinary unit:</p> <p>Date:</p> <p>Stamp <sup>(2)</sup></p>	<p>Qualification and title</p> <p>No of relevant LVU:</p> <p>Signature <sup>(2)</sup>:</p>
<p>Name (in capitals):</p> <p>Local veterinary unit:</p> <p>Date:</p> <p>Stamp <sup>(2)</sup></p>	<p>Qualification and title</p> <p>No of relevant LVU:</p> <p>Signature <sup>(2)</sup>:</p>				

PART B

**MODEL HEALTH CERTIFICATE FOR IMPORTS OF RAW MATERIALS FOR THE PRODUCTION OF COLLAGEN INTENDED FOR HUMAN CONSUMPTION**

**COUNTRY**

**Veterinary certificate to EU**

<b>Part I: Details of dispatched consignment</b>	I.1. Consignor <input type="checkbox"/> Name Address Postal code		I.2.		I.2.a. Local reference number:			
			I.3. Central Competent Authority					
			I.4. Local Competent Authority					
	I.5. Consignee Name Address Postal code		I.6.					
	I.7. Country of origin	ISO code	I.8. Region of origin	Code	I.9. Country of destination	ISO code	I.10. Region of destination	Code
	I.11. Place of origin Establishment <input type="checkbox"/> Name Approval number Address Name Approval number Address Name Approval number Address				I.12. Place of destination Establishment <input type="checkbox"/> Custom warehouse <input type="checkbox"/> Name Approval number Address Postal code			
	I.13.				I.14. Estimated date and time of arrival			
	I.15. Means of transport (*) Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> Identification: Documentary references:				I.16.			
					I.17.			
	I.18. Animal species/Product				I.19. Commodity code (HS code)		I.20. Quantity	
I.21. Temperature of product Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>				I.22. Number of packages				
I.23. Identification of container/Seal number				I.24. Type of packaging				
I.25. Animals certified as/products certified for: Human consumption <input type="checkbox"/>								
I.26.				I.27. For import or admission into EU <input type="checkbox"/> Definitive import <input type="checkbox"/>				
I.28. Identification of the animals/products Species Nature of cuts/ treatment type Abattoir/ factory vessel Cutting plant/ manufacturing plant Freezer vessel Quantity Net weight Approval number of establishments								



## COUNTRY

## Raw materials for the production of collagen intended for human consumption

<b>Part II: Certification</b>	II.	Health information	II.a. Certificate reference number	II.b. Local reference number		
	1.	<p><b>Health attestation</b></p> <p>I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004 and 854/2004 and certify that the raw material described above complies with those requirements, in particular that:</p> <ul style="list-style-type: none"> <li>— hides and skins of farmed ruminant animals/pigskins, bones and intestines/poultry skin and bones/tendons and sinews described above derive from animals which have been slaughtered in a slaughterhouse and whose carcasses have been found fit for human consumption following ante- and post-mortem inspection <sup>(2)</sup>,</li> </ul> <p>and/or</p> <ul style="list-style-type: none"> <li>— wild game hides and skins described above derive from slaughtered animals whose carcasses have been found fit for human consumption following post-mortem inspection <sup>(2)</sup>,</li> </ul> <p>and/or</p> <ul style="list-style-type: none"> <li>— fish skin and bones described above derive from plants manufacturing fish products for human consumption authorised for export <sup>(2)</sup>.</li> </ul>				
	<p><b>Notes</b></p> <p>(1) Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship). This information is to be updated in case of unloading and reloading.</p> <p>(2) Delete as appropriate.</p> <p>(3) The colour of the stamp and signature must be different from that of the other particulars in the certificate.</p>					
	<p>Official veterinarian or official inspector</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 60%; border: none;">           Name (in capitals):            Local veterinary unit:            Date:            Stamp <sup>(3)</sup> </td> <td style="width: 40%; border: none;">           Qualification and title            No of relevant LVU:            Signature <sup>(3)</sup>:         </td> </tr> </table>				Name (in capitals): Local veterinary unit: Date: Stamp <sup>(3)</sup>	Qualification and title No of relevant LVU: Signature <sup>(3)</sup> :
Name (in capitals): Local veterinary unit: Date: Stamp <sup>(3)</sup>	Qualification and title No of relevant LVU: Signature <sup>(3)</sup> :					

## ANNEX VII

## AMENDMENTS TO REGULATION (EC) No 853/2004

Annexes II and III to Regulation (EC) No 853/2004 are amended as follows:

1. Annex II, Section I(B) is amended as follows:

(a) in point 6, the second subparagraph is replaced by the following:

'BE, CZ, DK, DE, EE, GR, ES, FR, IE, IT, CY, LV, LT, LU, HU, MT, NL, AT, PL, PT, SI, SK, FI, SE and UK';

(b) point 8 is replaced by the following:

'8. When applied in an establishment located within the Community, the mark must be oval in shape and include the abbreviation CE, EC, EF, EG, EK, EY, ES, EÜ, EK, EB or WE';

2. Annex III is amended as follows:

(a) in Section I, Chapter IV, point 8 is replaced by the following:

'8. Carcasses and other parts of the body intended for human consumption must be completely skinned, except in the case of porcine animals, the heads of ovine and caprine animals and calves and the feet of bovine, ovine and caprine animals. Heads and feet must be handled in such a way as to avoid contamination;'

(b) in Section II, the following Chapter VII is added:

'CHAPTER VII: WATER RETENTION AGENTS

Food business operators shall ensure that poultrymeat that has been treated specifically to promote water retention is not placed on the market as fresh meat but as meat preparations or used for the production of processed products.'

(c) in Section VIII, Chapter V(E), point 1 is replaced by the following:

'1. Fishery products derived from poisonous fish of the following families must not be placed on the market: *Tetraodontidae*, *Molidae*, *Diodontidae* and *Canthigasteridae*. Fresh, prepared and processed fishery products belonging to the family *Gempylidae*, in particular *Ruvettus pretiosus* and *Lepidocybium flavobrunneum*, may only be placed on the market in wrapped/packaged form and must be appropriately labelled to provide information to the consumer on preparation/cooking methods and on the risk related to the presence of substances with adverse gastrointestinal effects. The scientific name must accompany the common name on the label';

(d) Section IX is amended as follows:

(i) in Chapter I(II)(B)(1), point (e) is replaced by the following:

'(e) that teat dips or sprays are used only after authorisation or registration in accordance with the procedures laid down in Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (\*).

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(\*) OJ L 123, 24.4.1998, p. 1.;

- (ii) in Chapter II(II), point 1 is replaced by the following:
- ‘1. When raw milk or dairy products undergo heat treatment, food business operators must ensure that this satisfies the requirements laid down in Chapter XI of Annex II to Regulation (EC) No 852/2004. In particular, they shall ensure, when using the following processes, that they comply with the specifications mentioned:
- (a) Pasteurisation is achieved by a treatment involving:
- (i) a high temperature for a short time (at least 72 °C for 15 seconds);
- (ii) a low temperature for a long time (at least 63 °C for 30 minutes); or
- (iii) any other combination of time-temperature conditions to obtain an equivalent effect,
- such that the products show, where applicable, a negative reaction to an alkaline phosphatase test immediately after such treatment.
- (b) Ultra high temperature (UHT) treatment is achieved by a treatment:
- (i) involving a continuous flow of heat at a high temperature for a short time (not less than 135 °C in combination with a suitable holding time) such that there are no viable micro-organisms or spores capable of growing in the treated product when kept in an aseptic closed container at ambient temperature; and
- (ii) sufficient to ensure that the products remain microbiologically stable after incubating for 15 days at 30 °C in closed containers or for 7 days at 55 °C in closed containers or after any other method demonstrating that the appropriate heat treatment has been applied.’;
- (e) in Section X, Chapter II is amended as follows:
- (i) in Part III, point 5 is replaced by the following:
- ‘5. After breaking, each particle of the liquid egg must undergo processing as quickly as possible to eliminate microbiological hazards or to reduce them to an acceptable level. A batch that has been insufficiently processed may immediately undergo processing again in the same establishment if this processing renders it fit for human consumption. Where a batch is found to be unfit for human consumption, it must be denatured to ensure that it is not used for human consumption.’;
- (ii) in Part V, point 2 is replaced by the following:
- ‘2. In the case of liquid egg, the label referred to in point 1 must also bear the words: “non-pasteurised liquid egg — to be treated at place of destination” and indicate the date and hour of breaking.’;
- (f) in Section XIV, the following Chapter V is added:

‘CHAPTER V: LABELLING

Wrapping and packaging containing gelatine must bear the words “gelatine fit for human consumption” and must indicate the date of preparation.’

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## ANNEX VIII

## AMENDMENTS TO REGULATION (EC) No 854/2004

Annexes I, II and III to Regulation (EC) No 854/2004 are amended as follows:

1. Annex I, Section I, Chapter III(3) is amended as follows:

(a) in point (a), the second subparagraph is replaced by the following:

‘BE, CZ, DK, DE, EE, GR, ES, FR, IE, IT, CY, LV, LT, LU, HU, MT, NL, AT, PL, PT, SI, SK, FI, SE and UK;’

(b) point (c) is replaced by the following:

‘(c) when applied in a slaughterhouse within the Community, the mark must include the abbreviation CE, EC, EF, EG, EK, EY, ES, EÜ, EK, EB or WE;’

2. in Annex II, Chapter II(A), points 4 and 5 are replaced by the following:

‘4. The competent authority may classify as being of Class B areas from which live bivalve molluscs may be collected and only placed on the market for human consumption after treatment in a purification centre or after relaying so as to meet the health standards referred to in paragraph 3. Live bivalve molluscs from these areas must not exceed 4 600 *E. coli* per 100 g of flesh and intravalvular liquid. The reference method for this analysis is the five-tube, three dilution Most Probable Number (MPN) test specified in ISO 16649-3. Alternative methods may be used if they are validated against this reference method in accordance with the criteria in EN/ISO 16140.

5. The competent authority may classify as being of Class C areas from which live bivalve molluscs may be collected and only placed on the market after relaying over a long period so as to meet the health standards referred to in paragraph 3. Live bivalve molluscs from these areas must not exceed 46 000 *E. coli* per 100 g of flesh and intravalvular liquid. The reference method for this analysis is the five-tube, three dilutions MPN test specified in ISO 16649-3. Alternative methods may be used if they are validated against this reference method in accordance with the criteria in EN/ISO 16140.’;

3. in Annex III, Chapter II(G), point 1 is replaced by the following:

‘1. Fishery products derived from poisonous fish of the following families must not be placed on the market: *Tetraodontidae*, *Moridae*, *Diodontidae* and *Canthigasteridae*. Fresh, prepared and processed fishery products belonging to the family *Gempylidae*, in particular *Ruvettus pretiosus* and *Lepidocybium flavobrunneum*, may only be placed on the market in wrapped/packaged form and must be appropriately labelled to provide information to the consumer on preparation/cooking methods and on the risk related to the presence of substances with adverse gastrointestinal effects. The scientific name must accompany the common name on the label.’

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**COMMISSION REGULATION (EC) No 2075/2005**  
**of 5 December 2005**  
**laying down specific rules on official controls for *Trichinella* in meat**  
**(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 854/2004 of the European Parliament and of the Council of 29 April laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption <sup>(1)</sup>, and in particular points 9 and 10 of Article 18 thereof,

Whereas:

- (1) 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 <sup>(2)</sup>, Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on the official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules <sup>(3)</sup> lay down the health rules and requirements regarding food of animal origin and the official controls required.
- (2) In addition to those rules, more specific requirements should be laid down for *Trichinella*. Meat of domestic swine, wild boar, horses and other animal species may be infested with nematodes of the genus *Trichinella*. Consumption of meat infested with *Trichinella* can cause serious disease in humans. Measures should be put in place to prevent human disease caused by the consumption of meat infested with *Trichinella*.

- (3) On 22 November 2001, the Scientific Committee on Veterinary Measures relating to Public Health adopted an opinion on trichinellosis, epidemiology, methods of detection and *Trichinella*-free pig production. On 1 December 2004, the Scientific Panel on biological hazards (Biohaz) of the European Food Safety Authority adopted an opinion on the suitability and details of freezing methods to allow human consumption of meat infected with *Trichinella* or *Cysticercus*. On 9 and 10 March 2005, Biohaz adopted an opinion on risk assessment of a revised inspection of slaughter animals in areas with low prevalence of *Trichinella*.

- (4) Council Directive 77/96/EEC of 21 December 1976 on the examination for trichinae (*trichinella spiralis*) upon importation from third countries of fresh meat derived from domestic swine <sup>(4)</sup> was 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 <sup>(5)</sup>.

- (5) Various laboratory methods have been approved for the detection of *Trichinella* in fresh meat. The magnetic stirrer method for pooled-sample digestion is recommended as a reliable method for routine use. Sample size for parasitic analysis should be increased if the sample cannot be collected at the predilection site and if the type or species of animal is at higher risk of being infected. Trichinoscopic examination fails to detect non-encapsulated *Trichinella* species infecting domestic and sylvatic animals and humans and is no longer suitable as a detection method for standard use. The trichinoscopic method should only be used under exceptional circumstances for the examination of a small number of animals slaughtered per week, provided that measures are taken by the food business operator to process the meat in such a way that it is completely safe for consumption. However, the method should be replaced by a more reliable detection method within a transitional period.

<sup>(1)</sup> OJ L 139, 30.4.2004, p. 206, corrected by OJ L 226, 25.6.2004, p. 83.

<sup>(2)</sup> OJ L 139, 30.4.2004, p. 55, corrected by OJ L 226, 25.6.2004, p. 22.

<sup>(3)</sup> OJ L 165, 30.4.2004, p. 1, corrected by OJ L 191, 28.5.2004, p. 1.

<sup>(4)</sup> OJ L 26, 31.1.1977, p. 67.

<sup>(5)</sup> OJ L 157, 30.4.2004, p. 33, corrected by OJ L 195, 2.6.2004, p. 12.

Other methods, such as serological tests, can be useful for monitoring purposes once the tests have been validated by a Community reference laboratory as soon as such a laboratory has been appointed by the Commission. Serological tests are not suitable for detecting *Trichinella* infestation in individual animals intended for human consumption.

- (6) Freezing meat under specified conditions can kill any parasites present but certain *Trichinella* species occurring in game and horses are resistant when freezing is carried out using the recommended temperature and time combinations.
- (7) Holdings should be officially recognised by the competent authority as *Trichinella*-free, provided specific conditions are met. Fattening pigs coming from such holdings should be exempted from inspection for *Trichinella*. Categories of holdings should be officially recognised by the competent authority as *Trichinella*-free, provided specific conditions are met. Such recognition should reduce the number of on-site inspections to be carried out by the competent authority, but is only feasible in Member States with a history of very low disease prevalence.
- (8) Regular monitoring of domestic swine, wild boar, horses and foxes or other indicator animals is an important tool for assessing changes in disease prevalence. The results of such monitoring should be communicated in an annual report in accordance with Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents <sup>(1)</sup>.
- (9) Regulation (EC) No 853/2004 does not apply to wild game or wild game meat directly supplied to the final consumer or to local retail establishments directly supplying the final consumer. It should therefore be the responsibility of the Member States to adopt national measures to mitigate the risk of *Trichinella*-infested wild boar meat reaching the final consumer.
- (10) The measures provided 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

### GENERAL PROVISION

#### Article 1

#### Definition

For the purposes of this Regulation '*Trichinella*' means any nematode belonging to species of the genus *Trichinella*.

## CHAPTER II

### OBLIGATIONS OF COMPETENT AUTHORITIES AND OF FOOD BUSINESS OPERATORS

#### Article 2

#### Sampling of carcasses

1. Carcasses of domestic swine shall be systematically sampled in slaughterhouses as part of the post-mortem examination.

A sample shall be collected from each carcass and the sample shall be examined for *Trichinella*, in a laboratory designated by the competent authority, using one of the following methods of detection:

- (a) the reference method of detection set out in Chapter I of Annex I; or
- (b) an equivalent method of detection set out in Chapter II of Annex I.

2. Pending the results of the *Trichinella* examination and provided full traceability is guaranteed by the food business operator.

- (a) Such carcasses may be cut up into a maximum of six parts in a slaughterhouse or in a cutting plant on the same premises as the slaughterhouse (the premises).
- (b) By way of derogation from subparagraph (a) and following approval by the competent authority, such carcasses may be cut up at a cutting plant attached to or separate from the slaughterhouse provided that:
  - (i) the procedure is under supervision by the competent authority;
  - (ii) a carcass or the parts thereof will not have more than one cutting plant as its destination;
  - (iii) the cutting plant is situated within the territory of the Member State; and

<sup>(1)</sup> OJ L 325, 12.12.2003, p. 31.

- (iv) in case of a positive result all the parts will be declared unfit for human consumption.

3. Carcasses of horses, wild boar and other farmed and wild animal species susceptible to *Trichinella* infestation shall be systematically sampled in slaughterhouses or game-handling establishments as part of the post-mortem examination.

Such sampling must not be carried out where the competent authority has ascertained by risk assessment that the risk of *Trichinella* infestation of a particular farmed or wild species is negligible.

A sample shall be collected from each carcass and the sample shall be examined in accordance with Annex I and III in a laboratory designated by the competent authority.

#### Article 3

### Derogations

1. By way of derogation from Article 2(1), meat of domestic swine that has undergone a freezing treatment in accordance with Annex II under the supervision of the competent authority shall be exempt from *Trichinella* examination.
2. By way of derogation from Article 2(1), carcasses and meat of domestic swine kept solely for fattening and slaughter shall be exempt from *Trichinella* examination where the animals come from:
  - (a) a holding or category of holdings that has been officially recognised by the competent authority as free from *Trichinella* in accordance with the procedure set out in Chapter II of Annex IV;
  - (b) a region where the risk of *Trichinella* in domestic swine is officially recognised as negligible following:
    - (i) forwarding of a notification to that effect by the Member State concerned, together with an initial report containing the information set out in Chapter II(D) of Annex IV, to the Commission and the other Member States; and
    - (ii) approval of the region as a region presenting a negligible *Trichinella* risk in accordance with the following procedure:

the other Member States shall have three months from receipt of the notification referred to in (i) to send written comments to the Commission. If the Commission or a Member State raises no objections, the region is recognised as a region presenting a negligible *Trichinella* risk and domestic swine coming from that region shall be exempted from examination for *Trichinella* at the time of slaughter;

the Commission shall publish the list of regions recognised as such on its website.

3. Where a competent authority implements the derogation provided for in paragraph 2, the Member State concerned shall submit an annual report to the Commission containing the information referred to in Chapter II(D) of Annex IV in accordance with Article 9(1) of Directive 2003/99/EC.

Where a Member State fails to submit that annual report or the annual report is unsatisfactory for the purposes of this Article, then the derogation shall cease to apply to that Member State.

#### Article 4

### Trichinella examination and application of health mark

1. Carcasses as referred to in Article 2 or parts thereof, except for those referred to in Article 2(2)(b), may not leave the premises, before the result of the *Trichinella* examination is found to be negative.

Similarly, other parts of an animal intended for human or animal consumption which contain striated muscle tissue may not leave the premises before the result of the *Trichinella* examination is found to be negative.

2. Animal waste and animal by-products not intended for human consumption and not containing striated muscle may leave the premises before the results of the *Trichinella* examination are available.

However, the competent authority may require a *Trichinella* examination or prior treatment of animal by-products to be carried out before permitting them to leave the premises.

3. Where a procedure is in place in the slaughterhouse to ensure that no part of carcasses examined leaves the premises until the result of the *Trichinella* examination is found to be negative and the procedure is formally approved by the competent authority, the health mark provided for in Article 5(2) of Regulation (EC) No 854/2004 may be applied before the results of the *Trichinella* examination are available.

#### Article 5

### Training

The competent authority shall ensure that all personnel involved in the examination of samples to detect *Trichinella* shall be properly trained and participate in:

- (a) a quality control programme of the tests used to detect *Trichinella*; and

- (b) a regular assessment of the testing, recording and analysis procedures used in the laboratory.

#### Article 6

#### Methods of detection

1. The methods of detection set out in Chapters I and II of Annex I shall be used for examining samples as referred to in Article 2:

- (a) where they provide grounds for suspecting *Trichinella* infestation; or
- (b) when samples coming from the same holding were previously found to be positive using the trichinoscopic method referred to in Article 16(1).

2. All positive samples shall be forwarded to the national reference laboratory or the Community reference laboratory for determination of the *Trichinella* species involved.

#### Article 7

#### Contingency plans

The competent authorities of the Member States shall prepare a contingency plan by 31 December 2006 outlining all action to be taken where samples as referred to in Articles 2 and 16 test positive to *Trichinella*. That plan shall include details covering:

- (a) traceability of infested carcase(s) and parts thereof containing muscle tissue;
- (b) measures for dealing with infested carcase(s) and parts thereof;
- (c) investigation of the source of infestation and any spreading among wildlife;
- (d) any measures to be taken at the retail or consumer level;
- (e) measures to be taken where the infested carcase cannot be identified at the slaughterhouse;
- (f) determination of the *Trichinella* species involved.

#### Article 8

#### Recognition of officially *Trichinella*-free holdings

The competent authority may officially recognise holdings or categories of holdings as free from *Trichinella* where the following requirements are complied with:

- (a) in the case of holdings, the requirements laid down in Chapter I and Chapter II(A), (B) and (D) of Annex IV;
- (b) in the case of categories of holdings, the requirements laid down in Chapter II(C) and (D) of Annex IV.

#### Article 9

#### Obligation on food business operators to inform

Food business operators of holdings recognised as free from *Trichinella* shall inform the competent authority of any requirement as laid down in Chapter I and II(B) of Annex IV that is no longer fulfilled or of any other change that might affect holdings' *Trichinella*-free status.

#### Article 10

#### Inspection of *Trichinella*-free holdings

The competent authority shall ensure that inspections are carried out periodically of holdings recognised as free from *Trichinella*.

The frequency of inspections shall be risk-based, taking account of disease history and prevalence, previous findings, the geographical area, local susceptible wildlife, animal husbandry practices, veterinary supervision and farmers' compliance.

The competent authority shall ensure that all breeding sows and boars coming from *Trichinella*-free holdings are examined in accordance with Article 2(1).

#### Article 11

#### Monitoring programmes

The competent authority shall implement a monitoring programme covering domestic swine, horses and other animal species susceptible for *Trichinella* coming from holdings or categories of holdings recognised as free from *Trichinella* or from regions where the risk of *Trichinella* in domestic swine is recognised as negligible, in order to verify that the animals are effectively free from *Trichinella*.

The frequency of testing, the number of animals to be tested and the sampling plan shall be laid down in the monitoring programme. To that end, meat samples shall be collected and examined for presence of *Trichinella* parasites in accordance with Chapter I or II of Annex I.

The monitoring programme may include serological methods as an additional tool once a suitable test is validated by the Community reference laboratory.



## Article 12

**Withdrawal of official recognition of *Trichinella*-free holdings or regions with negligible risk**

1. Where domestic swine, or other animal species susceptible to *Trichinella* infestation, from a holding officially recognised as free from *Trichinella* test positive to *Trichinella*, the competent authority shall without delay:

- (a) withdraw the holding's official recognition as free from *Trichinella*;
- (b) examine all domestic swine at the time of slaughter in accordance with Article 2(1) and conduct a serological test on all animals susceptible to *Trichinella* infestation on the holding once a suitable test has been validated by the Community reference laboratory;
- (c) trace and test all breeding animals that arrived on the holding and, as far as possible, all those that left the holding in at least the six months preceding the positive finding; to that end, meat samples shall be collected and examined for presence of *Trichinella* parasites using the detection methods in Chapters I and II of Annex I; a serological test may be used once a suitable test is validated by the Community reference laboratory;
- (d) as far as is feasible, investigate the spread of parasite infestation due to the distribution of meat from domestic swine slaughtered in the period preceding the positive finding;
- (e) inform the Commission and the other Member States;
- (f) initiate an epidemiological investigation to elucidate the cause of infestation;
- (g) increase the frequency of testing under, and the scope of the monitoring programme provided for in Article 11;
- (h) take appropriate measures where any infested carcass cannot be identified at the slaughterhouse, including:
  - (i) increasing the size of each meat sample collected for testing of the suspect carcasses; or
  - (ii) declaring the carcasses unfit for human consumption; and
  - (iii) taking appropriate measures for the disposal of suspect carcasses or parts thereof and those testing positive.

2. The competent authority shall withdraw official recognition of holdings or categories of holdings as free from *Trichinella* where:

- (i) any of the requirements laid down in Chapter I or II of Annex IV is no longer fulfilled;
  - (ii) serological results or laboratory findings following sampling of slaughtered swine show that the holding or category of holdings can no longer be considered free from *Trichinella*.
3. When information from the monitoring programme or the wildlife monitoring programme shows that a region can no longer be considered a region where the risk of *Trichinella* in domestic swine is recognised as negligible, the Commission shall withdraw the region from the list and inform the other Member States.
4. Following withdrawal of recognition, holdings may be recognised as officially free from *Trichinella* again once the problems identified have been solved and the requirements laid down in Chapter II(A) of Annex IV are fulfilled to the satisfaction of the competent authority.

## CHAPTER III

**IMPORTS**

## Article 13

**Import health requirements**

Meat of animal species that may be carriers of *Trichinella*, containing striated muscles and coming from a third country may only be imported into the Community if it has been examined for *Trichinella* in that third country before export.

Such examination shall be carried out in accordance with Article 2 on the whole carcass or, failing this, on each half-carcass, quarter, part or cut thereof.

## Article 14

**Derogations from Article 13**

1. Meat of domestic swine may be imported without having undergone the examination referred to in Article 13, provided it comes from a holding in a third country that has been recognised by the Community as officially free from *Trichinella* in accordance with Article 12 of Regulation (EC) No 854/2004 on the basis of a request from the competent authority of that country, accompanied by a report to the Commission providing evidence that the requirements set out in Chapter I of Annex IV are met.

2. Meat of domestic swine may be imported without having undergone the examination referred to in Article 13, provided

it has undergone a freezing treatment in accordance with Annex II carried out under the supervision of the competent authority in the third country.

*Article 15*

**Documents**

The health certificate accompanying imports of meat as referred to in Article 13 shall be endorsed with a statement by the official veterinarian to the effect that:

- (a) the meat has been examined in the third country of origin in accordance with Article 13; or
- (b) the meat satisfies the requirements set out in Article 14 (1) or (2).

That document shall accompany the meat in the original unless an exemption has been granted in accordance with Article 14(4) of Regulation (EC) No 854/2004.

CHAPTER IV

**TRANSITIONAL AND FINAL PROVISIONS**

*Article 16*

**Transitional provisions**

1. The Member State may allow the trichoscopic method set out in Chapter III of Annex I to be used for domestic swine

and wild boar in exceptional cases until 31 December 2009, where:

- (a) single carcasses as referred to in Article 2 need to be examined individually in an establishment that does not slaughter more than 15 domestic swine per day or 75 domestic swine per week or prepare for placing on the market more than 10 wild boar per day; and
- (b) the detection methods set out in Chapters I and II of Annex I are not available.

2. Where the trichoscopic method is used, the competent authority shall ensure that:

- (a) the meat is marked with a health mark that is clearly different from the health mark provided for in Article 5 (1)(a) of Regulation (EC) No 853/2004, and the meat is supplied directly to the final consumer or to retail establishments directly supplying the final consumer; and
- (b) the meat is not used for the production of products where the production process does not kill *Trichinella*.

*Article 17*

**Entry into force**

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, 5 December 2005.

*For the Commission*

Markos KYPRIANOU

*Member of the Commission*

## ANNEX I

**Detection methods**

## CHAPTER I

**REFERENCE METHOD OF DETECTION****Magnetic stirrer method for pooled sample digestion**

1. *Apparatus and reagents*
  - (a) Knife or scissors and tweezers for cutting specimens
  - (b) Trays marked off into 50 squares, each of which can hold samples of approximately 2 g of meat, or other tools giving equivalent guarantees as regards the traceability of the samples
  - (c) A blender with a sharp chopping blade. Where the samples are larger than 3 g, a meat mincer with openings of 2 to 4 mm or scissors must be used. In the case of frozen meat or tongue (after removal of the superficial layer, which cannot be digested), a meat mincer is necessary and the sample size will need to be increased considerably
  - (d) Magnetic stirrers with thermostatically controlled heating plate and teflon-coated stirring rods approximately 5 cm long
  - (e) Conical glass separation funnels, capacity of at least 2 litres, preferably fitted with teflon safety plugs
  - (f) Stands, rings and clamps
  - (g) Sieves, mesh size 180 microns, external diameter 11 cm, with stainless steel mesh
  - (h) Funnels, internal diameter not less than 12 cm, to support the sieves
  - (i) Glass beakers, capacity 3 litres
  - (j) Glass measuring cylinders, capacity 50 to 100 ml, or centrifuge tubes
  - (k) A trichinoscope with a horizontal table or a stereo-microscope, with a substage transmitted light source of adjustable intensity
  - (l) A number of 9 cm diameter petri dishes (for use with a stereo-microscope), marked on their undersides into 10 × 10 mm square examination areas using a pointed instrument
  - (m) A larval counting basin (for use with a trichinoscope), made of 3 mm thick acrylic plates as follows:
    - (i) the bottom of the basin to be 180 × 40 mm, marked off into squares,
    - (ii) the sides to be 230 × 20 mm,
    - (iii) the end to be 40 × 20 mm. The bottom and the ends must be inserted between the sides, to form two small handles at the ends. The upper side of the bottom must be raised 7 to 9 mm from the base of the frame formed by the sides and the ends. The components must be stuck together with glue suitable for the material
  - (n) Aluminium foil

- (o) 25 % hydrochloric acid
- (p) Pepsin, strength: 1: 10 000 NF (US National Formulary) corresponding to 1: 12 500 BP (British Pharmacopoea) and to 2 000 FIP (Fédération internationale de pharmacie)
- (q) Tap water heated to 46 to 48 °C
- (r) A balance accurate to at least 0,1 g
- (s) Metal trays, capacity 10 to 15 litres, to collect the remaining digestive juice
- (t) Pipettes of different sizes (1, 10 and 25 ml) and pipette holders
- (u) A thermometer accurate to 0,5 °C within the range 1 to 100 °C
- (v) Siphon for tap water.

## 2. *Collecting of specimens and quantity to be digested*

- (a) In the case of whole carcasses of domestic swine, a specimen weighing at least 1 g is to be taken from a pillar of the diaphragm at the transition to the sinewy part. Special trichinae forceps can be used provided an accuracy of between 1,00 and 1,15 g can be guaranteed.

In the case of breeding sows and boars, a larger sample weighing at least 2 g is to be taken from a pillar of the diaphragm at the transition to the sinewy part.

In the absence of diaphragm pillars, a specimen of twice the size 2 g (or 4 g in the case of breeding sows and boars) is to be taken from the rib part or the breastbone part of the diaphragm, or from the jaw muscle, tongue or abdominal muscles.

- (b) For cuts of meat, a sample weighing at least 5 g of striated muscle, containing little fat is to be taken, where possible from close to bones or tendons. A sample of the same size is to be collected from meat that is not intended to be cooked thoroughly or other types of post-slaughter processing.
- (c) For frozen samples, a sample weighing at least 5 g of striated muscle tissue is to be taken for analysis.

The weight of meat specimens relates to a sample of meat that is free of all fat and fascia. Special attention must be paid when collecting muscle samples from the tongue in order to avoid contamination with the superficial layer of the tongue, which is indigestible and can prevent reading of the sediment.

## 3. *Procedure*

### I. Complete pools (100 g of samples at a time)

- (a)  $16 \pm 0,5$  ml of hydrochloric acid is added to a 3 litre beaker containing 2,0 litre of tap water, preheated to 46 to 48 °C; a stirring rod is placed in the beaker, the beaker is placed on the preheated plate and the stirring is started.
- (b)  $10 \pm 0,2$  g of pepsin is added.
- (c) 100 g of samples collected in accordance with point 2 is chopped in the blender.
- (d) The chopped meat is transferred to the 3 litre beaker containing the water, pepsin and hydrochloric acid.
- (e) The mincing insert of the blender is immersed repeatedly in the digestion fluid in the beaker and the blender bowl is rinsed with a small quantity of digestion fluid to remove any meat still adhering.
- (f) The beaker is covered with aluminium foil.
- (g) The magnetic stirrer must be adjusted so that it maintains a constant temperature of 44 to 46 °C throughout the operation. During stirring, the digestion fluid must rotate at a sufficiently high speed to create a deep whirl without splashing.

- (h) The digestion fluid is stirred until the meat particles disappear (approximately 30 minutes). The stirrer is then switched off and the digestion fluid is poured through the sieve into the sedimentation funnel. Longer digestion times may be necessary (not exceeding 60 minutes) in the processing of certain types of meat (tongue, game meat, etc.).
- (i) The digestion process is considered satisfactory if not more than 5 % of the starting sample weight remains on the sieve.
- (j) The digestion fluid is allowed to stand in the funnel for 30 minutes.
- (k) After 30 minutes, a 40 ml sample of digestion fluid is quickly run off into the measuring cylinder or centrifuge tube.
- (l) The digestion fluids and other liquid waste are kept in a tray until reading of the results is completed.
- (m) The 40 ml sample is allowed to stand for 10 minutes. 30 ml of supernatant is then carefully withdrawn by suction to remove the upper layers and leave a volume of not more than 10 ml.
- (n) The remaining 10 ml sample of sediment is poured into a larval counting basin or petri dish.
- (o) The cylinder or centrifuge tube is rinsed with not more than 10 ml of tap water, which has to be added to the sample in the larval counting basin or petri dish. Subsequently, the sample is examined by trichinoscope or stereo-microscope at a 15 to 20 times magnification. Visualisation using other techniques is allowed, provided examination of positive control samples has been shown to give an equal or better result than traditional visualisation methods. In all cases of suspect areas or parasite-like shapes, higher magnifications of 60 to 100 times must be used.
- (p) Digests are to be examined as soon as they are ready. Under no circumstances should examination be postponed until the following day.

Where the digests are not examined within 30 minutes of preparation, they must be clarified as follows. The final sample of about 40 ml is poured into a measuring cylinder and allowed to stand for 10 minutes. 30 ml of the supernatant fluid is then removed, leaving a volume of 10 ml. This volume is made up to 40 ml with tap water. After a further settling period of 10 minutes, 30 ml of the supernatant fluid is withdrawn by suction, leaving a volume of no more than 10 ml for examination in a petri dish or larval counting basin. The measuring cylinder is washed with no more than 10 ml of tap water and these washings are added to the sample in the petri dish or the larval counting basin for examination.

If the sediment is found to be unclear on examination, the sample is poured into a measuring cylinder and made up to 40 ml with tap water and then the above procedure is followed. The procedure can be repeated 2 to 4 times until the fluid is clear enough for a reliable reading.

## II. Pools of less than 100 g

Where needed, up to 15 g can be added to a total pool of 100 g and examined together with these samples in accordance with 3(l). More than 15 g must be examined as a complete pool. For pools of up to 50 g, the digestion fluid and the ingredients may be reduced to 1 litre of water, 8 ml of hydrochloric acid and 5 g of pepsin.

## III. Positive or doubtful results

Where examination of a collective sample produces a positive or uncertain result, a further 20 g sample is taken from each pig in accordance with 2(a). The 20 g samples from five pigs are pooled and examined using the method described above. In this way samples from 20 groups of five pigs will be examined.

When *Trichinella* is detected in a pooled sample from five pigs, further 20 g samples are collected from the individual pigs in the group and each is examined separately using the method described above.

Parasite samples are to be kept in 90 % ethyl alcohol for conservation and identification at species level at the Community or national reference laboratory.

After parasite collection, positive fluids (digestive juice, supernatant fluid, washings, etc.) are to be decontaminated by heating to at least 60 °C.

## CHAPTER II

### EQUIVALENT METHODS

#### A. Mechanically assisted pooled sample digestion method/sedimentation technique

##### 1. Apparatus and reagents

- (a) Knife or scissors for cutting specimens
- (b) Trays marked off with 50 squares, each of which can hold samples of approximately 2 g of meat, or other tools giving equivalent guarantees as regards the traceability of the samples
- (c) Meat mincer or electrical blender
- (d) A stomacher lab-blender 3 500 thermo model
- (e) Plastic bags suitable for the stomacher lab-blender
- (f) Conical separation funnels, capacity 2 litres, preferably fitted with teflon safety plugs
- (g) Stands, rings and clamps
- (h) Sieves, mesh size 180 microns, external diameter 11 cm, with stainless steel or brass mesh
- (i) Funnels, internal diameter not less than 12 cm, to support the sieves
- (j) 100 ml glass measuring cylinders
- (k) A thermometer accurate to 0,5 °C within the range 1 to 100 °C
- (l) A vibrator, e.g. an electric shaver with the head removed
- (m) A relay which will switch on and off at one-minute intervals
- (n) A trichinoscope with a horizontal table or a stereo-microscope, with a sub-stage transmitted light source of adjustable intensity
- (o) A larval counting basin and a number of 9 cm diameter petri dishes as in Chapter I(1)(l) and (m)
- (p) 17,5 % hydrochloric acid
- (q) Pepsin, strength 1: 10 000 NF (US national formulary) corresponding to 1: 12 500 BP (British Pharmacopoeia) and to 2 000 FIP (Fédération internationale de pharmacie),
- (r) A number of 10 litre bins to be used for decontamination of apparatus, e.g. with formol, and for digestive juice remaining where specimens test positive
- (s) A balance accurate to 0,1 g.

##### 2. Collecting of specimens and quantity to be digested

As stipulated in Chapter I(2).

### 3. Procedure

#### I. Grinding

Grinding the meat samples in a meat mincer beforehand will improve the digestion quality. If an electrical blender is used, the blender must be operated three to four times for approximately one second each time.

#### II. Digestion procedure

This procedure may involve complete pools (100 g of samples at a time) or pools of less than 100 g.

##### (a) Complete pools (100 samples at a time)

- (i) The stomacher lab-blender 3 500 is fitted with a double plastic bag and the temperature control set at 40 to 41 °C.
- (ii) One and a half litres of water preheated to 40 to 41 °C is poured into the inner plastic bag.
- (iii) 25 ml of 17,5 % hydrochloric acid is added to the water in the stomacher.
- (iv) 100 samples weighing approximately 1 g each (at 25 to 30 °C) taken from each individual sample in accordance with 2 are added.
- (v) Lastly, 6 g pepsin is added. This order must be followed strictly to avoid decomposition of the pepsin.
- (vi) The stomacher is then allowed to pound the content of the bag for 25 minutes.
- (vii) The plastic bag is removed from the stomacher and the digestion fluid is filtered through the sieve into a 3 litre beaker.
- (viii) The plastic bag is washed with approximately 100 ml of water, which is then used to rinse the sieve and lastly added to the filtrate in the beaker.
- (ix) Up to 15 individual samples can be added to a total pool of 100 samples and examined together with these samples.

##### (b) Smaller pools (less than 100 samples)

- (i) The stomacher lab-blender 3 500 is fitted with a double plastic bag and the temperature control set at 40 to 41 °C.
- (ii) A digestion fluid is prepared by mixing about one and a half litres of water and 25 ml of 17,5 % hydrochloric acid. 6 g of pepsin is added and the whole mixed at a temperature of 40 to 41 °C. This order must be followed strictly to avoid decomposition of the pepsin.
- (iii) Of the digestion fluid, a volume corresponding to 15 ml per gram of sample is measured (e.g. for 30 samples the volume required is  $30 \times 15 \text{ ml} = 450 \text{ ml}$ ) and transferred to the inner of the two plastic bags, together with the meat samples weighing approximately 1 g (at 25 to 30 °C) taken from each individual sample in accordance with 2.
- (iv) Water at a temperature of approximately 41 °C is poured into the outer bag to make up a total volume in the two bags of one and a half litres. The stomacher is then allowed to pound the content of the bag for 25 minutes.
- (v) The plastic bag is removed from the stomacher and the digestion fluid is filtered through the sieve into a 3 litre beaker.
- (vi) The plastic bag is washed with approximately 100 ml of water (at 25 to 30 °C), which is then used to rinse the sieve and lastly added to the filtrate in the beaker.

#### III. Recovery of larvae by sedimentation

- Ice (300 to 400 g of ice flakes, scaly ice or crushed ice) is added to the digestion fluid to bring its volume up to about 2 litres. The digestion fluid is then stirred until the ice has melted. In the

case of smaller pools (see II(b)), the amount of ice must be reduced correspondingly.

- The chilled digestion fluid is transferred to a 2 litre separation funnel, equipped with a vibrator in an extra clamp.
- Sedimentation is allowed to proceed for 30 minutes, during which time the sedimentation funnel is vibrated intermittently, i.e. one minute vibration followed by a one-minute pause.
- After 30 minutes, a 60 ml sample of the sediment is quickly run off into a 100 ml measuring cylinder (the funnel is rinsed with detergent solution after use).
- The 60 ml sample is allowed to stand for at least 10 minutes, after which time the supernatant is withdrawn by suction to leave a volume of 15 ml, to be examined for presence of larvae.
- For suction, a disposable syringe, equipped with a plastic tube, can be used. The length of the tube must be such that 15 ml remains in the measuring cylinder when the flanges of the syringe rest on the cylinder's rim.
- The remaining 15 ml is poured into a larval counting basin or two petri dishes and examined using a trichinoscope or stereo-microscope.
- The measuring cylinder is washed with 5 to 10 ml of tap water and the washings are added to the sample.
- Digests are to be examined as soon as they are ready. Under no circumstances is examination to be postponed until the following day.

Where the digests are unclear or they are not examined within 30 minutes of their preparation, they must be clarified as follows:

- the final sample of 60 ml is poured into a measuring cylinder and allowed to stand for 10 minutes; 45 ml of supernatant fluid is then removed by suction and the remaining 15 ml is made up to 45 ml with tap water,
- after a further settling period of 10 minutes, 30 ml of supernatant fluid is removed by suction and the remaining 15 ml is poured into a petri dish or larval counting basin for examination,
- the measuring cylinder is washed with 10 ml of tap water and these washings are added to the sample in the petri dish or the larval counting basin for examination.

#### IV. Positive or doubtful results

Where the result is positive or uncertain, the provisions laid down in Chapter I(3)(III) shall apply.

### B. Mechanically assisted pooled sample digestion method/'on filter isolation' technique

#### 1. Apparatus and reagents

As stipulated in Chapter II(A)(1).

Additional equipment:

- (a) 1 litre Gelman funnel, complete with filter holder (diameter 45 mm);
- (b) filter discs, consisting of a circular stainless steel mesh with an aperture of 35 microns (disc diameter: 45 mm), two rubber rings 1 mm thick (external diameter: 45 mm; internal diameter: 38 mm), the circular mesh being placed between the two rubber rings and bonded to them using a two-component glue suitable for the two materials;
- (c) an Erlenmeyer flask, capacity 3 litres, fitted with a side tube for suction;
- (d) a filter pump;



- (e) plastic bags, capacity at least 80 ml;
- (f) equipment for sealing the plastic bags;
- (g) rennilase, strength 1: 150 000 soxhlet units per gram.

## 2. *Collecting of specimens*

As stipulated in Chapter I(2).

## 3. *Procedure*

### I. Grinding

Grinding the meat samples in a meat mincer beforehand will improve the digestion quality. If an electrical blender is used, the blender must be operated three to four times for approximately one second each time.

### II. Digestion procedure

This procedure may involve complete pools (100 g of samples at a time) or pools of less than 100 g.

#### (a) Complete pools (100 samples at a time)

See Chapter II(A)(3)(II)(a).

#### (b) Smaller pools (less than 100 samples)

See Chapter II(A)(3)(II)(b).

### III. Recovery of larvae by filtration

(a) Ice (300 to 400 g of ice flakes, scaly ice or crushed ice) is added to the digestion fluid to bring its volume up to about 2 litres. In the case of smaller pools, the amount of ice must be reduced correspondingly.

(b) The digestion fluid is stirred until the ice has melted. The chilled digestion fluid is then left for at least three minutes to let the larvae coil.

(c) The Gelman funnel, fitted with a filter holder and filter disc, is mounted on an Erlenmeyer flask connected to a filter pump.

(d) The digestion fluid is poured into the Gelman funnel and filtered. Towards the end of filtration, the digestion fluid can be helped to pass through the filter by applying suction with the filter pump. Suction must cease before the filter becomes dry, i.e. when 2 to 5 ml of fluid is left in the funnel.

(e) Once all the digestion fluid has been filtered, the filter disc is removed and placed in an 80 ml capacity plastic bag, together with 15 to 20 ml of rennilase solution. The rennilase solution is made by adding 2 g of rennilase to 100 ml of tap water.

(f) The plastic bag is sealed twice and placed between the inner and outer bags in the stomacher.

(g) The stomacher is allowed to pound for three minutes, e.g. while it is working on a complete or incomplete pool.

(h) After three minutes, the plastic bag, complete with filter disc and rennilase solution, is removed from the stomacher and opened with scissors. The liquid contents are poured into a larval counting basin or petri dish. The bag is washed out with 5 to 10 ml of water, which is then added to the larval counting basin for examination by trichinoscope or to the petri dish for examination by stereo-microscope.

- (i) Digests must be examined as soon as they are ready. Under no circumstances is examination to be postponed until the following day.

*Note:* Filter discs must never be used when not completely clean. Unclean discs must never be allowed to dry out. Filter discs can be cleaned by leaving them in rennilase solution overnight. Before use, they must be washed in fresh rennilase solution using the stomacher.

IV. Positive or doubtful results

Where the result is positive or uncertain, the provisions laid down in Chapter I(3)(III) shall apply.

C. **Automatic digestion method for pooled samples of up to 35 g**

1. *Apparatus and reagents*

- (a) Knife or scissors for cutting specimens
- (b) Trays marked off with 50 squares, each of which can hold samples of approximately 2 g of meat, or other tools giving equivalent guarantees as regards the traceability of the samples
- (c) A Trichomatic 35<sup>®</sup> blender with filtration insert
- (d) Hydrochloric acid 8,5 ± 0,5 % weight
- (e) Transparent polycarbonate membrane filters with a diameter of 50 mm and a pore size of 14 microns
- (f) Pepsin, strength 1: 10 000 NF (US National Formulary) corresponding to 1: 12 500 BP (British Pharmacopoeia) and to 2 000 FIP (Fédération internationale de pharmacie)
- (g) A balance accurate to 0,1 g
- (h) Tweezers with a flat tip
- (i) A number of microscope slides with a side-length of at least 5 cm or a number of petri dishes at least 6 cm in diameter, marked on their undersides into 10 × 10 mm square areas using a pointed instrument
- (j) A (stereo-)microscope with transmitted light (magnification 15 to 60 times) or a trichinoscope with a horizontal table
- (k) A bin for collection of waste liquids
- (l) A number of 10 litre bins to be used for decontamination of apparatus, e.g. with formol, and for digestive juice remaining where specimens test positive
- (m) a thermometer accurate to 0,5 °C within the range 1 to 100 °C.

2. *Collecting of specimens*

As stipulated in Chapter I(2).

3. *Procedure*

I. *Digestion procedure*

- (a) Place the blender with the filtration insert, connect the waste tube and place the tube so it drains into the waste bin.
- (b) When the blender is switched on, heating will start.
- (c) Before this is done, the bottom valve located below the reaction chamber must be opened and closed.

- (d) Up to 35 samples weighing approximately 1 g each (at 25 to 30 °C) taken from each individual sample in accordance with point 2 are then added. Ensure that larger pieces of tendons are removed as they may clot the membrane filter.
- (e) Pour water up to the edge of a liquid chamber connected to the blender (approximately 400 ml).
- (f) Pour about 30 ml hydrochloric acid ((8,5 %) to the edge of the smaller, connected liquid chamber.
- (g) Place a membrane filter under the coarse filter in the filter holder in the filter insert.
- (h) Lastly, add 7 g of pepsin. This order must be followed strictly to avoid decomposition of the pepsin.
- (i) Close the lids of the reaction and liquid chambers.
- (j) Select the period of digestion. A short digestion period (5 minutes) must be set for pigs at the normal slaughter age and a longer time (8 minutes) for other samples.
- (k) When the start button on the blender is turned on, the process of dispensing and digestion starts automatically, followed by filtration. After 10 to 13 minutes the process is completed and stops automatically.
- (l) Open the lid of the reaction chamber after checking that the chamber is empty. If there is foam or any digestion liquid remaining in the chamber, repeat the procedure in accordance with V.

#### II. Recovery of larvae

- (a) Remove the filter holder and transfer the membrane filter to a slide or Petri dish.
- (b) Examine the membrane filter using a (stereo-) microscope or a trichinoscope.

#### III. Cleaning equipment

- (a) Where the result is positive, fill the blender reaction chamber with boiling water until it is two-thirds full. Ordinary tap water is poured into the connecting liquid chamber until it covers the lower sensor. Automatic cleaning then takes place. Decontaminate the filter-holder and any other equipment, e.g. using formol.
- (b) After work is completed for the day, fill the blender liquid chamber with water and put it through a standard cycle.

#### IV. Use of membrane filters

Each polycarbonate membrane filter may be used no more than five times. The filter is to be turned between each use. In addition, the filter must be checked after each use for any damage which would make it unsuitable for further use.

#### V. Method to be applied when digestion is incomplete and filtration cannot be carried out

Once the blender has been put through an automatic cycle in accordance with C(3)(l), open the lid of the reaction chamber and check whether there is foam or any liquid remaining in the chamber. If this is the case, proceed as follows:

- (a) close the bottom valve below the reaction chamber;
- (b) remove the filter holder and transfer the membrane filter to a slide or Petri dish;
- (c) put a new membrane filter in the filter holder and attach the filter holder;
- (d) fill the blender liquid chamber with water until the lower sensor is covered;
- (e) carry out the automatic cleaning cycle;
- (f) after the cleaning cycle has ended, open the lid of the reaction chamber and check whether any liquid remains;

- (g) if the chamber is empty, remove the filter holder and transfer the membrane filter to a slide or Petri dish with tweezers;
- (h) examine the two membrane filters in accordance with C(3)(II). If the filters cannot be examined, repeat the entire digestion process with a longer digestion time in accordance with C(3)(I).

VI. Positive or doubtful results

Where the result is positive or uncertain, the provisions laid down in Chapter I(3)(III) shall apply.

CHAPTER III

**TRICHINOSCOPIC EXAMINATION**

1. *Apparatus*

- (a) An incandescent-lamp trichinoscope with 30 to 40 times and 80 to 100 times magnification or a stereomicroscope with a substage transmitted light source of adjustable intensity
- (b) A compressorium being a pressure glass consisting of two glass plates (one of which is divided into equal fields)
- (c) Small curved scissors
- (d) Small forceps
- (e) A knife for cutting specimens
- (f) Small numbered containers for storing the specimens separately
- (g) A dropping pipette
- (h) A glass of acetic acid and a glass of potassium hydroxide solution for brightening any calcifications and softening dried meat.

2. *Collecting of specimens*

In the case of whole carcasses, several hazelnut-size samples are taken from each animal:

- (a) in domestic swine, such samples are taken from both diaphragm pillars at the transition of the sinewy part;
- (b) in wild boar samples are taken from both diaphragm pillars at the transition of the sinewy part and in addition from the jaw, the muscles of the lower leg, the intercostal muscles and the tongue muscles, giving a total of six samples from each individual animal;
- (c) if certain muscles are not available for sampling, a total of four samples are taken from the muscles that are available;
- (d) in pieces of meat, four hazelnut-size samples of striated muscle tissue containing if possible no fat, taken from different points, are taken from each piece, where possible close to bones or tendons.

3. *Procedure*

- (a) In general a compressorium is filled with  $1,0 \pm 0,1$  g of meat, normally corresponding with 28 oat-kernel-size pieces. If necessary, two compressoria need to be filled to examine 56 oat-kernel-size pieces.
- (b) If both diaphragm pillars are present in a domestic swine, the *Trichinella* inspector cuts 28 oat-kernel-size pieces from each of the above specimens taken from a whole carcass, making 56 pieces in all.
- (c) If only one diaphragm pillar is present, 56 pieces are cut in different places, if possible from the transition to the sinewy part.

- (d) The samples collected from the other four muscles of wild boar are each cut into seven oat-kernel-size pieces, giving a total of 28 additional pieces.
  - (e) The *Trichinella* inspector then compresses the 56 (or 84) pieces between the glass plates so that normal print can be clearly read through the slide preparation.
  - (f) If the flesh of the specimens to be examined is dry and old, the preparations must be softened for 10 to 20 minutes before pressing with a mixture of one part of potassium hydroxide solution to about two parts of water.
  - (g) From each of the samples taken from pieces of meat, the *Trichinella* inspector cuts 14 oat-kernel-size pieces, making 56 pieces in all.
  - (h) The microscopic examination must be carried out by scanning each preparation slowly and carefully at a magnification of 30 to 40 times.
  - (i) If the trichinoscopic examination reveals suspect areas, they must be examined at the trichinoscope's most powerful magnification (80 to 100 times).
  - (j) Where the result is uncertain, the examination is repeated on other specimens and slide preparations until the information required is obtained. The trichinoscopic examination must be carried out for at least six minutes.
  - (k) The minimum time fixed for the examination does not include the time necessary for taking samples and making the preparations.
  - (l) As a general rule, the trichinoscopic examiner must not inspect more than 840 pieces a day, corresponding with examinations of 15 domestic swine or 10 wild boar.
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## ANNEX II

**Freezing treatments**A. *Freezing method 1*

- (a) Meat brought in already frozen is to be kept in this condition.
- (b) The technical equipment and energy supply of the refrigeration room must be such as to ensure that the required temperature is reached very rapidly and maintained in all parts of the room and of the meat.
- (c) Insulated packaging must be removed before freezing, except in the case of meat that is already at the required temperature throughout when it is brought into the refrigeration room or meat so packaged that the packaging will not prevent it from reaching the required temperature within the specified time.
- (d) Consignments in the refrigeration room must be kept separately and under lock and key.
- (e) The date and time when each consignment is brought into the refrigeration room must be recorded.
- (f) The temperature in the refrigeration room must be at least  $-25^{\circ}\text{C}$ . It must be measured using calibrated thermo-electric instruments and recorded continuously. It may not be measured directly in the cold air flow. The instruments must be kept under lock and key. The temperature charts must include the relevant data from the meat inspection register on import and the date and time of commencement and completion of freezing, and must be retained for one year after compilation.
- (g) Meat of a diameter or thickness of up to 25 cm must be frozen for at least 240 consecutive hours, and meat of a diameter or thickness of between 25 and 50 cm must be frozen for at least 480 consecutive hours. This freezing process must not be applied to meat that is thicker or of a larger diameter. The freezing time is calculated from the point when the temperature in the freezing room reaches that specified in (f).

B. *Freezing method 2*

The general provisions of (a) to (e) of method 1 are complied with, and the following time-temperature combinations applied:

- (a) meat of a diameter or thickness of up to 15 cm must be frozen for one of the following time-temperature combinations:
  - 20 days at  $-15^{\circ}\text{C}$ ,
  - 10 days at  $-23^{\circ}\text{C}$ ,
  - 6 days at  $-29^{\circ}\text{C}$ ;
- (b) meat of a diameter or thickness of between 15 cm and 50 cm must be frozen for one of the following time-temperature combinations:
  - 30 days at  $-15^{\circ}\text{C}$ ,
  - 20 days at  $-25^{\circ}\text{C}$ ,
  - 12 days at  $-29^{\circ}\text{C}$ .

The temperature in the refrigeration room must be no higher than the level of the selected inactivation temperature. It must be measured using calibrated thermoelectric instruments and recorded continuously. It must not be measured directly in the cold air flow. The instruments must be kept under lock and key.

The temperature charts must include the relevant data from the meat inspection register on importation and the date and time of commencement and completion of freezing, and must be retained for one year after compilation.

Where freezing tunnels are used and the above procedures are not followed strictly, the food business operator must be able to prove to the competent authority that the alternative method is effective in killing *Trichinella* parasites in pigmeat.

C. *Freezing method 3*

Treatment consists of commercial freeze-drying or freezing of meat for specified time-temperature combinations with temperature monitored at the centre of each cut.

- (a) The general provisions of (a) to (e) of Method 1 are to be complied with for the following time-temperature combinations:
- 106 hours at  $-18^{\circ}\text{C}$ ,
  - 82 hours at  $-21^{\circ}\text{C}$ ,
  - 63 hours at  $-23,5^{\circ}\text{C}$ ,
  - 48 hours at  $-26^{\circ}\text{C}$ ,
  - 35 hours at  $-29^{\circ}\text{C}$ ,
  - 22 hours at  $-32^{\circ}\text{C}$ ,
  - 8 hours at  $-35^{\circ}\text{C}$ ,
  - 1/2 hour at  $-37^{\circ}\text{C}$ .
- (b) The temperature is to be measured using calibrated thermoelectric instruments and recorded continuously. The thermometer probe is inserted in the centre of a cut of meat no smaller in size than the thickest piece of meat to be frozen. This cut must be placed at the least favourable position in the refrigeration room, not close to the cooling equipment or directly in the cold air flow. The instruments must be kept under lock and key. The temperature charts must include the data numbers from the meat inspection register on import and the date and time of commencement and completion of freezing, and must be retained for one year after compilation.
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## ANNEX III

**Examination of animals other than swine**

Horse meat, wild game meat and other meat that could contain *Trichinella* parasites must be examined in accordance with one of the digestion methods specified in Chapter I or II of Annex I, with the following changes:

- (a) specimens weighing at least 10 g are taken from the lingual or jaw muscle of horses and from the foreleg, tongue or diaphragm of wild boar;
  - (b) in the case of horse, where those muscles are lacking, a larger-sized specimen is to be taken from a pillar of the diaphragm at the transition to the sinewy part. The muscle must be clean of connective tissue and fat;
  - (c) at least 5 g of sample is digested following the reference method of detection in Chapter I of Annex I or an equivalent method in Chapter II. For each digest, the total weight of muscle examined must not exceed 100 g in the case of the method in Chapter I and methods A and B in Chapter II and 35 g in the case of method C in Chapter II;
  - (d) where the result is positive, a further 50 g specimen is taken for a subsequent independent examination;
  - (e) without prejudice to the rules on conservation of animal species, all meat of game animals other than wild boar, such as bears, carnivorous mammals (including marine mammals) and reptiles, are to be tested by sampling 10 g of muscle at the predilection sites or larger amounts if those sites are not available. Predilection sites are:
    - (i) in bear: diaphragm, masseter muscle and tongue;
    - (ii) in walrus: tongue;
    - (iii) in crocodiles: masseter, pterygoid and intercostal muscles;
    - (iv) in birds: muscles of the head (e.g. masseter and neck muscles).
  - (f) The digestion time must suffice to ensure adequate digestion of the tissue of these animals but must not exceed 60 minutes.
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## ANNEX IV

**Detailed conditions for *Trichinella*-free holdings and regions with a negligible *Trichinella* risk**

For the purpose of this Annex,

'controlled housing conditions in integrated production systems' means a type of animal husbandry where swine are kept at all times under conditions controlled by the food business operator with regard to feeding and housing.

## CHAPTER I

**OBLIGATIONS ON FOOD BUSINESS OPERATORS**

- A. The following requirements must be met by food business operators to obtain official recognition of holdings as free from *Trichinella*:
- (a) the operator must have taken all practical precautions with regard to building construction and maintenance in order to prevent rodents, any other kind of mammals and large carnivorous birds from having access to buildings where animals are kept;
  - (b) the operator must apply a pest-control programme, in particular for rodents, effectively to prevent infestation of pigs. The operator must keep records of the programme to the satisfaction of the competent authority;
  - (c) the operator must ensure that all feed has been obtained from a facility that produces feed in accordance with the principles described in Regulation (EC) No 1831/2003 of the European Parliament of 12 January 2003 and of the Council laying down requirements for feed hygiene <sup>(1)</sup>;
  - (d) the operator must store feed intended for *Trichinella* susceptible species in closed silos or other containers that are impenetrable to rodents. All other feed supplies must be heat-treated or produced and stored to the satisfaction of the competent authority;
  - (e) the operator must ensure that dead animals are collected for disposal by sanitary means within 24 hours of death. However, dead piglets may be collected and stored on the holding in a properly closed container pending disposal;
  - (f) if a rubbish dump is located in the neighbourhood of the holding, the operator must inform the competent authority. Subsequently, the competent authority must assess the risks involved and decide whether the holding is to be recognised as free from *Trichinella*;
  - (g) the operator must ensure that piglets coming onto the holding from outside and pigs purchased are born and bred under controlled housing conditions in integrated production systems;
  - (h) the operator must ensure that pigs are identified so each animal can be traced back to the holding;

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<sup>(1)</sup> OJ L 35, 8.2.2005, p. 1.

- (i) the operator may introduce new animals, onto the holding only if they:
    - (i) come from holdings officially recognised as free from *Trichinella*; or
    - (ii) are accompanied by a certificate authenticated by the competent authority in the exporting country stating that the animal comes from a holding recognised as free from *Trichinella*; or
    - (iii) are kept in isolation until the results of a serological test approved by the Community reference laboratory prove to be negative. Serological sampling must commence only after the animals have been on the holding for four weeks;
  - (j) the operator shall ensure that no pigs intended for slaughter have had outdoor access during the entire production period;
  - (k) outdoor access during the first few weeks of life before weaning shall be permitted if all the following conditions are met:
    - (i) no *Trichinella* infestations have been diagnosed in domestic animals in the country in the past 10 years;
    - (ii) an annual surveillance programme exists for wildlife susceptible to *Trichinella*. The programme shall be risk-based and shall be conducted in an area epidemiologically related to the geographical location of the *Trichinella*-free farms. The programme shall test the relevant indicator species on the basis of previous findings. The results shall show a prevalence of *Trichinella* in indicator animals below 0,5 %;
    - (iii) when outdoors, the animals shall be in properly fenced areas;
    - (iv) the monitoring program referred to in Article 11 shall be in place and monitoring shall be more frequent on the holdings involved;
    - (v) all sows and boars kept for breeding purposes on the holding shall be systematically sampled at slaughter for examination using the reference method of detection described in Chapter I of Annex I or one of the equivalent methods described in Chapter II of Annex I, and
    - (vi) steps shall be taken to prevent access by large carnivorous and omnivorous birds (e.g. crows, birds of prey).
- B. Food business operators of holdings recognised as free from *Trichinella* shall inform the competent authority where any of the requirements in point A is no longer fulfilled or where any other change has occurred that might affect the *Trichinella*-free status of the holding.

## CHAPTER II

### OBLIGATIONS ON THE COMPETENT AUTHORITIES

- A. The competent authorities in Member States where *Trichinella* has been detected in domestic swine in the last 10 years may recognise a holding as free from *Trichinella* provided that:
- (a) at least two control visits are made in the 12 months preceding recognition of the holding to verify compliance with the requirements of Chapter I(A) of Annex IV; and
  - (b) all pigs sent for slaughter during the 24 months preceding recognition or a longer time period if the competent authority decides it to be necessary have been tested to ensure to the satisfaction of the competent authority that a sufficient number of animals from the holding have been tested using one of the parasite detection methods described in Chapters I and II of Annex I; and
  - (c) the results of the tests have been negative; and
  - (d) a risk-based wildlife monitoring programme has been put in place in those areas where wildlife and holdings applying for *Trichinella*-free status coexist; the monitoring programme optimises parasite detection by applying the most suitable indicator animal and detection technique, by sampling as wide a number of animals and taking as large a meat sample as is feasible; parasites detected in wildlife are identified at species level in a Community or national reference laboratory; the Community reference laboratory can assist by preparing a standardised protocol for a wildlife monitoring programme. Historical

data may be used for the fulfilment of the requirements listed in this part.

- B. The competent authorities in Member States where *Trichinella* has not been detected in domestic swine in the last 10 years may recognise a holding as free from *Trichinella* provided that, the requirement in part A(d) above has been fulfilled.
- C. The competent authority may decide to recognise a category of holdings as free from *Trichinella* where all of the following conditions are met:
- (a) all the requirements set out in Chapter I(A) of Annex IV are met, with the exception of point (k), which does not apply; and
  - (b) no autochthonous *Trichinella* infestations in domestic animals have been detected in the country in the past 10 years, during which time continuous testing has been conducted on slaughtered swine population such as to provide at least 95 % confidence that where the prevalence of *Trichinella* exceeds 0,0001 %, any infestations will be detected; and
  - (c) a clear description must be available of the category of holdings, the type of farming and the type of animals involved; and
  - (d) a risk-based monitoring programme for wildlife has been established in accordance with Chapter II(A)(d) of Annex IV.
- D. In addition to the requirements laid out in Annex IV to Directive 2003/99/EC, the initial report and the subsequent annual reports to the Commission shall contain the following information:
- (a) the number of cases (imported and autochthonous) of *Trichinella* in humans, including epidemiological data;
  - (b) the results of testing for *Trichinella* in domestic swine not raised under controlled housing conditions in integrated production systems; the results must include the age and sex of affected animals, the type of management system, the type of diagnostic method used, the degree of infestation (if known), and any relevant additional information;
  - (c) the results of testing for *Trichinella* in breeding sows and boars; the results must include the information mentioned under (b);
  - (d) the results of testing for *Trichinella* in carcasses of wild boar, horses, game and any indicator animals;
  - (e) the results of serological tests as referred to in Article 11 once a suitable test has been validated by the Community reference laboratory;
  - (f) other cases where *Trichinella* is suspected, either imported or autochthonous, and all relevant laboratory results;
  - (g) details of all positive results and the *Trichinella* species verification by the Community or national reference laboratory;
  - (h) the data are to be submitted in the format and according to the timetable determined by EFSA for the reporting of zoonoses.
  - (i) for reports concerning *Trichinella*-free holdings or category of holdings: information on the number of *Trichinella*-free holdings and summary results of inspections of *Trichinella*-free holdings, including information on farmer compliance;
  - (j) for reports concerning a region with negligible risk, information is to be submitted on:
    - (i) the monitoring programme implemented according to Article 11, or equivalent information;
    - (ii) the risk-based wildlife monitoring programmes implemented according to part A(d) above, or equivalent information.

## COMMISSION REGULATION (EC) No 2076/2005

of 5 December 2005

**laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004**

(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 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin <sup>(1)</sup>, and in particular Article 9 thereof,

Having regard to Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption <sup>(2)</sup>, and in particular Article 16 thereof,

Having regard to 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 <sup>(3)</sup>, and in particular Article 63(1) thereof,

Whereas:

(1) The entry into application on 1 January 2006 of Regulations (EC) No 852/2004 of the European Parliament and of the Council <sup>(4)</sup>, (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 will entail considerable changes to the rules and procedures to be followed by food operators and the competent authorities of the Member States. The application of some of these measures with immediate effect from 1 January 2006 would present practical difficulties in some cases. A period should therefore be envisaged in order to permit a smooth transition to the full implementation of the new rules and procedures.

(2) It is appropriate that the duration of the transitional period be fixed taking into account a first review of the new regulatory framework on hygiene scheduled within the first four years.

(3) Provision should therefore be made for a transitional period during which certain requirements laid down in

those Regulations can be progressively implemented. With a view to a harmonised approach, that transitional period should in principle last four years but could, where justified, be shorter. Provision should also be made for the possibility of reviewing any of those arrangements in the light of experience gained.

(4) As a standard transitional arrangement, it should continue to be possible to place on the market products produced before the application of the new rules. The arrangement should apply for the whole of the transitional period, unless the shelf-life of the product is shorter.

(5) Regulation (EC) No 853/2004 excludes from its scope the direct supply by the producer of small quantities of meat from poultry and lagomorphs to the final consumer or to local retail establishment supplying directly the final consumer as fresh meat. Council Directive 71/118/EEC of 15 February 1971 <sup>(5)</sup> on health problems affecting the production and placing on the market of fresh poultrymeat and Council Directive 91/495/EEC of 27 November 1991 <sup>(6)</sup> concerning public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat also allowed the Member States to derogate from the general requirements for such a purpose without limiting it to fresh meat. That possibility should be maintained during the transitional period.

(6) The work of approving establishments, in particular those that did not have to be approved under the previously applicable rules but were allowed to market their production on their national market only, places a heavy burden on the competent authorities. Provision should therefore be made for a transitional arrangement to allow such establishments to continue marketing on their national markets until they are actually approved.

(7) The transitional arrangement covering the use of wrapping and packaging materials and marking equipment in point 6 of Section I of Annex II to Regulation

<sup>(1)</sup> OJ L 139, 30.4.2004, p. 55, corrected by OJ L 226, 25.6.2004, p. 22.

<sup>(2)</sup> OJ L 139, 30.4.2004, p. 206, corrected by OJ L 226, 25.6.2004, p. 83.

<sup>(3)</sup> OJ L 165, 30.4.2004, p. 1, corrected by OJ L 191, 28.5.2004, p. 1.

<sup>(4)</sup> OJ L 139, 30.4.2004, p. 1, corrected by OJ L 226, 25.6.2004, p. 3.

<sup>(5)</sup> OJ L 55, 8.3.1971, p. 23.

<sup>(6)</sup> OJ L 268, 24.9.1991, p. 41.

(EC) No 853/2004 needs to be reviewed in order to tighten up the previous rules on the use of marking equipment while giving due consideration to the expectations of food business operators concerning the tolerance regarding the use of marking material purchased prior to the implementation of the new framework. The relevant provisions of that Regulation should therefore be deleted and a new arrangement adopted under this Regulation. Given the risk of abuse of such a transitional arrangement, its duration should be limited and care taken to ensure that old marking equipment not complying with the new rules is withdrawn as soon as possible and not later than the end of the transitional period. Annex II to Regulation (EC) No 853/2004 and Annex I to Regulation (EC) No 854/2004 should be amended accordingly.

- (8) The health import requirements for food of animal origin will not be completely harmonised for certain types of products and the import conditions applicable to such products during the transitional period should be made clear.
- (9) The provision of food chain information is a new requirement on food business operators. A transitional period should be introduced for the full implementation of food chain information requirements. In particular, a smooth flow of information from the farm to the slaughterhouse should be facilitated by a transitional arrangement relaxing the requirement to supply the information 24 hours in advance of the animals' arrival at the slaughterhouse.
- (10) Section III of Annex III to Regulation (EC) No 853/2004 requires the official veterinarian or approved veterinarian to sign the certificate accompanying the farmed non domestic ungulates from the farm to the slaughterhouse. Directive 91/495/EEC requires the signature of the veterinary service. That provision should be maintained during the transitional period.
- (11) The certificate required by Regulation (EC) No 854/2004 in Chapter X Part B of Annex I is more detailed than the certificate previously prescribed. The model certificate set out in Annex III to Directive 91/495/EEC should be accepted during the transitional period.
- (12) Section V of Annex III to Regulation (EC) No 853/2004 requires the raw material for minced meat to meet certain criteria and lays down labelling requirements. Composition criteria of minced meat regarding in particular the content of fat and the connective tissue: meat protein ratio should be assessed. Pending the outcome of this assessment, it is appropriate to maintain current criteria established by Council Directive 94/65/EC of 14 December 1994<sup>(1)</sup> laying down the requirements for the production and placing on the market of minced meat and meat preparations.
- (13) Notwithstanding the general principle laid down in Article 3(2) of Regulation (EC) No 853/2004 whereby

food business operators are not to use, where hygiene so requires, any substance other than potable water, provisions allowing the use of clean water for the handling of fish are set out in Chapter VII of Annex II to Regulation (EC) No 852/2004 and Part II of Chapter I and Chapters III and IV of Section VIII of Annex III to Regulation (EC) No 853/2004, in particular for handling fish on board vessels. Since the use of clean water does not represent a risk for public health as long as it meets the definition laid down in Regulation (EC) No 852/2004, and with a view to allowing land-based establishments handling fishery products to adapt progressively, the scope of the relevant provisions in Regulation (EC) No 853/2004 should be extended to such establishments during the transitional period.

- (14) Part III(1)(a) of Chapter II of Section IX of Annex III to Regulation (EC) No 853/2004 provides that food business operators manufacturing dairy products must ensure that raw cows' milk meets a limit criterion before processing. Compliance with that limit is particularly important for food safety where the milk has to be heat-treated and has not been processed within a pre-defined time. By way of a transitional measure, verification of compliance with this criterion immediately before processing should be limited to such circumstances.
- (15) Section X of Annex III to Regulation (EC) No 853/2004 lays down specific hygiene rules for eggs and egg products. According to Chapter I(2), eggs should be stored and transported at a constant temperature that is best suited to ensuring optimal conservation of their hygiene properties. As before 1 January 2006 Member States were authorised to apply controlled temperature standards within their territory to egg storage facilities and to transport from one facility to another, it should be made clear that those standards may continue to apply on a transitional basis if still authorised by the competent authority. This will give operators time to adapt their activities and procedures to new temperature standards that may be required by the competent authority.
- (16) Under Part II(1) of Chapter II of Section X of Annex III to Regulation (EC) No 853/2004, cracked eggs may be used for the manufacture of egg products under certain conditions. As a transitional arrangement, provision should be made to extend this possibility to other establishments producing liquid egg, where they comply with the same conditions.
- (17) Regulation (EC) No 854/2004 requires the slaughterhouse staff authorised by the competent authority to carry out tasks of official auxiliaries to be trained and qualified in the same way as the official auxiliaries. During the transitional period, it is appropriate to allow the competent authority time for planning and organising additional training and qualification of slaughterhouse staff assisting with official controls, and to limit

<sup>(1)</sup> OJ L 368, 31.12.1994, p. 10.

consequently the requirement to ensuring that slaughterhouse staff is trained for the specific tasks they are allowed to carry out.

(18) Article 12 of Regulation (EC) No 882/2004 requires laboratories carrying out analysis of samples taken during official controls to be accredited. Laboratories, which were not required under previous Community legislation to be accredited, might require some additional time to obtain full accreditation, since accreditation is an intricate and laborious process. It is appropriate to give to such laboratories additional time to enable them to arrange for accreditation.

(19) 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

#### GENERAL PROVISION

##### Article 1

#### Transitional period

For the purposes of this Regulation, a transitional period of four years ending on 31 December 2009 (hereinafter referred to as the transitional period) is established.

The transitional arrangements provided for in this Regulation shall apply for the transitional period, except where otherwise provided for in Articles 5 and 8.

#### CHAPTER II

#### TRANSITIONAL ARRANGEMENTS FOR THE IMPLEMENTATION OF REGULATION (EC) No 853/2004

##### Article 2

#### Stocks of food of animal origin

1. Without prejudice to relevant Community legislation, and in particular Directive 2000/13/EC of the European Parliament and of the Council <sup>(1)</sup> on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, stocks of food of animal origin produced before 1 January 2006 may be placed on the market

provided that they bear, as appropriate, the marks provided for in the Acts listed in Article 2 of Directive 2004/41/EC of the European Parliament and of the Council <sup>(2)</sup>.

2. Products referred to in paragraph 1, for which the food business operator has defined a shelf-life longer than the transitional period, may remain on the market until the end of their shelf-life.

##### Article 3

#### Direct supply of small quantities of meat from poultry and lagomorphs

By way of derogation from Article 1(3)(d) and without prejudice to Article 1(4) of Regulation (EC) No 853/2004, the provisions laid down in that Regulation shall not apply to the direct supply, by the producer, of small quantities of meat from poultry and lagomorphs slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer.

##### Article 4

#### Placing of food of animal origin on the national market pending the approval of establishments

By way of derogation from Article 4(1) of Regulation (EC) No 853/2004, food business operators who before 1 January 2006 were allowed to place food of animal origin on their national market may continue to place such products on this market under a national mark that cannot be confused with the marks provided for in Article 5(1) of Regulation (EC) No 853/2004 until such time as the competent authority, in accordance with Article 4(2) of Regulation (EC) No 853/2004, has approved the establishments handling such products.

Food of animal origin bearing such national marks may be marketed only in the national territory of the Member State where they are produced.

##### Article 5

#### Wrapping, packaging and labelling materials bearing pre-printed health or identification marks

Food business operators may continue until 31 December 2007 to use stocks of wrapping, packaging and labelling materials bearing pre-printed health or identification marks purchased by them before 1 January 2006.

<sup>(1)</sup> OJ L 109, 6.5.2000, p. 29.

<sup>(2)</sup> OJ L 157, 30.4.2004, p. 33, corrected by OJ L 195, 2.6.2004, p. 12.

### Article 6

#### Marking equipment

Food business operators and competent authorities may continue to use marking equipment with which they are equipped on 31 December 2005 until its replacement or until the end of the transitional period at the latest, provided that the approval number of the establishment concerned remains unchanged.

When that equipment is replaced, the competent authority shall ensure that it is withdrawn so that it cannot be used any more.

### Article 7

#### Health import conditions

1. Article 6(1) of Regulation (EC) No 853/2004 shall not apply to imports of food of animal origin for which no harmonised health import conditions have been established, including lists of third countries and parts of third countries and of establishments from which imports are permitted.

Pending future harmonisation of Community legislation concerning imports of such products, such imports shall comply with the health import conditions of the Member State concerned.

2. By way of derogation from Article 6(4) of Regulation (EC) No 853/2004, food business operators importing food containing both products of plant origin and processed products of animal origin shall be exempt from the obligation provided for in that Article.

Pending the development of a risk-based approach for the implementation of harmonised health import conditions and checks of such food products, imports shall comply with the harmonised Community rules in force before 1 January 2006 where applicable, and with the national rules implemented by the Member States before that date in other cases.

### Article 8

#### Food chain information

1. By way of derogation from the requirements laid down in Section III of Annex II to Regulation (EC) No 853/2004, the Member States shall progressively implement these requirements in various sectors in addition to the poultry sector where they shall apply immediately, so that the porcine sector in that Member State is covered by the implementation of food chain information requirements by the end of the second year of transition, and the equine and veal calf sectors by the end of the third year.

Member States applying that transitional arrangement shall report to the Commission on its implementation at the end of each year.

2. By way of derogation from the requirements laid down in point 2 of Section III of Annex II to Regulation (EC) No 853/2004 concerning the provision of food chain information to slaughterhouse operators no less than 24 hours in advance, the competent authority may permit such information to be sent to the slaughterhouse operator with animals of all species to which it relates and in all circumstances where this does not jeopardise the objectives of Regulation (EC) No 853/2004.

However, any item of food chain information, knowledge of which may result in serious disruption of the slaughterhouse activity, shall be made available to the slaughterhouse operator in good time before the animals arrive at the slaughterhouse.

### Article 9

#### Meat of farmed non-domestic ungulates

By way of derogation from the requirements laid down in point (3)(j) of Section III of Annex III to Regulation (EC) No 853/2004, the certificate referred to in Article 16, attesting to a favourable result of the ante-mortem inspection, is issued and signed by the veterinary service.

### Article 10

#### Composition criteria and labelling requirements for minced meat

1. By way of derogation from the requirements laid down in Chapter II(1) of Section V of Annex III of Regulation (EC) No 853/2004, the food business operator must check the raw materials entering the establishment to ensure compliance with the name of the product in the table below in respect of the final product.

Table: Composition criteria checked on the basis of a daily average

	Fat content	Connective tissue: meat protein ratio
— lean minced meat	≤ 7 %	≤ 12
— minced pure beef	≤ 20 %	≤ 15
— minced meat containing pigmeat	≤ 30 %	≤ 18
— minced meat of other species	≤ 25 %	≤ 15

2. By way of derogation from the requirements laid down in Chapter IV of Section V of Annex III of Regulation (EC) No 853/2004, the labelling must also display the following words:

— 'percentage of fat under...'

— 'connective tissue: meat protein ratio under...'

CHAPTER III

3. The Member States may allow the placing on their national market of minced meat which does not comply with these criteria under a national mark that cannot be confused with the marks provided for in Article 5(1) of Regulation (EC) No 853/2004.

*Article 11*

#### **Use of clean water**

1. By way of derogation from Article 3(2) of Regulation (EC) No 853/2004 and Chapter III(A)(1) of Section VIII of Annex III to that Regulation, ice used to chill fresh fishery products may be made from clean water in establishments on land.

2. By way of derogation from Article 3(2) of Regulation (EC) No 853/2004 and Chapter III(A)(2) and (3) of Section VIII of Annex III to that Regulation, food business operators in establishments, including vessels, handling fishery products may use clean water.

3. By way of derogation from Article 3(2) of Regulation (EC) No 853/2004 and Chapter IV(1) of Section VIII of Annex III to that Regulation, food business operators in establishments on land may use clean water for cooling after cooking crustaceans and molluscs.

*Article 12*

#### **Raw milk and dairy products**

By way of derogation from the requirement set out in Chapter II(III)(1)(a) of Section IX of Annex III to Regulation (EC) No 853/2004, the maximum plate count for raw cows' milk shall apply only where such milk is to be heat-treated and has not been so treated within the period of acceptance specified in the HACCP-based procedures put in place by food business operators.

*Article 13*

#### **Eggs and egg products**

1. Member States which, before 1 January 2006, applied national temperature requirements for egg storage facilities and for vehicles transporting eggs between such storage facilities may continue to apply those requirements.

2. Food business operators may use cracked eggs for the production of liquid egg in an establishment approved for that purpose, provided that the establishment of production or a packing centre has delivered them directly and they are broken as soon as possible.

### **TRANSITIONAL ARRANGEMENTS FOR THE IMPLEMENTATION OF REGULATION (EC) No 854/2004**

*Article 14*

#### **Training of slaughterhouse staff assisting with official controls**

By way of derogation from Article 5(6)(a)(i) to Regulation (EC) No 854/2004 and Chapter III(A)(a) of Section III of Annex I to that Regulation, slaughterhouse staff authorised by the competent authority to carry out specific tasks of official auxiliaries shall be trained in the same way as official auxiliaries only with regard to the specific tasks they are authorised to perform and shall not be required to have passed the same examination as official auxiliaries.

The competent authority shall ensure that such training is satisfactory before authorising slaughterhouse staff to take over tasks of official auxiliaries.

It shall check that the additional training and organisation necessary for slaughterhouse staff to qualify through the examination procedure that apply to official auxiliaries are in place as soon as possible and at the latest by the end of the transitional period.

*Article 15*

#### **Certification of establishments using staff assisting with official controls in slaughterhouses**

By way of derogation from the second subparagraph of Chapter III(A)(a) of Section III of Annex I to Regulation (EC) No 854/2004, establishments wishing to use their staff assisting with official controls shall, during the transitional period, be exempted from the requirement to possess an internationally recognised certification, provided that the establishment demonstrates that it has initiated and is pursuing certification in accordance with international standards, such as relevant EN ISO standards on quality management or food safety.

*Article 16*

#### **Model certificate for meat from farmed non domestic ungulates**

By way of derogation from Chapter VII (A)(4) of Section IV of Annex I to Regulation (EC) No 854/2004, the model certificate set out in Annex III to Directive 91/495/EEC may be used for the transportation from the farm to the slaughterhouse of farmed non domestic ungulates.

*Article 17*

#### **Health import conditions**

Chapter III of Regulation (EC) No 854/2004 shall not apply to



imports of food of animal origin for which no harmonised health import conditions have been established, including lists of third countries and parts of third countries and of establishments from which imports are permitted.

Pending future harmonisation of Community legislation concerning imports of such products, such imports shall comply with the health import conditions of the Member State concerned.

#### CHAPTER IV

##### TRANSITIONAL ARRANGEMENTS FOR THE IMPLEMENTATION OF REGULATION (EC) No 882/2004

###### Article 18

###### Accreditation of laboratories

By way of derogation from Article 12(2) of Regulation (EC) No 882/2004, the competent authority may designate a laboratory not accredited, provided that the laboratory:

- (a) demonstrates that it has initiated and is pursuing the necessary accreditation procedures in accordance with Regulation (EC) No 882/2004;
- (b) provides the competent authority with satisfactory guarantees that quality control schemes for the analyses it conducts for the purpose of official controls are in place by 1 January 2006.

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

Done at Brussels, 5 December 2005.

#### CHAPTER V

##### FINAL PROVISIONS

###### Article 19

###### Review

The transitional arrangements, including the conditions thereof, laid down in this Regulation may be reviewed at any time in the light of experience gained in the implementation of those arrangements and of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004.

###### Article 20

###### Amendment to Regulation (EC) No 853/2004

In Section I(B)(6) of Annex II to Regulation (EC) No 853/2004, the third subparagraph is deleted.

###### Article 21

###### Amendment to Regulation (EC) No 854/2004

In point (6) in Section I, Chapter III of Annex I to Regulation (EC) No 854/2004, the second sentence is deleted.

###### Article 22

###### Entry into force

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

It shall apply from 1 January 2006.

*For the Commission*

Markos KYPRIANOU

*Member of the Commission*

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