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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,

Draft

COMMISSION REGULATION (EC) No …/..

of […]

laying down implementing measures and transitional arrangements in respect of certain products of animal origin under Regulation (EC) No 853/2004, in respect of the organisation of official controls on products of animal origin intended for human consumption under Regulation (EC) No 854/2004 and in respect of official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules under Regulation (EC) No 882/2004, granting a derogation under Regulation (EC) No 852/2004 and amending the Annexes of Regulations (EC) No 852/2004, 853/2004 and 854/2004

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THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs[1], 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[2], 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[3], 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[4] , and in particular Article 63 thereof,

Whereas:

(1) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 lays down general rules on the hygiene of foodstuffs[5].

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1 OJ L 226, 25.6.2004, p.3.
2 OJ L 226, 25.6.2004, p. 22.
3 OJ L 226, 25.6.2004, p. 83.
4 OJ L 191, 28.5.2004 p.1.

(2) Regulation (EC) No 853/2004 sets 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.

(3) Regulation (EC) No 854/2004 sets 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.

(4) Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules establishes at Community level a harmonised framework of general rules for the organisation of such controls. It is necessary to develop certain rules and further specify other requirements.

(5) The entry into application on 1 January 2006 of Regulations (EC) n° 852, 853, 854 and 882… will entail considerable changes to the rules and procedures to be followed by the food operators and by the competent authorities of the Member states… (to be completed)

(6) It is therefore appropriate to establish a transitional period during which certain requirements provided for in those regulations can be progressively implemented. In order to ensure a harmonised approach to this transition, it is appropriate to provide for a duration of [ ] years as a matter of principle, while providing explicitly for a shorter period where justified. It is also appropriate to provide for the possibility of reviewing any of those arrangements in the light of experience.

(7) Decision 20XX/../EC[6] repealed certain Decisions implementing measures provided for in the Directives repealed by Directive 2004/41/EC of the European Parliament and of the Council 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[7]. It is therefore appropriate to retain certain parts of relevant Decisions in the present Regulation.

(8) The provisions retained include stipulations in relation to, establishments in, reference laboratories for live bivalve molluscs, levels and analytical methods, of certain marine biotoxins, parasite detection of fishery products, TVB-N, storage and transport of fishery products in cooled water, frogs' legs and snails.

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5 OJ L 226, 25.06.2004, p. 3

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7 OJ L 195, 2.6.2004, p. 12.

(9) 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 for the presentation of relevant information to other Member States and to the public should be established.

(10) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs[8] 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.

(11) Regulation (EC) No 853/2004 also requires the slaughterhouse operator to request, receive, check and act upon the food chain information of 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 by Regulation (EC) No 853/2004.

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

(13) Existing systems for information flow should be used as much as possible and adapted to comply with the requirements for the food chain information as laid down in Regulation (EC) No 854/2004.

(14) In order to improve the management of animals at the level of the holding and in accordance with Regulation (EC) No 854/2004, the official veterinarian should record and if necessary communicate any disease or condition, which may affect public or animal health or compromise animal welfare observed at the slaughterhouse on individual animals or in the herd/flock, back to the food business operator of the holding of provenance and, if applicable, to the veterinarian attending the holding of provenance or, if applicable, the competent authority involved.

(15) Food chain information is a new requirement for the food business operator to comply with. A period of four years should be provided to the food business operators to enable the implementation of food chain information requirements. A smooth flow of information from the farm to the slaughterhouse should be assisted by a relaxation as a transitional arrangement of the requirement to supply the information 24 hours in advance of the arrival of the animals at the slaughterhouse.

(16) Mechanically separated meat (MSM) produced using techniques that do not alter the structure of the bones used in the production of MSM

[8] OJ L 226, 25.6.2004, p. 3.

should be considered differently from MSM produced using techniques that alter the structure of the bones.

(17) MSM of the first type produced under specified conditions and of a specified composition should be allowed in meat preparations that are clearly not intended to be consumed without first undergoing heat treatment. These conditions are particularly linked to the calcium content of the MSM, which, according to Article 11(2) of Regulation (EC) No 853/2004, should be specified. An adjustment should be made to the specified maximum Calcium content levels set in the present Regulation, once detailed information is available for the variations occurring when different types of raw material are used.

(18) Meat from domestic pigs, wild boars, horses and certain 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.*

(19) The Scientific Committee on Veterinary Measures relating to Public Health has adopted on 22 November 2001 an opinion on trichinellosis, epidemiology, methods of detection and *Trichinella*-free pig production. The scientific panel on biological hazards of EFSA has adopted on 1 December 2004 an opinion on the suitability and details of freezing methods to allow human consumption of meat infected with *Trichinella* or *Cysticercus*. The scientific panel on biological hazards of EFSA has adopted on xx 2005 an opinion on risk assessment of a revised inspection of slaughter animals in areas with low prevalence of *Trichinella*

(20) Directive 77/96/EEC on the examination for trichinae (trichinella spralis) upon importation from third countries of fresh meat derived from domestic swine has been repealed by Directive 2004/41/EC[9].

(21) Different laboratory methods have been approved to detect *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 from 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 can 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. In all other circumstances the method should be replaced within a transitional period by a more reliable detection

[9] OJ L 195, 02.06.2004, p. 0012-0015.

method. Other methods such as serological tests can be useful for monitoring purposes, once the tests have been validated by a Community Reference Laboratory. Serological tests are not suitable for the detection of *Trichinella* infection in individual animals intended for human consumption.

(22) Freezing of meat under specified conditions can kill the parasites, if present, but particular *Trichinella* species, occurring in game and horses, are resistant to the commonly recommended temperature and time combinations used for freezing.

(23) Holdings can be officially recognised by the competent authority as *Trichinella* free provided specific conditions are met. Fattening pigs originating from these holdings should be exempted from inspection for *Trichinella.* Categories of holdings can 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.

(24) Regular monitoring of pigs, wild boar, horses and indicator animals is an important tool for assessing changes in disease prevalence. The results should be communicated in an annual report in accordance with Directive 2003/99/EC[10].

(25) 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 is therefore the responsibility of the Member States to adopt national measures to mitigate the risk of *Trichinella* infested wild boar meat reaching the final consumer.

(26) The limits for Paralytic Shellfish Poison (PSP), Amnesic Shellfish Poison (ASP) and lipophilic toxins are established in Regulation (EC) No 853/2004. The reference method to detect certain toxins and prevent toxic shellfish being harvested is a bioassay. Maximum levels and methods of analysis should be harmonised and be implemented by the Member States in order to protect human health. In addition to biological testing methods, alternative detection methods such as chemical methods and in vitro assays should be accepted if it is demonstrated that the performance of the chosen methods is not less effective than the performance of 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 re-evaluated when new scientific evidence becomes available. Lack of reference materials and the use of non-bioassay tests only currently does not ensure in respect of all toxins prescribed an equivalent level of public health protection

[10] OJ L 325, 12.12.2003, p.31.

to the level afforded by biological tests. Provision should be made for the replacement of biological tests as soon as possible.

(27) Regulation (EC) No 853/2004 and Regulation (EC) No 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 of the production of fishery products. in accordance with the rules laid down in Section VIII, Chapter V point D 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 implies that the concepts of visible parasites and visual inspection should be defined, and that the nature and frequency of the observations to be made must be determined.

(28) 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 checking total volatile basic nitrogen (TVB-N). It is necessary to set levels of TVB-N which are not to be exceeded in the case of certain species categories and to specify the analysis methods to be used. The analysis methods which are scientifically recognized for checking TVB-N should continue to be used as a matter of routine but it is advisable to specify a reference method which may be used in case of doubt regarding the results or in the event of dispute;

(29) Notwithstanding the general principle [laid down in Article 3.2 of Regulation (EC) n° 853/2004] whereby business operators shall not use any substance other than potable water where hygiene so require, provisions allowing the use of clean water for the handling of fish are laid down under Annex II, Chapter VII to Regulation (EC) n° 852/2004 and under Annex III, Section VIII, Chapter I part II and Chapters III and IV to Regulation (EC) n° 853/2004, in particular for fish handling on board vessels. Considering that the use of clean [sea?] water does not represent a risk for public health as long as its quality respects the definition laid down in Regulation (EC) n° 852/2004, and with a view to allow a progressive adaptation of land-based fish handling establishments, it is appropriate to further broaden to such establishments, during the transitional period, the scope of the relevant provisions in Regulation (EC) n° 853/2004.

(30) 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,* are dangerous. It is therefore appropriate to include these dangerous fishery products in the list of fishery products that must not be placed on the market in accordance with Section VIII, Chapter V point E 1 of Annex III of Regulation (EC) No 853/2004.

(31) Scientific progress has led to the establishment of ISO 16649-3 as an agreed Reference method for analysis of *E. coli* in bivalve molluscs. Consequently, ISO 16649-3 should be specified as the Reference MPN method for analysis of *E. coli* also in bivalve molluscs originating from B and C areas. This Reference method is already established for live bivalve molluscs from A areas according to Regulation (EC) No ***Microbiological Criteria.*** The use of alternative methods should be allowed only if they are considered equivalent to the Reference method.

(32) 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, due to the specificity of certain heat-treatments used in this sector and their impact on food safety and animal heath, it is appropriate to give clearer guidance to food business operators in this regard. It is therefore necessary to amend Annex III, Section IX, Chapter II, point II (1) accordingly.

(33) Section XIV of Annex III to Regulation (EC) No 853/2004 lays down specific hygiene rules for gelatine. These rules include requirements on the nature of raw materials that may be used to produce gelatine and on transport and storage of such materials. Furthermore, specifications applicable to the manufacture of gelatine are set down. However, it is also appropriate to specify the rules applying to its labelling. Annex III, Section XIV should therefore be amended accordingly.

(34) Annex III Section IX Chapter II Part III (1) to Regulation (EC) No 853/2004, food business operators manufacturing dairy products should ensure that raw cows' milk meets a limit criterion before processing. . Controlling such a limit is particularly relevant to food safety when the milk has to be heat-treated and if it has not been processed within a pre-defined time period. It is appropriate, on a transitional basis, to limit the verification of this criterion immediately before processing, to such circumstances.

(35) 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 assure optimal conservation of their hygiene properties. As before 1 January 2006, Member States were authorised to apply in their territory controlled temperature standards for egg storage facilities and for transport from one facility to another, it is appropriate to clarify that these standards can still apply on a trasnsitional basis if still authorised by the competent authority in order to give operators time to adapt their activities and procedures to the new requirements.

(36) According to Annex III Section X Chapter II Part II (1) to Regulation (EC) No 853/2004, cracked eggs may be used for the manufacture of egg products under certain conditions. Provision should be made, on a

transitional basis, for extending this possibility to other establishments producing liquid egg, provided they comply with the same conditions.

(37) 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 specimen of health certificates, should also be drawn up when importing from third countries frogs' legs and snails intended for human consumption.

(38) Section XIV of Annex III to Regulation (EC) No 853/2004 lays down rules for the production and placing on the market of gelatine intended for human consumption. Specific requirements, including specimens of health certificates, should also be established when importing from third countries gelatine and raw materials destined for the production of gelatine intended for human consumption.

(39) Section XV of Annex III to Regulation (EC) No 853/2004 lays down rules for the production and placing on the market of collagen intended for human consumption. Specific requirements, including specimens of health certificates, should also be established when importing from third countries collagen and raw materials destined for the production of collagen intended for human consumption.

(40) Certain practices can mislead the consumer regarding the composition of certain products. In particular in order to meet consumer expectation, it is necessary to prohibit that fresh poultry meat treated with water retention agents is sold as fresh meat.

(41) 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 enable them to arrange for accreditation.

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

(43) Flexibility is appropriate to enable the continued production of foods with traditional characteristics. Member States have already granted derogations to a wide range of such foods on the basis of the legislation in force before 1.1.2006. Food business operators should be able to

continue using existing practices after this date without interruption. A procedure allowing Member States to exercise flexibility is provided for in Regulations (EC) No 852/2004, 853/2004 and 854/2004. However, since in most cases where derogations have already been granted it is only a question of continuing well-known practices,, applying a full notification procedure, including a complete hazard analysis, may be out of proportion in these cases and create an unnecessary burden for Member States. It is therefore necessary to define foods with traditional characteristics and to set general conditions applicable to such foods with due regard to food hygiene objectives.

(44) The transitional arrangement already provided for in point 6 of Annex II, section I to Regulations (EC) n° 853/2004 and n° 854/2004 for the use of marking material and equipment need to be reviewed in order to restrict further the transitional use of the marking equipment used under the previous rules, while restoring the expectation of the food business operators concerning the tolerance established for the use of marking material purchased prior to the implementation of the new framework. It is therefore appropriate to delete the provision laid down to that effect in that Regulation, and to adopt a new arrangement under the present Regulation. Considering the risk of abuse of such a transitional arrangement, it is appropriate to limit its duration, and to ensure the elimination of former marking equipment not complying with the new rules as soon as possible and not later than the end of the transitional period.

(45) As a standard transitional arrangement, it is appropriate to allow the continuing placing on the market of products produced before the application of the new rules. Considering the shelf-live of certain products, the arrangement should apply for the whole duration of the transitional period, without prejudice to the shorter shelf-life of most products.

(46) Considering the workload of the competent authorities for approving establishments and in particular those which were not subjected to an approval procedure under the previously applicable rules but subjected also to a limitation to the marketing of their production on the national market only, it is appropriate to provide for a transitional arrangement allowing the continuation of the activities of those establishments on the national market until they can be effectively approved following at least one on-site visit by the competent authority. However, it is appropriate to exclude from this arrangement the marketing of products issued from animals having undergone an emergency slaughter.

(47) On 1 May 2004, the Czech Republic, Cyprus Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia and Slovenia became Member States of the European Union. Regulations (EC) No 853/2004 and No 854/2004 were adopted on 29 April 2004 and therefore did not refer to these new Member States. It is consequently necessary to add to the relevant provisions of these Regulations the ISO codes in respect of the

new Member States and the new abbreviations in respect of the European Community.

(48) The full harmonisation of sanitary import requirements for food of animal origin will not be completed for certain types of products and it is appropriate to clarify the import conditions to be applied to such products during the transitional period.

(49) The measures provided for in this Regulation are in accordance with the opinion of the […] Committee,

HAS ADOPTED THIS REGULATION:

Article 1

Scope

1. This Regulation lays down implementing and specific measures referred to in Articles 9 and 11 of Regulation (EC) No 853/2004 and in Articles 16 and 18 of Regulation (EC) No 854/2004

2. This Regulation lays down transitional arrangements provided for in Article 9 of Regulation (EC) No 853/2004 and Article 16 of Regulation (EC) No 854/2004.

3. This Regulation lays down implementing and specific measures referred to in Article 63 of Regulation (EC) No 882/2004.

4. This Regulation grants a derogation as regards traditional products pursuant to Article 13(2) of Regulation (EC) No 852/2004.

5. This Regulation lays down amendments to certain Annexes of Regulations (EC) No 853/2004 and 854/2004.

Article 2

Implementing and specific measures

1. Measures in relation to lists of establishments as referred to in Article 31 (2) (f) of Regulation (EC) No 882/2004 are set down in Annex I to this Regulation.

2. Measures in relation to Food Chain Information in accordance with Article 9 as referred to in Annex II, Section III of Regulation (EC) No 853/2004 and in accordance with Article 18 (2) and as referred to in Annex I, Section I, Chapter II (A) of Regulation (EC) No 854/2004 are set down in Annex III to this Regulation.

3. Measures in relation to mechanically separated meat as referred to in Article 11 (2) of, and point 1(14) of Annex I and Section V of Annex III to Regulation (EC) No 853/2004 are set down in Annex IV to this Regulation.

4. Measures in relation to *Trichinella* infestation as referred to in Article 18(9) and (10) of Regulation (EC) No 854/2004 are set down in Annex V to this Regulation.

5. Measures laying down the analytical methods for detecting marine biotoxins as referred to in Article 11(4) to Regulation (EC) No 853/2004 are set down in Annex VI to this Regulation.

6. Measures in relation to fishery products as referred to in Article 11(9) of Regulation (EC) No 853/2004 and in Article 18 (14) and (15) of Regulation (EC) No 854/2004 are set down in Annex VII to this Regulation.

7. Certificates for importation 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 set down in Annex VIII to this Regulation.

Article 3

Transitional arrangements

1. Transitional arrangements are set down in Annexes IX, X, XI, XII, XIII, XIV, XV, XVI, XVII and XVIII to this Regulation.

2. The arrangements set down apply until 31.12.2009.

3. The transitional arrangements laid down in this Regulation may be reviewed at any time in the light of the experience gained from their implementation and the implementation of the new hygiene regulatory framework.

Article 4

Derogation for foods with traditional characteristics

1. For the purpose of this Regulation, foods with traditional characteristics shall mean foods which are, in the Member State in which they are traditionally manufactured:

   - recognized historically as a traditional product, or

   - manufactured according to codified or registered technical references to the traditional process, or according to traditional production methods, or

   - protected as a traditional food product by a national, regional or local law.

2. Member States are hereby authorised to grant to establishments manufacturing certain foods with traditional characteristics as defined in paragraph 1 individual or general derogations from the requirements set out:

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

The frequency and nature of cleaning and disinfecting measures in such premises shall be adjusted to this type of activity in order to take account of their specific ambient flora;

(b) in Annex II, Chapter II, point 1 (f) and Chapter V, point 1 to Regulation (EC) No 852/2004 as regards the nature of the materials making up the instruments and the equipment used specifically for the preparation, packaging and wrapping of these products.

Such instruments and equipment must, however, be constantly maintained in a satisfactory state of hygiene and be regularly cleaned and disinfected.

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

(a) provide with a short description of the requirements having been adapted;

(b) describe the foodstuffs and establishments concerned; and

(c) give any other relevant information.

Article 5

Amendments

1. Pursuant to Article 10 of Regulation (EC) No 853/2004, Annexes II and III to that Regulation are amended as follows:

(a) In Annex II Section I Part B Point 6 second subparagraph, the following codes are inserted in the list of ISO codes: CY, CZ, EE, HU, LT, LV, MT, PL, SI, SK.

(b) In Annex II Section I Part B Point 6 the following sentence is deleted : "Food business operators may continue to use stocks and equipment that they ordered before the entry into force of this Regulation until they are exhausted or require replacement".(c) In Annex II Section I Part B Point 8, the following abbreviations are inserted: ES, EÜ, EK, EB, WE.

(d) In Annex III Section I Chapter IV Point 8, the first sentence is replaced by the following:

"8. Complete skinning of the carcase and other parts of the body intended for human consumption must be carried out, except for porcine animals, the heads of ovine and caprine animals and calves and the feet of bovine, ovine and caprine animals."

(e) In Annex III Section II, the following Chapter VI is added:

"CHAPTER VII: WATER RETENTION AGENTS

Food business operators [must implement procedures to] shall ensure that poultry meat that has been treated with agents used specifically to promote water retention is not placed on the market as fresh meat, but exclusively used for the production of processed products where this promotion justified."

(f) In Annex III Section VIII Chapter V Part E, Point 1 is replaced by the following:

"1. Fishery products derived from poisonous or dangerous fish of the following families must not be placed on the market: *Tetraodontidae, Molidae, Diodontidae, Canthigasteridae* and *Gempylidae*."

(g) Annex III Section IX is amended as follows:

(i) In Chapter I Part II (B) Point 1 (e), the words "if the competent authority has approved them" are replaced by "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,".

(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 shall ensure that this satisfies the requirements of Regulation (EC) No 852/2004, Annex II, Chapter XI. In particular, when using the following processes, they shall ensure that they comply with the specifications mentioned below.

(a) Pasteurisation is achieved by means of a treatment:

(i) involving a high temperature for a short time (at least 72°C for 15 seconds) or a low temperature for a long time (at least 63°C for 30 minutes) or any other time-temperature conditions to obtain equivalent effect;

(ii) sufficient to ensure that the products show a negative reaction to a alkaline phosphatase test immediately after heat treatment.

(b) Ultra High Temperature (UHT) treatment is achieved by means of 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 appropriate holding time) in order to result in the absence of viable microorganisms and their spores capable to grow in the treated product when kept in a aseptic closed container at ambient temperature;

(ii) sufficient to ensure that the products remain microbiologically stable after having spent 15 days or 7 days in closed containers respectively at 30°C or 55°C or after any

other equivalent methods able to demonstrate that the appropriate heat treatment has been applied."

(h) Annex III, Section X, Chapter II is amended as follows:

(i) In Part III, point 5, the words "each particle of the egg product" are replaced by "each particle of the liquid egg";

(ii) In Part V, point 2, the words "non-pasteurised egg products" are replaced by "non-pasteurised liquid egg".

(i) In Annex III, Section XIV, a new Chapter V is added as follows:

"CHAPTER V: LABELLING

Wrapping and packaging containing gelatine must bear the words 'gelatine fit for human consumption' and indicate the date of preparation."

2. Regulation (EC) No 854/2004 is amended as follows:

(a) In Annex I Section I Chapter III Point 3 (a) second subparagraph, the following codes are inserted in the list of ISO codes l: CY, CZ, EE, HU, LT, LV, MT, PL, SI, SK.

(b) In Annex I Section I Chapter III Point 3 (c), the following abbreviations are inserted: ES, EÜ, EK, EB, WE.

(c) In Annex I, Section I Chapter III Point 6 the following sentence is deleted : "Competent authorities and food business operators may continue to use equipment that they ordered before the entry into force of this Regulation until it is exhausted or requires replacement.".

(d) In Annex II Chapter II (A) the last sentence of point 4 is replaced by the following:

"Live bivalve molluscs from these areas must not exceed 4600 *E. coli* per 100g 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 according to the criteria in EN/ISO 16140."

(e) In Annex II Chapter II (A) the last sentence of point 5 is replaced by the following:

"Live bivalve molluscs from these areas must not exceed 46000 *E. coli* per 100g 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 according to the criteria in EN/ISO 16140.'"

(f) In Annex III, Chapter II Part G Point 1 is replaced by the following:

"1. Poisonous or dangerous fish of the following families are not placed on the market: *Tetraodontidae, Molidae, Diodontidae, Canthigasteridae* and *Gempylidae."*

Article 6
Entry into force and applicability

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, except the provisions laid down in Annex I, Chapters II and III, which shall apply at the latest by 1 January 2007.

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

Done at Brussels, […]

For the Commission
[…]
Member of the Commission

ANNEX I

LISTS OF APPROVED FOOD ESTABLISHMENTS AS REFERRED TO IN ARTICLE 31(2)(f) OF REGULATION (EC) No 882/2004

CHAPTER I: FACILITATION OF MAKING LISTS OF APPROVED ESTABLISHMENTS AVAILABLE

In order to facilitate Member States to make up-to-date lists of approved 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 respective national website.

CHAPTER II: FORMAT FOR THE NATIONAL WEBSITE CONTAINING LISTS OF APPROVED ESTABLISHMENTS

A- Master-list

1. Each Member State shall provide to the Commission a linking address to a single national website which contains the master-list of lists of approved establishments for products of animal origin as defined in point 8(1) of Annex I to Regulation (EC) No 853/2004.

2. The master-list referred to in point 1 above 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 master-list 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 master-list shall include links to:

a) other web pages located on the same website;

b) where certain lists of approved 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 in order to ensure a wide availability of the information concerning approved establishments and to improve readability of the lists.

CHAPTER IV: TECHNICAL SPECIFICATIONS

The tasks and activities referred to in Chapters II and III of this Annex shall be performed in conformity with the technical specifications presented at the meeting of the Standing Committee on the Food Chain and Animal Health on (…) as published on the Commission website.

ANNEX III

FOOD CHAIN INFORMATION

SECTION I: OBLIGATIONS FOR THE FOOD BUSINESS OPERATORS [11]

The food business operator who raises animals dispatched for slaugher shall ensure, if necessary with the assistance of the official veterinarian, that the food chain information referred to in to Regulation (EC) N° 853/2004 is included as appropriate in the documentation related to the animals dispatched, in such a way as to be accessible to the slaughterhouse operator concerned. .

By way of derogation, for a transitional period ending at the latest on 31 December 2009, the provision in Annex II Section III paragraph 7 (a) may apply also to (bovine? other species?) animals.

During the transitional period Member States shall submit an annual report to indicate the progression and problems encountered.

SECTION II: OBLIGATIONS FOR THE COMPETENT AUTHORITY[12]

CHAPTER I: IMPLEMENTATION OF FOOD CHAIN INFORMATION

1. The competent authority at the place of dispatch shall specify to the dispatching food business operator the minimal requirements of the food chain information to be delivered to the slaughterhouse in accordance with Annex II, Section III to Regulation (EC) No 853/2004.

2. The competent authority at the place of slaughter shall verify:

   a) that 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 validity and reliability of the food chain information;

   c) the feedback of relevant information to the holding, if applicable.

3. When the animals are dispatched for slaughter to another Member state, the competent authorities for the place of dispatch and for the place of slaughter respectively shall cooperate to ensure that the information provided by the dispatching food business operator is easily accessible to the slaughterhouse operator receiving it.

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11 See Annex X

12 See Annex X

CHAPTER II: FEEDBACK TO THE HOLDING OF PROVENANCE

1. Where inspection results must be communicated to the holding where the animals were raised before slaughter in accordance with Annex I, Section II, Chapter I to Regulation (EC) No 854/2004 in the same Member State.

2. The official veterinarian may use the model document laid down in the Appendix.

3. The competent authority shall be in charge of communicating the relevant inspection results in case the holding where the animals were raised is in another Member State and shall use the model document laid down in the Appendix using a version in the language of the dispatching country and in the language of the recipient country.

APPENDIX to Annex III

1. identification details

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. findings ante-mortem

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[13]

3. findings post-mortem

3.1. (macroscopic) findings

number of animals affected

[13] microbiological, chemical, serological, etc. (include results as attached)

type/class/age

organ or location of the animal (s) affected

Date of slaughter

3.2. disease (coding can be used[14])

number of animals affected

type/class/age

organ or location of the animal (s) affected

partially or totally condemned carcase (give reason)

Date of slaughter

3.3. laboratory results[15]

3.4. other results (e. g; parasites, foreign objects, etc)

3.5. welfare findings (e.g., broken legs)

4. additional information

5. contact details

5.1. slaughterhouse (approval number)

name

full address

telephone number

5.2 electronic address if available

6. official veterinarian (print name)

signature and stamp

7. date

8. number of pages attached to this form:

[14] Codes can be used as follows: Code A can be used for OIE listed diseases; for welfare issues codes B100and B200 can be used (Annex I, Section I, Chapter II, C of Regulation (EC) No 854/2004) and for decisions concerning meat C100 through C290 can be used (Annex I, Section II, Chapter V 1 a) through u) of Regulation (EC) No 854/2004). Further subdivisions can be made in the coding system if necessary (e.g. C141 to indicate a mild generalised disease, C142 a more severe disease, etc.).

[15] microbiological, chemical, serological, etc. (include results as attached).

ANNEX IV

MECHANICALLY SEPARATED MEAT AS REFERRED TO IN ARTICLE 11(2) OF REGULATION (EC) No 853/2004

MSM as referred to in Annex III, Section V, Chapter III, Point 3 of Regulation (EC) No 853/2004 shall have a Calcium content:

1. not exceeding 0.1% (=100 mg/100 g or 1000 ppm) of the fresh product

2. determined according to a standardised international method.

ANNEX V

TRICHINELLA INFESTATION AS REFERRED TO IN ARTICLE 18(9) AND (10) OF REGULATION (EC) No 854/2004

SECTION I: DEFINITIONS

1. '*Trichinella*' means any nematode belonging to species of the genus *Trichinella*.

2. 'Controlled housing conditions in integrated production systems' means a type of animal husbandry where pigs are continuously kept under conditions controlled by the food business operator with regard to feeding and housing.

SECTION II: OBLIGATIONS FOR THE COMPETENT AUTHORITY

CHAPTER I: GENERAL OBLIGATIONS

1. Carcases of domestic pigs shall be systematically sampled in slaughterhouses as part of the post mortem examination. A sample shall be collected from each carcase and the sample shall be examined for *Trichinella* using the reference detection method mentioned in Section III, A or one of the equivalent methods of detection mentioned in Section III, B in a laboratory designated by the competent authority.

2. Carcases of the following species shall be systematically sampled in slaughterhouses or game handling establishments as part of the post mortem examination. A sample shall be collected from each carcase and the sample examined in a laboratory approved by the competent authority for *Trichinella* in accordance with Section III:

   a) horses

   b) wild boar

   c) other farmed and wild species, when

      i) susceptible to *Trichinella* infestation and

      iii) unless the competent authority has established through a thorough risk assessment that the risk of infestation of a particular farmed or wild species is negligible.

3. Domestic pig carcases may be cut up pending the results of the *Trichinella* examination:

   a) in a maximum of six parts

   b) in the slaughterhouse or

   c) in a cutting plant in the same premises.

4. The carcase or the parts may not leave the premises of the slaughterhouse or if applicable the cutting plant in the same premises as the slaughterhouse, respectively, before the result of *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 of the slaughterhouse before the result of *Trichinella* examination is found to be negative. Animal waste and animal by products not intended for human consumption are allowed to leave the slaughterhouse. The competent authority may require *Trichinella* examination or prior treatment of animal by-products before permitting them to leave the slaughterhouse.

5. Where the procedure in place in the slaughterhouse to ensure that no part of examined animals leave the slaughterhouse until a negative result to the *Trichinella* examination has been obtained has been formally approved by the CA, the health mark may be applied before the results of the examination for *Trichinella* are available.

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6. The competent authority shall ensure that all personnel, involved in the examination of samples to detect *Trichinella* is properly trained, and participate in a proficiency sample programme and in a regular assessment of the sensitivity and the specificity of the test involved.

7. The trichinoscopic examination method shall not be used as a standard method for detecting *Trichinella* in meat[16].

8. The Member State may allow the use of the trichinoscopic method mentioned in Section III C in exceptional cases for domestic pigs and wild boar if:

   a) single carcases need to be examined individually in an establishment, which does not slaughter more than 15 domestic pigs or 10 wild boars per week and

   b) the detection methods mentioned in Section III, A or B are not available.

9. Whenever the trichinoscopic method is used the competent authority shall ensure that,

   a) the meat shall be delivered directly to the final consumer or to retail establishments directly supplying the final consumer and,

   b) the meat shall be marked with a health marking that is clearly distinct from community health marking,

[16] See Annex XI

c) the meat shall not be used for the production of products where the production process does not kill *Trichinella.*

10. The detection methods mentioned in Section III, A or B shall be used for verification of the *Trichinella* species, if samples are found to be suspect or positive using the trichinoscopic method. Where samples are found to be positive, the competent authority should encourage the use of the detection methods in Section III, A or B for animals originating from the same holding as the infected ones.

11. The competent authority of all Member States shall have a contingency plan outlining all actions to be followed whenever a sample proves to be positive for *Trichinella*. The plan shall include details on:

a) ability to trace back the infected carcase (s) and other parts containing muscle tissue and

b) measures to be taken with regard to infected carcase (s) or parts thereof and

c) investigation of the source of infection and possible extension in wild animals and

d) other measures at the retail or consumer level, if applicable, and

e) measures to be taken if the infected carcase can not be traced back to a single one within the slaughterhouse and

f) determination of the *Trichinella* species involved.

CHAPTER II: DEROGATIONS

1. By way of derogation from Chapter I (1), the examination for *Trichinella* of carcases or meat of pigs kept for no purpose other than for fattening and slaughter is not compulsory if the animals come from a holding or category of holdings that has been officially recognised by the competent authority as being free from *Trichinella* in accordance with the procedure laid down in Section VI, Chapter II.

2. By way of derogation from Chapter I (1), the examination for *Trichinella* of carcases or meat of pigs kept for no purpose other than for fattening and slaughter is not compulsory if the animals come from a region, area or country officially recognised as having a negligible prevalence of *Trichinella* in domestic pigs following a notification by the Member State of the Commission and the other Member States and approval according to the procedure mentioned in Article 19 of Regulation (EC) No 854/2004.

3. If a competent authority is applying the derogation mentioned in paragraph 1, the Member State concerned shall submit an annual report to the Commission, containing the information referred to in Section VI, Chapter II (3). The annual report shall be made in accordance with Article 9 of Directive 2003/99/EC. If the Member State does not submit the report or submits a report not containing the information referred to in Section VI, Chapter II of this Annex, then Section II, Chapter II, point 1 does not apply.

4. Meat of domestic pigs that has been submitted to a one of the freezing treatments pursuant to the requirements in Section IV under supervision of the competent authority, does not need to be examined for *Trichinella*.

CHAPTER III: DETAILED OBLIGATIONS FOR RECOGNITION AND SUPERVISION OF *TRICHINELLA* FREE HOLDINGS

1. The competent authority may officially recognise any holding as being free from *Trichinella* once the requirements laid down in Section VI, Chapter I and in Section VI, Chapter II (3) have been fulfilled. Food business operators of holdings recognised as *Trichinella* free shall inform the competent authority when one of the requirements can no longer be fulfilled or if any other change has occurred that might affect the *Trichinella* free status of the holding.

2. The competent authority can decide to recognise a category of holdings instead of individual holdings as being free from *Trichinella* once the requirements laid down in Section VI, Chapter II (2) and (3) have been fulfilled.

3. The competent authority shall ensure that periodically inspections are conducted of holdings recognised as *Trichinella* free. The frequency of the inspections shall be risk based taking into account disease history and prevalence, previous findings, the geographical area, local wildlife density, animal husbandry practices, veterinary supervision and farmer compliance.

4. A monitoring programme of animals originating from holdings or category of holdings recognised as *Trichinella* free shall be implemented by the competent authority in order to verify that the animals are free of *Trichinella*. The frequency of testing, the number of animals tested and the sampling plan shall be based on risk assessment. For this purpose meat samples shall be collected and examined for the presence of *Trichinella* parasites according to Section III, A or B. Serological methods can be used as an additional tool as part of the monitoring programme once a suitable test has been validated by the Community Reference laboratory.

5. Where pigs from a holding officially recognised as *Trichinella* free are found to be *Trichinella* positive, the competent authority shall without delay

   a) withdraw the official recognition of the holding as *Trichinella* free,

   b) test all animals when slaughtered and those on the holding using a serological test, 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, those that left the holding during at least six months preceding the finding. For this purpose meat samples shall be collected and examined for the presence of *Trichinella* parasites using the detection methods in Section III, A or B. A serological test can be used, once a suitable test has been validated by the Community Reference laboratory,

   d) investigate as far as feasible the spread of parasite infestation due to pigs slaughtered during the period preceding the 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 and extent of the monitoring programme mentioned in paragraph (4),

i) take appropriate measures if the infected carcase cannot be traced back to a single one within the slaughterhouse. These measures shall include

i) increase the size of the meat sample collected for testing of the suspected carcases or

ii) declare the carcases unfit for human consumption and

iii) take appropriate measures for the disposal of the positive or suspected carcases or pieces thereof.

6. The competent authority shall withdraw the official recognition of a holding or category of holdings as *Trichinella* free if:

i) one of the requirements laid down in Section VI, Chapter I or II is not fulfilled any more;

ii) serological results or laboratory findings following sampling of slaughtered pigs indicate that the holding or category of holdings can no longer be considered free from *Trichinella.*

7. Following a withdrawal a holding can be recognised again as officially free from *Trichinella* once the problems have been resolved to the satisfaction of the competent authority and the obligations have been fulfilled in accordance with Section VI, Chapter II, 2.

8. The competent authority shall ensure that all breeding sows and boars originating from *Trichinella* free holdings are examined according to Chapter I (1).

SECTION III: DETECTION METHODS

A. REFERENCE METHOD OF DETECTION: **The magnetic stirrer method for pooled sample digestion**

a) Apparatus and reagents:

– knife or scissors and tweezers for cutting specimens,

– 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,

– a blender, with a sharp chopping blade. In case the samples are heavier than 3g, a meat mincer with openings of 2-4 mm or scissors should be used. In the case of frozen meat or tongue (after removal of the

superficial layer, which can not be digested) a meat mincer is necessary and the sample size will need to be increased considerably,

– magnetic stirrers, with thermostatically controlled heating plate and teflon coated stirring rods, approximately 5 cm long,

– conical glass separation funnels of 2-4 litre capacity, preferably fitted with teflon safety plugs,

– stands, rings and clamps,

– sieves, mesh size 180 microns, external diameter 11 cm with stainless steel mesh.

– funnels with an internal diameter not less than 12 cm, to support the sieves,

– glass beakers of 3 litre capacity,

– measuring glass cylinders of 50-100 ml capacity, or centrifuge tubes,

– a trichinoscope with horizontal table or a stereo-microscope, with a sub-stage transmitted light source with adjustable intensity ,

– a number of 9 cm diameter petri dishes (when using a stereo-microscope) marked on their undersides into 10 x 10 mm square examination areas using a pointed instrument,

– a larval counting basin (when using a trichinoscope): the larval counting basin is made from 3 mm thick acrylic plates as follows:

  i) the bottom of the basin to be 180 x 40 mm, marked off into squares,

  ii) the sides to be 230 x 20 mm,

  iii) the end to be 40 x 20 mm. The bottom and the ends should be inserted between the sides, thus forming two small handles in both ends. The upper side of the bottom should be raised 7 to 9 mm from the base of the frame formed by the sides and the ends. The parts should be fixed by using glue appropriate for the material,

– aluminium foil,

– 25% hydrochloric acid,

– pepsin strength: 1: 10 000 NF (US National Formulary) corresponding to 1:12 500 BP (British Pharmacopoea) corresponding to 2 000 FIP (Fédération Internationale de Pharmacie),

– tap-water heated to 46 to 48°C,

– a balance accurate to at least 0.1 g,

– metal trays of 10 – 15 litre capacity to collect the remaining digestive juice,

– pipettes of different sizes (1, 10, 25 ml) and pipette holders,

– a thermometer accurate to 0.5°C within the range 1 to 100°C,

– siphon for tap-water.

b) Collection of specimens and quantity to be digested:

i) In the case of whole carcases of domestic pigs, a specimen to be taken of at least 1 g from a pillar of the diaphragm at the transition to the sinewy part. A special trichinae-forceps can be used if an accuracy between 1 and 1,15 g can be guaranteed .

In the case of breeding sows and boars a larger sample shall be taken of at least 2 g 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, to be taken from the rib part or the breastbone part of the diaphragm, from the jaw muscle, tongue or the abdominal muscles.

ii) For cuts of meat, a sample of at least 5 g of striated muscle to be taken, containing little fat and, where possible, near to bones or tendons. The same sample size should be collected from meat, which is not intended for thorough cooking or other post-slaughter processing.

iii) For frozen samples, a sample of at least 5 g of striated muscle tissue to be taken for analysis.

The weight of meat specimens refers to a meat sample free of all fat and fascia. Particular attention should be made collecting muscle samples from the tongue to avoid sample contamination with the superficial layer of the tongue, which is indigestible and can prevent reading of the sediment.

c) Method:

i) a) Complete pools (100 g of samples at a time)

– 16 ± 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.

– 10 ± 0,2 g of pepsin is added.

– 100 g of samples collected in accordance with (b), are chopped in the blender.

– The chopped meat is transferred to the 3 litre beaker containing water, pepsin and hydrochloric acid.

– 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.

– The beaker is covered with aluminium foil.

– The magnetic stirrer should be adjusted so that it maintains a constant temperature of 44 to 46°C throughout the period of operation. During the stirring process, the digestion fluid should rotate at a sufficiently high speed to create a deep whirl without splashing.

– The digestion fluid is stirred until the meat particles disappear (approximately 30 minutes), at the end of which the stirrer is 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 meat types (tongue, game meat, etc.).

– The digestion process is considered satisfactory, if not more than 5% of the starting sample weight remains on the sieve.

– The digestion fluid is allowed to stand in the funnel for 30 minutes.

– After 30 minutes, a 40 ml sample of digestion fluid is quickly run off into the measuring cylinder or centrifuge tube.

– The digestion fluids and other liquid waste are kept in a tray until reading of the results is completed.

– The 40 ml sample is allowed to stand for 10 minutes, at the end of which time 30 ml of supernatant is carefully withdrawn by suction removing the upper layers and leaving a volume of not more than 10 ml.

– The remaining 10 ml sample of sediment is poured into a larval counting basin or petri dish.

– Then 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 routinely at a (15-) 20 x magnification. Visualisation using other techniques is allowed as long as examination of positive controls has 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 x should be used.

– Digests should be examined as soon as they are ready. Under no circumstances should examination be postponed until the following day.

If the digests are not examined within 30 minutes of their preparation, they should be clarified as follows. The final sample of about 40 ml is poured into a measuring cylinder and allowed to stand for 10 minutes, after which time 30 ml of the supernatant fluid is 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 maximum 10 ml for examination in a petri dish or larval counting basin. The measuring cylinder should be washed with maximum 10 ml of tap-water and these washings should be 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 should be poured into a measuring cylinder and made up to 40 ml with tap-water and then the above procedure should be followed. The procedure can be repeated 2 to 4 times until the fluid is clear enough for reliable reading.

ß) Pools of less than 100 g

When needed, up to 15 g may be added to a total pool of 100 g and examined together with these samples according to (c)(i)(a). More than 15 g should be examined as a complete pool. For pools 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.

ii) In the case of a positive or doubtful result following the examination of a collective sample, a further 20 g sample should be taken from each pig in accordance with (b) above. The 20 g samples from five pigs should be pooled and examined by 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 should be collected from the individual pigs in the group and each should separately be examined using the method described above.

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

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

B. EQUIVALENT METHODS

1. **The mechanically assisted pooled sample digestion method/sedimentation technique**

a) Apparatus and reagents:

– knife or scissors for cutting specimens,

– trays marked off with 50 squares each which can hold samples of approximately 2 g of meat, or other tools giving equivalent guarantees as regards the traceability of the samples,

– meat mincer or electrical blender,

– a stomacher lab-blender 3 500 thermo model,

– plastic bags suitable for the stomacher lab-blender,

– conical separation funnels of 2 litre capacity, preferably fitted with teflon safety plugs,

– stands, rings and clamps,

– sieves, mesh size 180 microns, external diameter 11 cm with stainless steel or brash mesh.

– funnels with an internal diameter not less than 12 cm, to support the sieves,

– 100 ml glass measuring cylinders,

– a thermometer accurate to 0,5°C within the range 1 to 100°C,

– a vibrator, e.g. an electric shaver with the head removed,

– a relay which will switch on and off at one minute interval,

– a trichinoscope with a horizontal table or a stereo-microscope, with a sub-stage transmitted light source with adjustable intensity ,

– a larval counting basin and a number of 9 cm diameter petri dishes as in Section III, A, 1 (a),

– 17,5% hydrochloric acid solution,

– pepsin strength 1:10 000 NF (US national formulary) corresponding to 1:12 500 BP (British Pharmacopoeia) corresponding to 2 000 FIP (Fédération Internationale de Pharmacie),

– a number of 10 litre bins to be used when applying decontamination, such as formol treatment, to the apparatus and for the remaining digestive juice in the case of positive results,

– a balance accurate to 0,1 g.

b) Collection of specimens and quantity to be digested:

The same as mentioned under Section III, A, (b).

c) Method:

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

ii) Digestion procedure

a) Complete pools (100 samples at a time)

– The stomacher lab-blender 3 500 should be fitted with a double plastic bag and the temperature control set at 40 to 41°C.

– One and a half litres of water preheated to 40 to 41°C is poured into the inner plastic bag.

– 25 ml of 17,5% hydrochloric acid is then added to the water in the stomacher.

– 100 samples of approximately 1 g each (at 25 to 30°C) taken from each of the individual samples, in accordance with (b), are then added.

– 6 g pepsin is finally added. This order of addition should be strictly adhered to in order to avoid decomposition of the pepsin.

– The stomacher is then allowed to pound the content of the bag for 25 minutes.

– The plastic bag is then removed from the stomacher and the digestion fluid is filtered through the sieve into a 3 litre beaker.

– The plastic bag is washed with approximately 100 ml of water, which is then used to rinse the sieve and finally added to the filtrate in the beaker.

Up to 15 single samples could be added to a total pool of 100 samples and be examined together with these samples.

ß) Smaller pools (less than 100 samples)

– The stomacher lab-blender 3 500 should be fitted with a double plastic bag and the temperature control set at 40 to 41°C.

– 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 of addition should be strictly adhered to in order to avoid decomposition of the pepsin.

– 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 x 15 ml or 450 ml) and transferred to the inner of the two plastic bags together with the meat samples of approximately 1 g (at 25 to 30°C) taken from each of the individual samples in accordance with (b).

– Water at a temperature of approximately 41°C is poured into the outer bag to 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.

– The plastic bag is then removed from the stomacher and the digestion fluid is filtered through the sieve into a 3 litre beaker.

– The plastic bag is washed with approximately 100 ml of water (at 25 to 30ºC), which is then used to rinse the sieve and finally 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, bringing 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 1 (ii)), the amount of ice should be reduced correspondingly.

– The chilled digestion fluid is transferred to a 2 litre separation funnel, equipped with a vibrator in an extra clamp.

– Sedimentation for 30 minutes, during which time the sedimentation funnel is vibrated intermittently, i.e. one minute vibration followed by 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 should be withdrawn by suction, leaving a volume of 15 ml to be examined for the presence of larvae.

– For suction, a disposable syringe can be used, equipped with a plastic tube. The length of the tube should be such that 15 ml will

remain 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, respectively.

– The measuring cylinder should be washed with 5-10 ml of tap water and the washings should be added to the sample.

– Digests should be examined as soon as they are ready. Under no circumstances should examination be postponed until the following day.

If the digests are unclear, or are not examined within 30 minutes of their preparation, they should be clarified as follows.

The final sample of 60 ml is poured into a measuring cylinder and allowed to stand for 10 minutes. At the end of this time, 45 ml of supernatant fluid is 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 should be washed with 10 ml of tap-water and these washings should be added to the sample in the petri dish or the larval counting basin for examination.

iv) In the case of a positive or doubtful result, see Section III, , A, (c) ii).

2. **The mechanically assisted pooled sample digestion method/"on filter isolation" technique**

a) Apparatus and reagents:

Those indicated in Section III, B, 1 (a).

Supplementary equipment to the above mentioned:

– 1 litre Gelman funnel, complete with filter holder (diameter 45 mm),

– filter discs; the filter discs consist of: a circular stainless steel mesh with an aperture of 35 microns (the diameter of the disc should be 45 mm), two rubber rings made of 1 mm thick rubber (the external diameter should be 45 mm and the internal diameter 38 mm), the circular mesh is placed between the two rubber rings and bonded to them using a two-component glue suitable for the two materials,

– an Erlenmeyer flask with a capacity of 3 litres and fitted with a side tube for suction,

– a filter pump,

– plastic bags with a capacity of at least 80 ml,

– equipment for sealing the plastic bags,

– rennilase, strength 1: 150 000 soxhlet units per gram.

b) Collection of specimens:

The same as mentioned under Section III, A, (b).

c) Method:

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

ii) Digestion procedure

a) Complete pools (100 samples at a time)

see B (1) (c) (ii) (a).

ß) Smaller pools (less than 100 samples)

see B (1) (c) (ii) (ß).iii) Recovery of larvae by filtration

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

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

– The Gelman funnel, fitted with a filter holder and filter disc, is mounted on the Erlemeyer flask connected to a filter pump.

– The digestion fluid is poured into the Gelman funnel and filtered. Towards the end of filtration, the passage of the digestion fluid through the filter can be assisted by applying suction with the filter pump. Suction should cease before the filter becomes dry, i.e. when 2 to 5 ml of fluid are left in the funnel.

– When 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 solution of rennilase is made by adding 2 g of rennilase to 100 ml of tap-water.

– The plastic bag is sealed twice and placed in the stomacher between the inner and outer bag.

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

– 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.

– Digests should be examined as soon as they are ready. Under no circumstances should examination be postponed until the following day.

Note: Filter discs should never be used when not completely clean. Unclean discs should never be allowed to dry out. Filter discs can be cleaned by leaving them in rennilase solution overnight. Before use, they should be washed in fresh rennilase solution using the stomacher.iv) In the case of a positive or doubtful result, following the examination of a collective sample, a further 20 g sample should be taken from each pig in accordance with (b) above. The 20 g samples from five pigs should be pooled and examined by 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 should be collected from the individual pigs in the group and each should separately be examined using the method described above.

Positive fluids shall be decontaminated according to laboratory routines.

3. **The automatic digestion method for pooled samples of up to 35 g**

a) Apparatus and reagents:

– Knife or scissors for cutting specimens,

– 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,

– a Trichomatic 35® blender with filtration insert,

– hydrochloric acid solution 8,5 % ± 0,5 weight,

– transparent polycarbonate membrane filters with a diameter of 50 mm and a pore size of 14 microns,

– pepsin strength 1: 10 000 NF (US National Formulary) corresponding to 1: 12 5000 BP (British Pharmacopoeia) corresponding to 2 000 FIP (Fédération Internationale de Pharmacie),

– a balance, accurate to 0,1 g,

– tweezers with a flat tip,

– a number of microscope slides with a side-length of at least 5 cm or a number of at least 6 cm diameter Petri dishes marked on their underside equipped into 10 × 10 mm large areas using a pointed instrument,

– a (stereo-) microscope with transmitted light (magnification 15 to 60 times) or a trichinoscope with a horizontal table,

– a bin for collection of waste liquids,

– a number of 10 litre bins to be used when applying de-contamination, such as formol treatment, to the apparatus and for the remaining digestive juice in the case of positive results,

– a thermometer accurate to 0,5°C within the range 1 to 100°C.

b) Collection of specimens

The same as mentioned under Section III, A, (b).

c) Method

i) Digestion Procedure

– Place the blender with filtration-insert, connect the waste tube and lead the tube to the waste bin.

– When the blender is switched on, the heat-up will start.

– Before start, the bottom valve, located below the reaction chamber, should be opened and closed.

– Up to 35 samples of approximately 1 g each (at 25 to 30°C) taken from each of the individual samples, in accordance with point b, are then added. Make sure that larger pieces of tendons are removed as this may clot the membrane filter.

– Pour water to the edge of a liquid chamber connected to the blender (approximately 400 ml).

– Pour about 30 ml hydrochloric acid (8,5 %) to the edge of the smaller, connected liquid chamber.

– Place a membrane filter under the coarse filter in the filter holder in the filter insert.

– 5 g of pepsin is added last. The order of addition should be strictly adhered to in order to avoid decomposition of the pepsin.

– Close the lids to the reaction- and liquid chambers.

– Select the period of digestion. Short digestion period (5 minutes) for pigs at normal age of slaughtering and extended digestion time (8 minutes) for other samples.

– The automatic dispensing starts when the start button on the blender is activated and digestion with following filtration will proceed automatically. After 10 to 13 minutes the process is completed and stops automatically.

– The lid to the reaction chamber is opened once it is checked that the chamber is emptied. If there is foam or remains of digestion liquid in the chamber repeat the procedure according to point 4.

ii) Recovery of larvae

– Dismount the filter holder and transfer the membrane filter to a slide or a Petri dish.

– The membrane filter is examined by means of a (stereo-) microscope or a trichinoscope.

iii) Cleaning of equipment

– In the case of a positive result, fill the reaction chamber in the blender 2/3 with boiling water. Ordinary tap-water is poured into the connecting liquid chamber until the lower level sensor is covered. The automatic cleaning programme is then carried out. De-contaminate the filter-holder together with the remaining equipment, for example by means of formal treatment.

– After the day's work fill the liquid chamber in the blender with water and carry out a standard programme.

iv) Method to be used when digestion is incomplete and filtration cannot therefore be carried out.

When the automatic process in the blender is carried out according to point 1, open the lid to the reaction chamber and check whether there is foam or liquid remaining in the chamber. It this is the case, carry out the following procedure:

– Close the bottom valve below the reaction chamber.

– Dismount the filter holder and transfer the membrane filter to a slide or a Petri dish.

– Put a new membrane filter in the filter holder and mount the filter holder.

– Fill water into the liquid chamber in the blender until the lower level-sensor is covered.

– Carry out the automatic cleaning programme.

– After the cleaning programme has been completed open the lid to the reaction chamber and check for liquid remains.

– If the chamber is empty, dismount the filter holder and transfer the membrane filter with a tweezer to a slide or a Petri dish.

– The two membrane filters are examined according to point 2. If the filters cannot be examined repeat the entire digestion process with extended digestion time according to point 1.

v) In the case of a positive or doubtful result, following the result of a collective sample, a further 20 g sample should be taken from each pig in accordance with point b above. These samples shall be investigated individually according to the abovementioned method.

Positive fluids shall be decontaminated according to laboratory routines.

C. TRICHINOSCOPIC EXAMINATION

1. Apparatus

An incandescent lamp trichinoscope with 30 to 40 x and 80 to 100 x magnification or a stereomicroscope with a sub-stage transmitted light source with adjustable intensity. A pressure glass consisting of two glass plates - one of which is divided into equal fields - small curved scissors, small forceps, a knife for cutting specimens, small numbered containers for storing the specimens separately, a dropping pipette, a glass of acetic acid and a glass of potassium hydroxide solution for brightening any calcifications or softening dried meat .

2. Collection of specimens

In the case of whole carcases, several samples of the size of a hazelnut are to be taken from each animal:

(a) In the case of domestic pigs:

- from both diaphragm pillars at the transition of the sinewy part.

(b) In the case of wild boar additional samples are to be taken:

- from the jaw, the muscles of the lower leg, the intercostal muscles and the tongue muscles,

- giving a total of 6 samples to be examined for each individual animal.

(c) If certain muscles are not available for sampling, a total of 4 samples shall be collected from the muscles that are available.

(d) In the case of pieces of meat, take from each piece 4 samples of striated muscle tissue, containing no fat, if possible, taken from different points, where possible near to bones or tendons the size of a hazelnut.

3. Method

In general a compressorium should be filled with 1,0 ± 0,1 g of meat, generally corresponding with 28 oat-kernel sized pieces. If necessary, two compressoria need to be filled to be able to examine 56 oat-kernel sized pieces.

If both diaphragm pillars are present in a domestic pig, the *Trichinella* inspector must cut, from each of the above specimens taken from a whole carcase, 28 pieces the size of an oat-kernel making 56 in all; if only one diaphragm pillar is present, 56 pieces, from different places and if possible from the transition to the sinewy part; The samples collected from the other four muscles of wild boar must each be cut in 7 pieces the size of an oat-kernel resulting in a total of 28 additional pieces.

The *Trichinella* inspector must then compress the 56 (or 84) pieces between the glass plates in such a way that normal print can be clearly read through the slide preparation. If the flesh of the specimens to be examined is dry and old, the preparations must be softened in a mixture of one part potassium hydroxide solution to about two parts water for 10 to 20 minutes before pressing.

From each of the samples taken from pieces of meat, the *Trichinella* inspector must cut 14 pieces the size of an oat-kernel, making 56 pieces in all.

The microscopic examination should be carried out in such a manner that each preparation is scanned slowly and carefully at a magnification of 30 to 40 x.

If the trichinoscopic examination reveals suspect areas, the nature must be ascertained with the most powerful magnification of the trichinoscope (80 to 100 x).

In the case of an uncertain result, the examination must be continued on a further number of specimens and slide preparations, until the information required is obtained. The trichinoscopic examination must be carried out for at least six minutes.

The minimum time fixed for the examination does not include the time necessary for sample-taking and for making the preparations.

As a general rule, the trichinoscopic examiner should not inspect more than 840 pieces a day, which corresponds with the examination of 15 domestic pigs or 10 wild boars.

SECTION IV: FREEZING TREATMENTS

1. Freezing method 1

a) Meat brought in already frozen must be kept in this condition.

b) The technical equipment and energy supply of the refrigerating 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 should be removed before freezing, except for meat which has already reached throughout the required temperature when it is brought into the refrigeration room or for meat that is packaged in such a way that the packaging will not prevent it from reaching the required temperature within the allotted time frame.

d) Consignments in the refrigeration room must be kept separately and under lock.

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 –25ºC. It should be measured with calibrated thermo-electric instruments and continuously recorded. It may not be measured directly in the cold air flow. The instruments must be kept under lock. The charts must include the relevant numbers from the meat inspection register on importation and the date and time of the commencement and completion of freezing, and must be retained for one year after compilation.

g) Meat with a diameter or thickness of up to 25 cm must be frozen for at least 240 consecutive hours, and meat with a diameter or thickness of between 25 and 50 cm must be frozen for at least 480 consecutive hours. This freezing process may not be applied to meat which has a larger diameter or is thicker. The freezing time shall be calculated from the point when the temperature referred to in paragraph f is reached in the freezing room.

2. Freezing method 2

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

a) Meat with a diameter or thickness of up to 15 cm must be frozen according to one of the following time-temperature combinations:

– 20 days at -15°C,

– 10 days at -23°C,

– 6 days at -29°C.

b) Meat with a diameter or thickness of between 15 cm and 50 cm must be frozen according to one of the following time-temperature combinations:

– 30 days at -15°C,

– 20 days at -25°C,

– 12 days at -29°C.

The temperature in the refrigeration room must be no higher than the level of the selected inactivation temperature. It should be measured with calibrated thermoelectric instruments and continuously recorded. It may not be measured directly in the cold air flow. The instruments must be kept under lock. The charts must include the relevant numbers from the meat inspection register on importation and the date and time of the commencement and completion of freezing, and must be retained for one year after compilation.

When deviating from the above mentioned procedures using freezing tunnels, the food business operator shall be able to prove to the competent authority the effectiveness of the alternative method in killing *Trichinella* parasites in pig meat.

3. Freezing method 3

Treatment may consist of commercial freeze drying or controlled freezing at the centre of the meat pieces in accordance with specified time-temperature combinations.

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

– 106 hours at -18ºC,

– 82 hours at -21ºC,

– 63 hours at -23,5ºC,

– 48 hours at -26ºC,

– 35 hours at -29ºC,

– 22 hours at -32ºC,

– 8 hours at -35ºC,

– ½ hour at -37ºC.

b) The temperature should be measured with calibrated thermoelectric instruments and continuously recorded. The probe of the thermometer has to be placed at the centre of a calibrated piece of meat of a size no smaller than the thickest piece of meat to be frozen. This calibrated piece of meat should be placed at the least favourable site in the freezing room, not close to the cooling equipment or directly in the cold air flow. The instruments must be kept under lock. The charts must include the relevant numbers from the meat inspection register on importation and the date and time of the commencement and completion of freezing, and must be retained for one year after compilation.

SECTION V: EXAMINATION OF OTHER ANIMALS THAN DOMESTIC PIGS

The examination of horse meat, wild game meat and other meat that could contain *Trichinella* parasites has to be performed according to one of the digestion methods mentioned in Section III, A or B with the following modifications:

– Specimens of at least 10 g are to be taken from the lingual or diaphragm muscle of horses and from the forearm, tongue or diaphragm of wild boar. In the absence of these muscles in the horse a larger sized specimen is to be taken from a pillar of the diaphragm at the transition to the sinewy part. The muscle should be clean of connective tissue and fat.

– At least 5 g of sample is digested following the standard detection method of Section III, A or one of the equivalent methods mentioned in B For each digest, the total weight of muscle under examination must not exceed 100 g for the method in A or the methods 1 or 2 in B and 35 g for method 3 of B.

– In the case of a positive result a further 50 g specimen must be taken for a subsequent independent examination.

– All meat from game animals other than wild boar, such as bears, carnivore mammals (including sea mammals) and reptiles without prejudice to the rules on conservation of animal species, should be tested by sampling 10 g of musculature of the predilection sites or larger amounts if these sites are not available. Predilection sites are in bear: diaphragm, masseter muscle and tongue; in walrus: tongue; in crocodiles: masseter, pterygoid and intercostals muscles; in birds muscles of the head (e.g. masseter and the neck muscles). Care should be taken that the digestion time is long enough (not exceeding 60 minutes) to ensure adequate digestion of the tissues of these animals.

SECTION VI: DETAILED CONDITIONS FOR TRICHINELLA FREE HOLDINGS

CHAPTER I: OBLIGATIONS FOR FOOD BUSINESS OPERATORS

1. The following requirements have to be met by the food business operator to obtain official recognition of the holding as free from *Trichinella*:

a) The operator shall have taken all practical precautions with regard to construction and maintenance of the buildings in order to prevent rodents, any kind of other mammals and large carnivorous birds from having access to the buildings, where animals are kept.

b) The operator shall initiate a pest control programme, in particular to control rodents, so as to effectively prevent infestation of pigs. The operator has to record the effectiveness of the programme to the satisfaction of the competent authority.

c) The operator shall ensure that all feed has been obtained from a facility, which produces feed according to Regulation (EC) No 183/2005 of the European Parliament and of the Council laying down requirements for feed hygiene.

d) The operator shall store feed in closed silos or other containers, impenetrable to rodents. All other feed supplies as well as bedding material shall be heat treated or produced and stored to the satisfaction of the competent authority.

e) The operator shall ensure that dead animals are collected for disposal within 24 hours of death by sanitary means. However, dead piglets may be collected, and stored in a hygienically closed container on the holding awaiting further disposal.

f) If a garbage dump is present in the neighbourhood of the holding, the operator shall inform the competent authority. Subsequently, the competent authority shall assess the risks involved and decide on the appropriateness of registering the holding as *Trichinella* free.

g) The operator shall ensure that incoming piglets or purchased pigs are born and bred under controlled housing conditions in integrated production systems.

h) The operator shall ensure that pigs are identified in such a way that it is possible to trace each animal back to holding level.

i) The operator shall only introduce new animals, irrespective of their origin, to the holding if they

– originate from holdings officially recognised as *Trichinella* free or

– are accompanied by a certificate authenticated by the competent authority from the exporting country stating that the animal originate from a holding recognised as *Trichinella* free or,

– are kept in isolation until the results of an immuno-diagnostic method approved by the Community Reference Laboratory have proven to be negative. Sampling for immuno-diagnostic testing shall not commence before four weeks after arrival of the animals on the holding.

j) The operator shall ensure that none of the pigs intended for slaughter have access to outdoor facilities during the entire production period.

k) Outdoor access during the first weeks of life before weaning is permitted if all the following conditions are met:

i) *Trichinella* infestations in domestic animals have not been diagnosed in the country during the past 10 years and

ii) an annual surveillance programme of wildlife susceptible to *Trichinella* is existing. 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 appropriate indicator species as based on previous findings. The results shall show a prevalence of *Trichinella* in indicator animals below 0.5% and

iii) when outdoors the animals are in properly fenced areas and

iv) the monitoring program mentioned in Section II, Chapter III, (4) is in place and the frequency of the monitoring is increased in the holdings involved and

v) all sows and boars kept for breeding purposes on the holding are being systematically sampled at slaughter for examination using the standard detection method in Section III, A or one of the equivalent methods in Section III, B and

vi) access of large carnivorous and omnivorous birds (e.g. crows, birds of prey) should be impeded.

2. Food business operators of holdings recognised as *Trichinella* free shall inform the competent authority when one of the requirements can no longer be fulfilled or if any other change has occurred that might affect the *Trichinella* free status of the holding.

CHAPTER II: OBLIGATIONS FOR THE COMPETENT AUTHORITIES

1. If a holding is situated in a Member State that has detected *Trichinella* in domestic pigs during the past 10 years, the competent authority can recognise the holding as free of *Trichinella* following:

a) at least two control visits during the 12 months preceding the recognition of the holding, to verify compliance with the requirements of Section III, Chapter I (1) and

b) testing of all pigs sent for slaughter during at least 24 months preceding the recognition or a longer time period to ensure that to the satisfaction of the competent authority enough animals from the holding have been tested using one of the parasite detection methods mentioned in Section II, Chapter IV, A or B and

c) negative results of the tests and

d) putting in place a risk based monitoring programme of wildlife in those areas where wildlife and holdings applying for a *Trichinella* free status co-exist. The monitoring programme shall optimise parasite detection by using the most

suitable indicator animal and detection technique and by sampling as large a number of animals and by using as large a meat sample as feasible. Parasites detected in wildlife shall be identified at the species level in a Community or national reference laboratory.

2. The competent authority can decide to recognise a category of holdings to be free of *Trichinella* if all of the following conditions are met:

   a) all requirements mentioned in Section VI, Chapter I (1) with the exception of point (k), which does not apply,

   b) autochthonous *Trichinella* infestations in domestic animals have not been detected in the country during the past 10 years, during which time continuous testing was conducted on a statistically based sample size from within the annual slaughter swine population to provide at least 95% confidence of detecting *Trichinella* infestation if it is present at a prevalence lower than 0.001%, but preferably approaching 0.0001%,

   c) a clear description must be available of the category of holdings, the type of rearing and the type of animals involved,

   d) a risk based monitoring programme of wildlife has been established in accordance with Section VI, Chapter II, 1 (d).

3. The (annual) report to the Commission shall in addition to the requirements laid out in Annex IV of Directive 2003/99/EC, contain the following information:

   a) the number of human cases (imported and autochthonous), including the epidemiological data in case of positive findings;

   b) the results of the testing for *Trichinella* of domestic pigs that are not raised under controlled housing conditions in integrated production systems; the results should include age and sex of affected animal, type of management system, type of diagnostic method used, level of infestation (if known) and additional relevant information if applicable;

   c) the results of the testing for *Trichinella* of breeding sows and boars; the results should include information as mentioned under b);

   d) the results of the testing for *Trichinella* of carcases of wild boars, horses, game and, if applicable, indicator animals;

   e) the serological results of tests as mentioned in Section II, Chapter III, 4 once a suitable test has been validated by the Community Reference laboratory;

   f) other *Trichinella* suspected cases, either imported or autochthonous and all relevant laboratory results;

   g) information on the number of *Trichinella* free holdings and summarised results of the inspections of *Trichinella* free holdings including information on farmer compliance;

h) details of confirmation and species identification in the Community or national reference laboratory of all positive results;

i) the data shall be submitted according to the format and timetable as determined by EFSA for the reporting of zoonoses.

SECTION VII: IMPORT REGULATIONS

1. To be allowed to be placed on the Community market, meat from animal species, which may be carriers of *Trichinella*, containing striated muscles and originating in third countries, shall be examined for *Trichinella* in the country of origin before exportation to Member States of the Community. The examination shall be carried out in accordance with Section II, Chapter I, on the whole carcase or, failing this, on each half carcase, quarter piece or cuts of meat.

2. If a third country wishes to designate holdings or categories of holdings as free from *Trichinella*, the competent authority of that country shall be able to prove unequivocally that the requirements as set out in this Annex are met and shall submit a report to the Commission as stated in Section II, Chapter III (1) and (2) of this Annex.

3. In the case of meat of domestic pigs, the freezing treatment referred to in Section IV may replace the examination carried out in accordance with Section II, Chapter I (1), provided it is done under supervision of the competent authority.

4. The freezing treatment in Section IV shall not be used as a replacement for the examination of horse meat or game meat for *Trichinella*.

5. A document as referred to in Article 4, point 3 of Directive 2004/41/EC or in Article 14 of Regulation (EC) No 854/2004 must be completed with a statement by the official veterinarian that the meat has been examined in the exporting third country in accordance with paragraph 1 or that a freezing treatment has been carried out in accordance with paragraph 3. The document shall accompany the meat in the original unless an exemption has been granted according to Article 14 point 4 of Regulation (EC) No 854/2004. These conditions are included in the veterinary certificates which should accompany the consignment.

ANNEX VI

ANALYTICAL METHODS FOR DETECTION OF MARINE BIOTOXINS AS REFERRED TO IN ARTICLE 11(4) OF REGULATION (EC) No 853/2004

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

CHAPTER I: PARALYTIC SHELLFISH POISON (PSP) DETECTION METHOD

1. The Paralytic Shellfish Poison (PSP) content in the edible parts of molluscs (the whole body or any part edible separately) must be detected in accordance with the biological testing method - in association if necessary with a chemical method for detection of Saxitoxin and its analogues for which a standard is available - or any other recognized method.

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) in the edible parts of molluscs (the entire body or any part edible separately) must be detected using the HPLC method or any other recognised method.

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

CHAPTER III: LIPOPHILIC TOXINS 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 the extraction and purification steps, can be used for detection of the toxins mentioned in Annex III, Section VII, Chapter V, point 2 (c), (d) and (e) of Regulation (EC) No 853/2004**.** Sensitivity and selectivity depend on the choice of the solvents used for the extraction and purification steps and this should be taken into account when making a decision on the method to be used, in order to cover the full range of toxins.

2. A single mouse bioassay involving acetone extraction can be used to detect okadaic acid, dinophysistoxins, pectenotoxins and yessotoxins. This assay may be complemented if necessary with liquid/liquid partition steps with ethyl acetate/water or dichloromethane/water to remove potential interferences. Azaspiracids detection at the regulatory levels by means of this procedure requires the use of the whole body as the test portion.

3. Three mice should be used for each test. The death of two out of three mice within 24 hours after inoculation into each of them of an extract equivalent to 5 g of hepatopancreas or 25 g whole body should be considered as a positive result for the presence of one or more of the toxins mentioned in Annex III, Section VII, Chapter

V, point 2 (c), (d) and (e) of Regulation (EC) No 853/2004 at levels above those established.

4. A mouse bioassay with acetone extraction followed by liquid/liquid partition with diethylether can 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 should be used for each test. The death of two out of three mice within 24 hours after inoculation into each of them of an extract equivalent to 5 g of hepatopancreas or 25 g whole body should be considered as a positive result for the presence of okadaic acid, dinophysistoxins, pectenotoxins and azaspiracids at levels above those established in Annex III, Section VII, Chapter V, point 2 (c) and (e) of Regulation (EC) No 853/2004.

5. The rat bioassay can detect okadaic acid, dinophysistoxins and azaspiracids. Three rats should be used for each test. A diarrhetic response in any of the three rats is considered a positive result for the presence of okadaic acid, dinophysistoxins and azaspiracids at levels above those mentioned in Annex III, Section VII, Chapter V, point 2 (c) and (e) of 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 can be used as alternative or complementary methods 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: an hydrolysis step may be required in order 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 will have to be available before chemical analysis will be possible. Total toxicity will be calculated using conversion factors based on the toxicity data available for each toxin.

3. The performance characteristics of these methods should 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 all toxins prescribed in Section VI, Chapter V of Annex III to Regulation (EC) No 853/2004 have become readily available, the methods have been validated and this Chapter has been amended accordingly.

ANNEX VII

FISHERY PRODUCTS REFERRED TO IN ARTICLE 11(8) AND PURSUANT TO ARTICLE 9 OF REGULATION (EC) No 853/2004 AND IN ARTICLE 18 (15) OF REGULATION (EC) No 854/2004

SECTION I: OBLIGATIONS FOR FOOD BUSINESS OPERATORS

This Section lays down detailed rules relating to the visual inspection for the purpose of detecting parasites in fishery products.

CHAPTER I: DEFINITIONS

1.

2. 'Visual inspection' means a non-destructive examination of fish or fishery products without optical means of magnifying and under good light conditions for human vision, including, if necessary, candling.

CHAPTER II: VISUAL INSPECTION

1. Visual inspection shall be performed on a representative number of samples. The persons in charge of on-shore establishments and qualified persons on board factory vessels shall determine the scale and frequency of the inspections by reference to the nature of the fishery products, their geographical origin and their use. During production the visual inspection of eviscerated fish must be carried out by qualified persons on the abdominal cavity and livers and roes intended for human consumption. According to 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 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 the provisions laid down in Annex III, Section VIII, Chapter II point 4 of 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 FOR 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 of this Section shall be regarded as unfit for human consumption where, organoleptic assessment having raised doubts as to their freshness, 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 is the method involving distillation of an extract deproteinized by perchloric acid set out in Chapter III.

2. Distillation as referred to in point 1 must be performed using apparatus which complies with the principles of 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 deproteinized by trichloracetic acid (Codex Alimentarius Committee on Fish and Fishery Products (1968)).

4. The sample must consist of about one hundred grams of flesh, taken from at least three different points and mixed together by grinding.

   Member States shall recommend to official laboratories the use, as a matter of routine, of the reference method above referred. In case of doubt 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 A TVB-N LIMIT VALUE IS 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 VOLATILE NITROGENOUS BASES (TVB-N) IN FISH AND FISHERY PRODUCTS

A. REFERENCE PROCEDURE

1. Purpose and area of application

This method describes a reference procedure for identifying the nitrogen concentration of volatile nitrogenous bases (Total-Volatile-Base-N: TVB-N) in fish and fish products. This procedure is applicable to TVB-N concentrations from 5 mg/100 g to at least 100 mg/100 g.

2. Definition

The TVB-N concentration is here understood to mean the nitrogen content of volatile nitrogenous bases determined by the procedure described.
The concentration is stated in terms of mg/100 g.

3. Brief description

The volatile nitrogenous bases are extracted from a sample by a solution of 0,6 M perchloric acid. After alkalinization the extract is submitted to 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 demineralized and of at least the same purity. Unless indicated otherwise, a 'solution` is to be understood as an aqueous solution.

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 0,01 mol/l (0,01 N).

d) Boric acid solution = 3 g/100 ml.

e) Silicone anti-foaming agent.

f) Phenolphtalein 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 revolutions between 8 000 min P1 and 45 000 min P1.

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 alkalizing 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 according to the following instructions:

a) Preparation of the sample:

The sample to be analysed should be ground carefully by a meat grinder as described in point 5 (a) Exactly 10 g +/ P 0,1 g of the ground sample are weighed in a suitable container, mixed with 90,0 ml perchloric acid solution as stated in point 4(a), homogenized 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 between approximately 2 °C and 6 °C.

b) Steam distillation 50,0 ml of the extract obtained according to point (a) above are put in an apparatus for steam distillation as described in point 5 (e) For a later check on sufficient alkalinization of the extract, several drops of phenolphtalein as specified in section 4.6 are added. After adding a few drops silicone anti foaming agent, 6,5 ml of sodium hydroxide solution as specified in point 4 (b) are added to the extract, and steam distillation begins immediately.

The steam distillation is regulated so that around 100 ml of distillate are produced within 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 4 (g) have been added. After exactly 10 minutes the 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 +/ P 0,1.

c) Titration Duplicate analyses are required. The applied method is correct if the difference of the duplicates is not higher than 2 mg/100 g.

d) Blank A blind test carried out as described in point b) above Instead of the extract, 50,0 ml perchloric acid solution as specified in point 4 (a) are 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 with the following equation:

TVB-N (expressed in mg/100 g sample) = (V1 PV0) × 0,14 × 2 × 100 M
V1 = Volume of 0,01 M hydrochloric acid solution in ml for sample;
V0 = Volume of 0,01 M hydrochloric acid solution in ml for blanc;
M = Weight of sample in g.

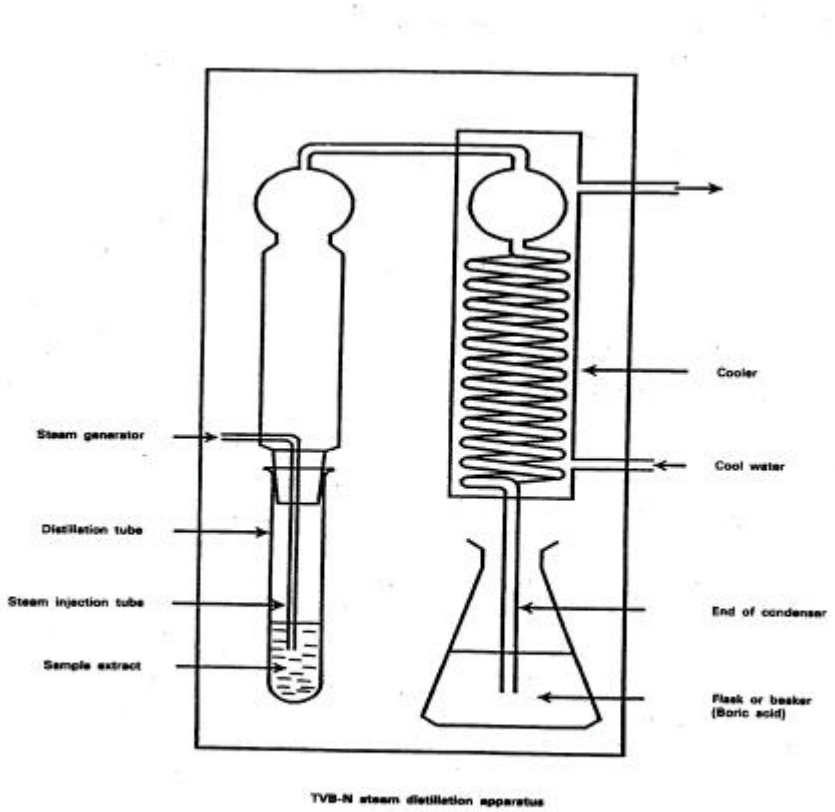
Remarks

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

2. Check the equipment by distilling solutions of NH4Cl equivalent to 50 mg TVB-/100 g.

3. Standard deviation of reproducibility Sr = 1,20 mg/100 g. Standard deviation of comparability SR = 2,50mg/100 g.

CHAPTER IV: TVB-N STEAM DISTILLATION APPARATUS



TVB-N steam distillation apparatus

ANNEX VIII

CERTIFICATES FOR IMPORTATION OF FROGS' LEGS, SNAILS, GELATINE AND COLLAGEN AS REFERRED TO IN ARTICLE 6(1)(d) OF REGULATION (EC) No 853/2004

SECTION I: FROGS' LEGS AND SNAILS

The health certificates referred to in Article 6(1)(d) of Regulation (EC) No 853/2004 for importation of frogs' legs and snails shall comply with the model laid down respectively in part A and part B of the Appendix I to this Annex.

SECTION II: GELATINE

Without prejudice to other specific Community legislation, including at least but not limited to Transmissible Spongiform Encephalopathies and hormones, the health certificates referred to in Article 6(1)(d) of Regulation (EC) No 853/2004 for importation of gelatine and raw materials for the production of gelatine shall comply with the model laid down in part A and part B respectively of the Appendix II to this Annex.

SECTION III: COLLAGEN

Without prejudice to other specific Community legislation, including at least but not limited to Transmissible Spongiform Encephalopathies and hormones, the health certificates referred to in Article 6(1)(d) of Regulation (EC) No 853/2004 for importation of collagen and raw materials for the production of collagen shall comply with the model laid down in part A and part B respectively of the Appendix III to this Annex.

Appendix I to Annex VIII

Part A: SPECIMEN HEALTH CERTIFICATE FOR CHILLED, FROZEN OR PREPARED FROGS' LEGS ORIGINATING IN THIRD COUNTRIES AND INTENDED FOR THE EUROPEAN COMMUNITY

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Postal code

I.2. Certificate reference number

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. Person responsible for the consignment in EU *
Name
Address
Postal code

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
* Holding ☐ * Semen centre ☐ Establishment/vessel ☐
Name Approval number
Address
Name Approval number
Address
Name Approval number
Address

I.12. Place of destination
* Holding ☐ * Assembly centre ☐ * Quarantine ☐
* Semen centre ☐ * Approved body ☐
Establishment/vessel ☐ Custom warehouse ☐ * Other ☐
Name Approval number
Address
Postal code

I.13. Place of loading *
Address Approval number

I.14. Date and time of departure * Estimated date and time of arrival

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU *
Name BIP unit no.:

I.17. No.(s) of CITES *

I.18. Animal species/Product

I.19. Commodity code (CN code)

I.20. Number/Quantity

I.21 Temperature of products
Ambient ☐ Chilled ☐ Frozen ☐

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:
* Breeding ☐ * Fattening ☐ * Slaughter ☐ * Approved body ☐
* Artificial reproduction ☐ * Quarantine ☐ * Registered equidae ☐ * Game restocking ☐
* Pets ☐ * Circus/exhibition ☐ * Relaying ☐ * Other ☐
Human consumption ☐ * Animal feedingstuff ☐ * Further process ☐ * Pharmaceutical use ☐ * Technical use ☐

I.26. For transit to 3rd Country vis-à-vis EU *
3rd country ISO code
Exit BIP: BIP unit no.:

I.27. For import or admission into EU ☐
Definitive import ☐
* Horses Re-entry ☐
* Temporary admission horses ☐

I.28. Identification of the animals/products

Species (Scientific name)	Nature of cuts/ treatment type	* Abattoir/ factory vessel (Approval number of establishments/vessels)	Cutting plant/ manufacturing plant (Approval number of establishments/vessels)	* Cold store/ freezing vessel (Approval number of establishments/vessels)	Quantity	Net weight	Batch number *

* Not to be completed

COUNTRY **frogs' legs**

Part II: Certification

II. Health information	II.a. Certificate reference number	II..b. Local reference number

1. Health attestation

I, the undersigned, [declare that I am aware of the relevant provisions of Regulations (EC) No 852/2004 and 853/2004 and certify that the frogs' legs described above were produced in accordance with these requirements.]

Notes

(1) Box reference I.28: Treatment type: Chilled, frozen, processed.
(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 case of unloading and reloading.
(3) 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 Capital):
Local Veterinary Unit:
Date:
Stamp(3)

Qualification and title
N° of the related LVU:
Signature(3):

Part B: SPECIMEN HEALTH CERTIFICATE FOR SHELLED, COOKED, PREPARED OR PRESERVED SNAILS ORIGINATING IN THIRD COUNTRIES AND INTENDED FOR THE EUROPEAN COMMUNITY

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
☐ Name
Address
Postal code

I.2. Certificate reference number

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. Person responsible for the consignment in EU *
Name
Address
Postal code

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
* Holding ☐ * Semen centre ☐ Establishment/vessel ☐
Name Approval number
Address
Name Approval number
Address
Name Approval number
Address

I.12. Place of destination
* Holding ☐ * Assembly centre ☐ * Quarantine ☐
* Semen centre ☐ * Approved body ☐
Establishment/vessel ☐ Custom warehouse ☐ * Other ☐
Name Approval number
Address
Postal code

I.13. Place of loading *
Address Approval number

I.14. Date and time of departure * Estimated date and time of arrival

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU *
Name BIP unit no.:

I.17. No.(s) of CITES *

I.18. Animal species/Product

I.19. Commodity code (CN code)

I.20. Number/Quantity

I.21 Temperature of products
Ambient ☐ Chilled ☐ Frozen ☐

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:
* Breeding ☐ * Fattening ☐ * Slaughter ☐ * Approved body ☐
* Artificial reproduction ☐ * Quarantine ☐ * Registered equidae ☐ * Game restocking ☐
* Pets ☐ * Circus/exhibition ☐ * Relaying ☐ * Other ☐
Human consumption ☐ * Animal feedingstuff ☐ * Further process ☐ * Pharmaceutical use ☐ * Technical use ☐

I.26. For transit to 3rd Country vis-à-vis EU *
3rd country ISO code
Exit BIP: BIP unit no.:

I.27. For import or admission into EU
Definitive import ☐
* Horses Re-entry ☐
* Temporary admission horses ☐

I.28. Identification of the animals/products

Species (Scientific name)	Nature of cuts/ treatment type	* Abattoir/ factory vessel (Approval number of establishments/vessels)	Cutting plant/ manufacturing plant (Approval number of establishments/vessels)	* Cold store/ freezing vessel (Approval number of establishments/vessels)	Quantity	Net weight	Batch number *

* Not to be completed

COUNTRY **snails**

Part II: Certification

II. Health information	II.a. Certificate reference number	II..b. Local reference number

1. Health attestation

I, the undersigned, [declare that I am aware of the relevant provisions of Regulations (EC) No 852/2004 and 853/2004 and certify that the snails described above were produced in accordance with these requirements.]

Notes

(1) Box reference I.28: Treatment type: Chilled, frozen, shelled, cooked, prepared, preserved.
(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 case of unloading and reloading.
(3) 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 Capital):
Local Veterinary Unit:
Date:
Stamp(3)

Qualification and title
N° of the related LVU:
Signature(3):

Appendix II to Annex VIII

Part A: SPECIMEN HEALTH CERTIFICATE FOR IMPORTS OF GELATINE INTENDED FOR HUMAN CONSUMPTION

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Postal code

I.2. Certificate reference number

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. Person responsible for the consignment in EU *
Name
Address
Postal code

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
* Holding * Semen centre Establishment/vessel
Name Approval number
Address
Name Approval number
Address
Name Approval number
Address

I.12. Place of destination
* Holding * Assembly centre * Quarantine
* Semen centre * Approved body
Establishment/vessel Custom warehouse * Other
Name Approval number
Address
Postal code

I.13. Place of loading *
Address Approval number

I.14. Date and time of departure * Estimated date and time of arrival

I.15. Means of transport
Aeroplane Ship Railway wagon
Road vehicle Other
Identification:
Documentary references:

I.16. Entry BIP in EU *
Name BIP unit no.:

I.17. No.(s) of CITES *

I.18. Animal species/Product

I.19. Commodity code (CN code)

I.20. Number/Quantity

I.21 Temperature of products
Ambient Chilled Frozen

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:
* Breeding * Fattening * Slaughter * Approved body
* Artificial reproduction * Quarantine * Registered equidae * Game restocking
* Pets * Circus/exhibition * Relaying * Other
Human consumption * Animal feedingstuff * Further process * Pharmaceutical use * Technical use

I.26. For transit to 3rd Country vis-à-vis EU *
3rd country ISO code
Exit BIP: BIP unit no.:

I.27. For import or admission into EU
Definitive import
* Horses Re-entry
* Temporary admission horses

I.28. Identification of the animals/products

Species (Scientific name)	Nature of cuts/ treatment type	* Abattoir/ factory vessel	Approval number of establishments/vessels: Cutting plant/ manufacturing plant	* Cold store/ freezing vessel	Quantity	Net weight	Batch number *

* Not to be completed

COUNTRY **gelatine intended for human consumption**

Part II: Certification

II. Health information	II.a. Certificate reference number	II..b. Local reference number

1. Health attestation

I, the undersigned, [declare that I am aware of the relevant provisions of Regulations (EC) No 852/2004 and 853/2004 and certify that the gelatine described above:
- was produced in accordance with these requirements, and ;
- satisfies the criteria of Regulation (EC) ***[microbiological criteria]***.]

Notes

(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) 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 Capital):
Local Veterinary Unit:
Date:
Stamp(2)

Qualification and title
N° of the related LVU:
Signature(2):

Part B: SPECIMEN HEALTH CERTIFICATE FOR IMPORTS OF RAW MATERIALS DESTINED TO THE PRODUCTION OF GELATINE INTENDED FOR HUMAN CONSUMPTION

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Postal code

I.2. Certificate reference number

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. Person responsible for the consignment in EU *
Name
Address
Postal code

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
* Holding * Semen centre Establishment/vessel
Name Approval number
Address
Name Approval number
Address
Name Approval number
Address

I.12. Place of destination
* Holding * Assembly centre * Quarantine
* Semen centre * Approved body
Establishment/vessel Custom warehouse * Other
Name Approval number
Address
Postal code

I.13. Place of loading *
Address Approval number

I.14. Date and time of departure * Estimated date and time of arrival

I.15. Means of transport
Aeroplane Ship Railway wagon
Road vehicle Other
Identification:
Documentary references:

I.16. Entry BIP in EU *
Name BIP unit no.:

I.17. No.(s) of CITES *

I.18. Animal species/Product

I.19. Commodity code (CN code)

I.20. Number/Quantity

I.21 Temperature of products
Ambient Chilled Frozen

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:
* Breeding * Fattening * Slaughter * Approved body
* Artificial reproduction * Quarantine * Registered equidae * Game restocking
* Pets * Circus/exhibition * Relaying * Other
Human consumption * Animal feedingstuff * Further process * Pharmaceutical use * Technical use

I.26. For transit to 3rd Country vis-à-vis EU *
3rd country ISO code
Exit BIP: BIP unit no.:

I.27. For import or admission into EU
Definitive import
* Horses Re-entry
* Temporary admission horses

I.28. Identification of the animals/products

Species (Scientific name)	Nature of cuts/ treatment type	Approval number of establishments/vessels: Abattoir/ factory vessel	Cutting plant/ manufacturing plant	* Cold store/ freezing vessel	Quantity	Net weight	Batch number *

* Not to be completed

Part II: Certification

II. Health information	II.a. Certificate reference number	II..b. Local reference number

1. Health attestation

I, the undersigned, [declare that I am aware of the relevant provisions of Regulations (EC) No 852/2004 and 853/2004 and certify that the raw material described above complies with these requirements, and if appropriate, that fish skin and bones described above come from plants manufacturing fish products for human consumption authorised for export(2).]

Notes

(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) 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 Capital):
Local Veterinary Unit:
Date:
Stamp(3)

Qualification and title
N° of the related LVU:
Signature(3):

Appendix III to Annex VIII

Part A: SPECIMEN HEALTH CERTIFICATE FOR IMPORTS OF COLLAGEN INTENDED FOR HUMAN CONSUMPTION

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Postal code

I.2. Certificate reference number

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. Person responsible for the consignment in EU *
Name
Address
Postal code

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
* Holding * Semen centre Establishment/vessel
Name Approval number
Address
Name Approval number
Address
Name Approval number
Address

I.12. Place of destination
* Holding * Assembly centre * Quarantine
* Semen centre * Approved body
Establishment/vessel Custom warehouse * Other
Name Approval number
Address
Postal code

I.13. Place of loading *
Address Approval number

I.14. Date and time of departure * Estimated date and time of arrival

I.15. Means of transport
Aeroplane Ship Railway wagon
Road vehicle Other
Identification:
Documentary references:

I.16. Entry BIP in EU *
Name BIP unit no.:

I.17. No.(s) of CITES *

I.18. Animal species/Product

I.19. Commodity code (CN code)

I.20. Number/Quantity

I.21 Temperature of products
Ambient Chilled Frozen

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:
* Breeding * Fattening * Slaughter * Approved body
* Artificial reproduction * Quarantine * Registered equidae * Game restocking
* Pets * Circus/exhibition * Relaying * Other
Human consumption * Animal feedingstuff * Further process * Pharmaceutical use * Technical use

I.26. For transit to 3rd Country vis-à-vis EU *
3rd country ISO code
Exit BIP: BIP unit no.:

I.27. For import or admission into EU
Definitive import
* Horses Re-entry
* Temporary admission horses

I.28. Identification of the animals/products

Species (Scientific name)	Nature of cuts/ treatment type	* Abattoir/ factory vessel	Approval number of establishments/vessels: Cutting plant/ manufacturing plant	* Cold store/ freezing vessel	Quantity	Net weight	Batch number *

* Not to be completed

COUNTRY **collagen intended for human consumption**

Part II: Certification

II. Health information	II.a. Certificate reference number	II..b. Local reference number

1. Health attestation

I, the undersigned, [declare that I am aware of the relevant provisions of Regulations (EC) No 852/2004 and 853/2004 and certify that the collagen described above:
- was produced in accordance with these requirements, and ;
- satisfies the criteria of Regulation (EC) ***[microbiological criteria]***.]

Notes

(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) 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 Capital):
Local Veterinary Unit:
Date:
Stamp(2)

Qualificat ion and title
N° of the related LVU:
Signature(2):

Part B: SPECIMEN HEALTH CERTIFICATE FOR IMPORTS OF RAW MATERIALS DESTINED TO THE PRODUCTION OF COLLAGEN INTENDED FOR HUMAN CONSUMPTION

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Postal code

I.2. Certificate reference number

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. Person responsible for the consignment in EU *
Name
Address
Postal code

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
* Holding ☐ * Semen centre ☐ Establishment/vessel ☐
Name Approval number
Address
Name Approval number
Address
Name Approval number
Address

I.12. Place of destination
* Holding ☐ * Assembly centre ☐ * Quarantine ☐
* Semen centre ☐ * Approved body ☐
Establishment/vessel ☐ Custom warehouse ☐ * Other ☐
Name Approval number
Address
Postal code

I.13. Place of loading *
Address Approval number

I.14. Date and time of departure * Estimated date and time of arrival

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU *
Name BIP unit no.:

I.17. No.(s) of CITES *

I.18. Animal species/Product

I.19. Commodity code (CN code)

I.20. Number/Quantity

I.21 Temperature of products
Ambient ☐ Chilled ☐ Frozen ☐

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:
* Breeding ☐ * Fattening ☐ * Slaughter ☐ * Approved body ☐
* Artificial reproduction ☐ * Quarantine ☐ * Registered equidae ☐ * Game restocking ☐
* Pets ☐ * Circus/exhibition ☐ * Relaying ☐ * Other ☐
Human consumption ☐ * Animal feedingstuff ☐ * Further process ☐ * Pharmaceutical use ☐ * Technical use ☐

I.26. For transit to 3rd Country vis-à-vis EU *
3rd country ISO code
Exit BIP: BIP unit no.:

I.27. For import or admission into EU
Definitive import
* Horses Re-entry
* Temporary admission horses

I.28. Identification of the animals/products

Species (Scientific name)	Nature of cuts/ treatment type	Approval number of establishments/vessels: Abattoir/ factory vessel	Cutting plant/ manufacturing plant	* Cold store/ freezing vessel	Quantity	Net weight	Batch number *

* Not to be completed

COUNTRY **raw materials destined to the production of collagen intended for human consumption**

Part II: Certification

II. Health information	II.a. Certificate reference number	II..b. Local reference number

1. Health attestation

I, the undersigned, [declare that I am aware of the relevant provisions of Regulations (EC) No 852/2004 and 853/2004 and certify that the raw material described above complies with these requirements, and if appropriate, that fish skin and bones described above derive from plants manufacturing fish products for human consumption authorised for export(2).]

Notes

(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) 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 Capital):
Local Veterinary Unit:
Date:
Stamp(3)

Qualification and title
N° of the related LVU:
Signature(3):

ANNEX IX

TRANSITIONAL ARRANGEMENTS CONCERNING FOOD CHAIN INFORMATION PURSUANT TO ARTICLE 9 OF REGULATION (EC) No 853/2004

1. During the transitional period, and by derogation to Annex II, Section III to Regulation (EC) N° 853/2004, the Member states shall progressively implement the food chain information requirements of Regulation (EC) N° 853/2004 to different species or categories beyond the immediate implementation to the poultry sector, so that at least [a target of 30% in the species or category chosen] in that Member state is achieved by the implementation of food chain requirements at the end of the first year of transition, 60% at the end of the second year, and 90% at the end of the third year. Member states availing themselves of this transitional mechanism shall report to the Commission on its implementation at the end of each year, and the Commission may decide each year until the end of the transitional period to review or repeal the present provision on the basis of the reports received, or of the absence of reports.

2. During the transitional period, and by derogation from the requirement to provide slaughterhouse operators with the food chain information no less than 24 hours in advance except in certain circumstances, as laid down in Annex II, Section III, point 2 to Regulation (EC) N° 853/2004, the competent authority may allow the food chain information to accompany to the slaughterhouse the animals to which it relates, for all species and in all circumstances where this tolerance will not compromise the achievement of the objectives of the Regulation. However, where necessary, the competent authority shall ensure that any element of the food chain information, the knowledge of which may have the consequence of seriously disrupting the flow of activity of the slaughterhouse, is made available to the slaughterhouse operator sufficiently in advance.

ANNEX X

TRANSITIONAL ARRANGEMENTS CONCERNING TRICHINELLA INFESTATION AS MENTIONED IN ANNEX I, SECTION IV, CHAPTER IX (C) TO REGULATION (EC) No 854/2004 PURSUANT TO ARTICLE 16 OF REGULATION (EC) No 854/2004

1. Member States may allow the use of the trichinoscopic method mentioned in Annex V, Section III C of this Regulation in exceptional cases for domestic pigs and wild boar if facilities to use the detection methods mentioned in Section III, A or B of Annex V to this Regulation are not available

2. Whenever the trichinoscopic method is used the competent authority shall ensure that

   a) the meat shall be delivered directly to the final consumer or to retail establishments directly supplying the final consumer and,

   b) the meat shall be marked with a health marking that is clearly distinct from community health marking that indicates that the meat has been examined for *Trichinella* and,

   c) the meat shall not be used for the production of products where the production process does not kill *Trichinella.*

ANNEX XI

TRANSITIONAL ARRANGEMENTS CONCERNING RAW MILK AND DAIRY PRODUCTS PURSUANT TO ARTICLE 9 OF REGULATION (EC) No 853/2004

By derogation to the provision laid down in Annex III, Section IX, Chapter II (III) (1) to Regulation (EC) No 853/2004 the plate count limit set down for raw cows' milk shall apply only when milk is to be heat-treated and if it has not been treated within the time period of acceptance that is specified in the HACCP-based procedures put in place by food business operators.

ANNEX XII

TRANSITIONAL ARRANGEMENTS CONCERNING EGGS AND EGG PRODUCTS PURSUANT TO ARTICLE 9 OF REGULATION (EC) No 853/2004

CHAPTER I: EGGS

Member States which, before 1 January 2006, applied in their territory temperature requirements for egg storage facilities and for the transport from storage to another may maintain these requirements.

CHAPTER II: EGG PRODUCTS

As is the case for processing establishments, establishments approved for the manufacture of liquid egg may receive cracked eggs, provided the provisions laid down in Annex III, Section X, Chapter II (1) to Regulation (EC) No 853/2004 are complied with.

ANNEX XIII

TRANSITIONAL ARRANGEMENTS CONCERNING STOCKS OF PRODUCTS [PRODUCED BEFORE JANUARY 2006] PURSUANT TO ARTICLE 9 OF REGULATION (EC) No 853/2004

1. Stocks of products of animal origin produced before 1 January 2006 may be placed on the market provided that they bear the Community mark prescribed before that date. For products having a shelf life which is shorter than four years, the competent authority shall ensure that their placing on the market is compatible with their shelf-life limits.

2. Food business operators, who were allowed before 1 January 2006 to place products of animal origin on the market in their national territory, may continue to place such products on this market with a national mark, which cannot be confused with the Community mark, until the competent authority is able to decide on their approval in accordance with Article 4 of Regulation (EC) n° 853/2004.. Food of animal origin marked with national marks may only be marketed in the national territory of the Member State where they are produced. This transitional arrangement is not applicable to the placing on the market of the meat of animals having undergone emergency slaughter.

ANNEX XIV

TRANSITIONAL ARRANGEMENTS CONCERNING ACCREDITATION OF LABORATORIES INVOLVED IN A LIMITED NUMBER OF ANALYSES OF SAMPLES TAKEN DURING OFFICIAL CONTROLS AS REFERRED TO IN ARTICLE 12(2) OF REGULATION (EC) No 882/2004

By derogation to Article 12 (2) of Regulation (EC) n° 882/2004, laboratories which were not required under the previous Community legislation to be accredited are exempted from this requirement during the transitional period, provided that :

- the laboratory provide 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, and
-
- the laboratory demonstrates that it has initiated the necessary accreditation procedures without undue delay.

ANNEX XV

TRANSITIONAL ARRANGEMENTS CONCERNING THE USE OF CLEAN SEAWATER IN ON-LAND ESTABLISHMENTS FOR CERTAIN OPERATIONS ON FISHERY PRODUCTS PURSUANT TO ARTICLE 9 OF REGULATION (EC) No 853/2004

By derogation to the provisions laid down in Annex III, section VIII, to Regulation (EC) n° 853/2004, in point 2 of Chapter III, part A, and in point 1 of Chapter IV, on-land establishments handling fishery products may use clean [sea?] water for the washing of products during heading and gutting operations, and for cooking and cooling cooked products.

ANNEX XVI

TRANSITIONAL ARRANGEMENTS CONCERNING SLAUGHTERHOUSE STAFF ASSISTING WITH OFFICIAL CONTROLS AS REFERRED TO IN ARTICLE 5 (6), AND PURSUANT TO ARTICLE 16 OF REGULATION (EC) No 854/2004

By derogation to Annex I, Section III, Chapter I, part A point (a) to Regulation (EC) n° 854/2004, slaughterhouse staff authorised by the competent authority to carry out specific tasks of official auxiliaries [or assistants] shall be trained in the same way as official auxiliaries only with regard to the specific tasks they are authorised for, and may not be required to have passed the same examination as those official auxiliaries. The competent authority shall ensure that this specific training is satisfactory before authorising the staff concerned and that the additional training and organisation necessary for qualifying such staff through the examination procedure applicable to official auxiliaries are in place as soon as possible and at the latest by the end of the transitional period.

ANNEX XVIII

TRANSITIONAL ARRANGEMENTS CONCERNING IMPORTS OF CERTAIN FOODS PURSUANT TO ARTICLE 9 OF REGULATION (EC) No 853/2004

1. For products of animal origin for which no harmonised sanitary import conditions have been established on 1 January 2006, and for which therefore there is no Community list of third countries and no lists of establishments from which imports are permitted, the requirements of Article 6, paragraph 1 of Regulation (EC) No 853/2004 and of Chapter III of Regulation (EC) No 854/2004 shall not apply.

   Pending a future harmonisation for such products, imports shall comply with the sanitary import conditions of the Member State.

2.

During the transitional period, Article 6 paragraph 4 of Regulation (EC) n° 853/2004 shall not apply. Pending the development of a risk-based approach for the implementation of harmonised sanitary import requirements and checks to products containing both products of plant origin and processed products of animal origin, imports of such products shall comply where applicable with the harmonised Community rules in force before the 1 January 2006, and with the national rules implemented by the Member states before that same date in other cases.

ANNEX XIX

MARKING MATERIAL AND EQUIPMENT

1. Food business operators may continue to use stocks of wrapping and packaging materials delivered before the date of application of this Regulation. The competent authority may restrict this tolerance to a period of one year where the material purchased and delivered to the operator before the date of application of this Regulation manifestly exceeds the reasonable needs of the establishment concerned for its annual activity.

2. Food business operators may continue to use marking equipment with which they are equipped by the date of application of this Regulation until its replacement, [and at the latest by…. ,] provided that the replacement cost of this equipment represents at least 2% of the annual turnover of the establishment concerned. By the time the equipment is replaced, the competent authority shall ensure the withdrawal of the equipment replaced so that it cannot be used any more.