Non-paper
in view of a
possible implementing act
based on Article 18(8)
of Regulation (EU) 2017/625
(Official Control Regulation)

ANNEXES

Revision dated 20 September 2017

ANNEX I

Practical arrangements of post-mortem inspection in accordance with Article 10

CHAPTER I

DOMESTIC BOVINE ANIMALS

A. BOVINE ANIMALS UNDER EIGHT MONTHS OLD

1. Carcases and offal of bovine animals under eight months old must undergo the following post-mortem inspection procedures:

   (a) visual inspection of the head and throat; palpation and examination of the retropharyngeal lymph nodes (Lnn retropharyngiales); inspection of the mouth and fauces;

   (b) visual inspection of the lungs, trachea and oesophagus; palpation of the lungs; palpation and examination of the bronchial and mediastinal lymph nodes (Lnn. bifucationes, eparteriales and mediastinales);

   (c) visual inspection of the pericardium and heart;

   (d) visual inspection of the diaphragm;

   (e) visual inspection of the liver and the hepatic and pancreatic lymph nodes, (Lnn portales);

   (f) visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (Lnn. gastrici, mesenterici, craniales and caudales); palpation of the gastric and mesenteric lymph nodes;

   (g) visual inspection of the spleen;

   (h) visual inspection of the kidneys;

   (i) visual inspection of the pleura and peritoneum;

   (j) visual inspection of the umbilical region and the joints of young animals.

2. Depending on the identified risks, the additional post-mortem procedures referred to in Chapter V may include:

   (a) incision of the retropharyngeal lymph nodes (Lnn retropharyngiales); palpation of the tongue;

   (b) incision of the bronchial and mediastinal lymph nodes (Lnn. bifucationes, eparteriales and mediastinales); lengthwise opening of the trachea and the main branches of the bronchi; the lungs must be incised in their posterior third, perpendicular to their main axes; these incisions are not necessary where the lungs are excluded from human consumption;

   (c) incision of the gastric and mesenteric lymph nodes;

   (d) palpation of the spleen;

   (e) incision of the kidneys and the renal lymph nodes (Lnn. renales);

   (f) palpation of the umbilical region and the joints. The umbilical region must be incised and the joints opened; the synovial fluid must be examined.

B. BOVINE ANIMALS OVER EIGHT MONTHS OLD

1. Carcases and offal of bovine animals over eight months old must undergo the following post-mortem inspection procedures:

   (a) visual inspection of the head and throat; incision and examination of the retropharyngeal lymph nodes (Lnn retropharyngiales); examination of the external masseters, in which two incisions must be made parallel to the mandible, and the internal masseters (internal pterygoid muscles), which must be incised along one plane. The tongue must be freed to permit a detailed visual inspection of the mouth and the fauces;

   (b) inspection of the trachea and oesophagus; visual examination and palpation of the lungs; incision and examination of the bronchial and mediastinal lymph nodes (Lnn. bifucationes, eparteriales and mediastinales);

   (c) visual inspection of the pericardium and heart, the latter being incised lengthways so as to open the ventricles and cut through the interventricular septum;

   (d) visual inspection of the diaphragm;

   (e) visual inspection of the liver and the hepatic and pancreatic lymph nodes (Lnn portales);

   (f) visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (Lnn. gastrici, mesenterici, craniales and caudales); palpation of the gastric and mesenteric lymph nodes;

   (g) visual inspection of the spleen;

   (h) visual inspection of the kidneys;

   (i) visual inspection of the pleura and the peritoneum;

   (j) visual inspection of the genital organs (except for the penis, if already discarded);

   (k) visual inspection of the udder and its lymph nodes (Lnn. supramammarii).

2. Depending on the identified risks, the additional post-mortem procedures referred to in Chapter V may include:

   (a) incision and examination of the sub-maxillary and parotid lymph nodes (Lnn mandibulares and parotidei); palpation of the tongue and the fauces;

   (b) incision of the bronchial and mediastinal lymph nodes (Lnn. bifucationes, eparteriales and mediastinales); lengthwise opening of the trachea and the main branches of the bronchi; the lungs must be incised in their posterior third, perpendicular to their main axes; these incisions are not necessary where the lungs are excluded from human consumption;

   (c) palpation of the liver and the hepatic and pancreatic lymph nodes (Lnn portales); incision of the gastric surface of the liver and at the base of the caudate lobe to examine the bile ducts;

   (d) incision of the gastric and mesenteric lymph nodes;

   (e) palpation of the spleen;

   (f) incision of the kidneys and the renal lymph nodes (Lnn. renales);

(g) palpation and incision of the udder and its lymph nodes (Lnn. supramammarii) in cows. Each half of the udder must be opened by a long, deep incision as far as the lactiferous sinuses (sinus lactiferes) and the lymph nodes of the udder must be incised, except when the udder is excluded from human consumption.

CHAPTER II

DOMESTIC SHEEP AND GOATS

A. SHEEP NOT HAVING ANY PERMANENT INCISOR ERUPTED AND BELOW 12 MONTHS OF AGE, AND GOATS BELOW SIX MONTHS OF AGE

1. Carcases and offal of sheep not having any permanent incisor erupted and below 12 months of age, and goats below six months of age must undergo the following post-mortem inspection procedures:

   (a) visual inspection of the head after flaying including the throat, mouth, tongue and parotid lymph nodes and palpation of the retropharyngeal lymph nodes. Without prejudice to animal-health rules, these examinations are not necessary if the competent authority is able to guarantee that the head, including the tongue and the brains, will be excluded from human consumption;

   (b) visual inspection of the lungs, trachea and oesophagus; palpation of the bronchial and mediastinal lymph nodes (Lnn. bifucationes, eparteriales and mediastinales);

   (c) visual inspection of the pericardium and heart;

   (d) visual inspection of the diaphragm;

   (e) visual inspection of the liver and the hepatic and pancreatic lymph nodes (Lnn portales);

   (f) visual inspection of the gastro-intestinal tract, the mesentery and the gastric and mesenteric lymph nodes (Lnn. gastrici, mesenterici, craniales and caudales);

   (g) visual inspection of the spleen;

   (h) visual inspection of the kidneys;

   (i) visual inspection of the pleura and peritoneum;

   (j) visual inspection of the umbilical region and joints.

2. Depending on the identified risks, the additional post-mortem procedures referred to in Chapter V may include:

   (a) palpation of the throat, mouth, tongue and parotid lymph nodes. Without prejudice to animal-health rules, these examinations are not necessary if the competent authority is able to guarantee that the head, including the tongue and the brains, will be excluded from human consumption;

   (b) palpation of the lungs; incision of the lungs, trachea, oesophagus, bronchial and mediastinal lymph nodes;

   (c) incision of the heart;

   (d) palpation of the liver and its lymph nodes; incision of the gastric surface of the liver to examine the bile ducts;

   (e) palpation of the spleen;

(f) incision of the kidneys and the renal lymph nodes (Lnn. renales);

(g) palpation of the umbilical region and joints; the umbilical region must be incised and the joints opened; the synovial fluid must be examined.

B. SHEEP HAVING A PERMANENT INCISOR ERUPTED OR ABOVE 12 MONTHS OF AGE, AND GOATS ABOVE SIX MONTHS OF AGE

1. Carcases and offal of sheep having a permanent incisor erupted or above 12 months of age, and goats above six months of age are to undergo the following post-mortem inspection procedures:

(a) visual inspection of the head after flaying including the throat, mouth, tongue and parotid lymph nodes and palpation of the retropharyngeal lymph nodes. Without prejudice to animal-health rules, these examinations are not necessary if the competent authority is able to guarantee that the head, including the tongue and the brains, will be excluded from human consumption;

(b) visual inspection of the lungs, trachea and oesophagus; palpation of the lungs, the bronchial and mediastinal lymph nodes (Lnn. bifucationes, eparteriales and mediastinales);

(c) visual inspection of the pericardium and heart;

(d) visual inspection of the diaphragm;

(e) visual inspection of the liver and the hepatic and pancreatic lymph nodes (Lnn portales); palpation of the liver and its lymph nodes; incision of the gastric surface of the liver to examine the bile ducts;

(f) visual inspection of the gastro-intestinal tract, the mesentery and the gastric and mesenteric lymph nodes (Lnn. gastrici, mesenterici, craniales and caudales);

(g) visual inspection of the spleen;

(h) visual inspection of the kidneys;

(i) visual inspection of the pleura and peritoneum;

(j) visual inspection of the genital organs (except for the penis, if already discarded);

(k) visual inspection of the udder and its lymph nodes.

2. Depending on the identified risks, the additional post-mortem procedures referred to in Chapter V may include:

(a) palpation of the throat, mouth, tongue and parotid lymph nodes. Without prejudice to animal-health rules, these examinations are not necessary if the competent authority is able to guarantee that the head, including the tongue and the brains, will be excluded from human consumption;

(b) incision of the lungs, trachea, oesophagus and the bronchial and mediastinal lymph nodes;

(c) incision of the heart;

(d) palpation of the spleen;

(e) incision of the kidneys and the renal lymph nodes (Lnn. renales).

CHAPTER III

DOMESTIC SOLIPEDS

1. Carcases and offal of domestic solipeds must undergo the following post-mortem inspection procedures:

   (a) visual inspection of the head and, after freeing the tongue, the throat; The tongue must be freed to permit a detailed visual inspection of the mouth and the fauces and must itself be visually examined;

   (b) visual inspection of the lungs, trachea, oesophagus and the bronchial and mediastinal lymph nodes (*Lnn. bifucationes*, *eparteriales* and *mediastinales*);

   (c) visual inspection of the pericardium and the heart;

   (d) visual inspection of the diaphragm;

   (e) visual inspection of the liver and the hepatic and pancreatic lymph nodes (*Lnn portales*);

   (f) visual inspection of the gastro-intestinal tract, the mesentery and the gastric and mesenteric lymph nodes (*Lnn. gastrici*, *mesenterici*, *craniales* and *caudales*);

   (g) visual inspection of the spleen;

   (h) visual inspection of the kidneys;

   (i) visual inspection of the pleura and peritoneum;

   (j) visual inspection of the genital organs of stallions (except for the penis, if already discarded) and mares;

   (k) visual inspection of the udder and its lymph nodes (Lnn. supramammarii);

   (l) visual inspection of the umbilical region and joints of young animals;

   (m) all grey horses must be inspected for melanosis and melanomata by examination of the muscles and lymph nodes (Lnn. subrhomboidei) of the shoulders beneath the scapular cartilage after loosening the attachment of one shoulder. The kidneys must be exposed.

2. Depending on the identified risks, the additional post-mortem procedures referred to in Chapter V may include:

   (a) palpation and incision of the sub-maxillary, retropharyngeal and parotid lymph nodes (Lnn retropharyngiales, mandibulares and parotidei); palpation of the tongue;

   (b) palpation of the lungs; palpation and incision of the bronchial and mediastinal lymph nodes. The trachea and the main branches of the bronchi must be opened lengthwise and the lungs must be incised in their posterior third, perpendicular to their main axes; however, these incisions are not necessary where the lungs are excluded from human consumption;

   (c) incision of the heart, lengthwise so as to open the ventricles and cut through the interventricular septum;

   (d) palpation and incision of the liver and the hepatic and pancreatic lymph nodes, (Lnn portales);

   (e) incision of the gastric and mesenteric lymph nodes;

(f) palpation of the spleen;

(g) palpation of the kidneys and incision of the kidneys and the renal lymph nodes (Lnn. renales);

(h) incision of the supramammary lymph nodes;

(i) palpation of the umbilical region and joints of young animals. In the event of doubt, the umbilical region must be incised and the joints opened; the synovial fluid must be examined;

(j) incision through the entire kidney in grey horses.

CHAPTER IV

DOMESTIC SWINE

1. Carcases and offal of domestic swine must undergo the following post-mortem inspection procedures:

(a) visual inspection of the head and throat;

(b) visual inspection of the mouth, fauces and tongue;

(c) cvisual inspection of the lungs, trachea and oesophagus;

(d) visual inspection of the pericardium and heart;

(e) visual inspection of the diaphragm;

(f) visual inspection of the liver and the hepatic and pancreatic lymph nodes (Lnn. portales); visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (Lnn. gastrici, mesenterici, craniales and caudales);

(g) visual inspection of the spleen; visual inspection of the kidneys; visual inspection of the pleura and peritoneum;

(h) visual inspection of the genital organs (except for the penis, if already discarded);

(i) visual inspection of the udder and its lymph nodes (Lnn. supramammarii);

(j) visual inspection of the umbilical region and joints of young animals.

2. Depending on the identified risks, the additional post-mortem procedures referred to in Chapter V may include:

(a) incision and examination of the submaxillary lymph nodes (Lnn. mandibulares);

(b) palpation of the lungs and the bronchial and mediastinal lymph nodes (Lnn. bifurcationes, eparteriales and mediastinales). The trachea and the main branches of the bronchi must be opened lengthwise and the lungs must be incised in their posterior third, perpendicular to their main axes; those incisions are not necessary where the lungs are excluded from human consumption;

(c) incision of the heart lengthwise so as to open the ventricles and cut through the interventricular septum;

(d) palpation of the liver and its lymph nodes;

(e) palpation and, if necessary, incision of the gastric and mesenteric lymph nodes;

(f) palpation of the spleen;

(g) incision of the kidneys and the renal lymph nodes (Lnn. renales);

(h) incision of the supramammary lymph nodes;

(i) palpation of the umbilical region and joints of young animals and, if necessary, incision of the umbilical region and opening of the joints.

CHAPTER V

INDICATIONS OF A POSSIBLE RISK TO PUBLIC HEALTH, ANIMAL HEALTH OR ANIMAL WELFARE

The official veterinarian shall proceed with additional post-mortem inspection procedures using incision and palpation of the carcase and offal, where, in his or her opinion, one of the following indicates a possible risk to public health, animal health or animal welfare:

(a) the checks and analysis of the documentary checks carried out in accordance with Article 6 to this Regulation;

(b) the findings of the ante-mortem inspection carried out in accordance with Article 7 to this Regulation and with Chapter II of Annex I to Commission Delegated Regulation [SANTE-2017-10193-00-00-TRA];

(c) the results of the verifications concerning compliance with animal welfare rules carried out in accordance with Article 8 to this Regulation;

(d) the findings of post-mortem inspection carried out in accordance with Article 9 to this Regulation and with point 1 of Chapters I to IV of this Annex;

(e) additional epidemiological data or other data from the holding of provenance of the animals.

CHAPTER VI

POULTRY

1. All poultry must undergo post-mortem inspection in accordance with Article 9 of this Regulation. In addition, the official veterinarian must carry out personally the following checks:

   (a) daily inspection of the viscera and body cavities of a representative sample of birds;

   (b) a detailed inspection of a random sample, from each batch of birds having the same origin, of parts of birds or entire birds declared unfit for human consumption following post-mortem inspection; and

   (c) any further investigations necessary when there is reason to suspect that the meat from the birds concerned could be unfit for human consumption.

2. In the case of poultry reared for the production of 'foie gras' and delayed eviscerated poultry obtained at the holding of provenance, post-mortem inspection must include a check on the certificate accompanying the carcases. When such carcases are transported directly from the holding to a cutting plant, post-mortem inspection must take place at the cutting plant.

CHAPTER VII

FARMED LAGOMORPHS

The requirements for poultry apply also to farmed lagomorphs.

CHAPTER VIII

FARMED GAME

1. Post-mortem inspection of farmed game must include palpation and, where judged necessary, incision of those parts of the animal which have undergone any change or are suspect for any other reason.

2. Post-mortem inspection procedures described for bovine and ovine animals, domestic swine and poultry must be applied to the corresponding species of farmed game. In case of reindeer of all ages, the post-mortem inspection procedures in Chapter II.A apply. However, the tongue of reindeer may be used for human consumption without the inspection of the head in accordance with point 1(a) of Chapter II.A.

3. When the animals have been slaughtered at the holding, the official veterinarian at the slaughterhouse must check the certificate accompanying them.

CHAPTER IX

WILD GAME

A. POST-MORTEM INSPECTION

1. Wild game must be inspected as soon as possible after admission to the game-handling establishment.

2.

3. The official veterinarian must check that a health certificate conforming to the specimen set out in the Annex to Commission Implementing Regulation (EU) No 636/2014[1] or the declaration(s) accompanies the unskinned large wild game transported to the game-handling establishment from the territory of another Member State, in accordance with point 8(b) of Chapter II of Section IV of Annex III to Regulation (EC) No 853/2004. The official veterinarian must take into account the content of that certificate or declaration(s).

4. During post-mortem inspection, the official veterinarian must carry out:

   (a) a visual examination of the carcase, its cavities and, where appropriate, organs with a view to:

      (i) detecting any abnormalities not resulting from the hunting process. For this purpose, the diagnosis may be based on any information that the trained person has provided concerning the behaviour of the animal before killing,

      (ii) checking that death was not caused by reasons other than hunting.

   If an assessment cannot be made on the basis of visual examination alone, a more extensive inspection must be carried out in a laboratory;

[1] Commission Implementing Regulation (EU) No 636/2014 of 13 June 2014 on a model certificate for the trade of unskinned large wild game (OL L 175, 14.6.2014, p. 16).

(b) an investigation of organoleptic abnormalities;

(c) palpation of organs, where appropriate;

(d) where there are serious grounds for suspecting the presence of residues or contaminants, an analysis by sampling of residues not resulting from the hunting process, including environmental contaminants. When a more extensive inspection is made on the basis of such suspicions, the veterinarian must wait until that inspection has been concluded before assessing all the game killed during a specific hunt, or those parts suspected of showing the same abnormalities;

(e) examination for characteristics indicating that the meat presents a health risk, including:

(i) abnormal behaviour or disturbance of the general condition of the live animal, as reported by the hunter,

(ii) the generalised presence of tumours or abscesses affecting different internal organs or muscles,

(iii) arthritis, orchitis, pathological changes in the liver or the spleen, inflammation of the intestines or the umbilical region,

(iv) the presence of foreign bodies not resulting from the hunting process in the body cavities, stomach or intestines or in the urine, where the pleura or peritoneum are discoloured (when relevant viscera are present),

(v) the presence of parasites,

(vi) formation of a significant amount of gas in the gastro-intestinal tract with discolouring of the internal organs (when these viscera are present),

(vii) significant abnormalities of colour, consistency or odour of muscle tissue or organs,

(viii) aged open fractures,

(ix) emaciation and/or general or localised oedema,

(x) recent pleural or peritoneal adhesions, and

(xi) other obvious extensive changes, such as putrefaction.

5. Where the official veterinarian so requires, the vertebral column and the head must be split lengthwise.

6. In the case of small wild game not eviscerated immediately after killing, the official veterinarian must carry out a post-mortem inspection on a representative sample of animals from the same source. Where inspection reveals a disease transmissible to man or any of the characteristics listed in point 4(e), the official veterinarian must carry out more checks on the entire batch to determine whether it must be declared unfit for human consumption or whether each carcase must be inspected individually.

7. The official veterinarian may perform any further cuts and inspections of the relevant parts of the animals necessary to reach a final diagnosis.

B. DECISIONS FOLLOWING CONTROLS

In addition to the cases provided for in Article 25 of this Regulation, meat presenting during post-mortem inspection any of the characteristics listed in point 4(e) of Chapter IX.A must be declared unfit for human consumption.

CHAPTER X

SPECIFIC HAZARDS

A. TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES

Official controls carried out in relation to transmissible spongiform encephalopathies must take account of the requirements of Regulation (EC) No 999/2001 and other relevant Union legislation.

B. CYSTICERCOSIS

1 The post-mortem inspection procedures described in Chapters I and IV of this Annex are the minimum requirements for the examination for cysticercosis in bovine animals over eight months old and swine. In addition, specific serological tests may be used. In the case of bovines over eight months old, incision of the masseters at post-mortem inspection is not compulsory when a specific serological test is used. The same applies when bovine animals over six weeks old have been raised on a holding officially certified to be free of cysticercosis.

2. Meat infected with cysticerci is to be declared unfit for human consumption. However, when the animal is not generally infected with cysticercus, the parts not infected may be declared fit for human consumption after having undergone a cold treatment.

C. TRICHINOSIS

1. Carcases of swine (domestic, farmed game and wild game), solipeds and other species susceptible to trichinosis are to be examined for trichinosis in accordance with Commission Implementing Regulation (EU) 2015/1375[2] unless that legislation provides otherwise.

2. Meat from animals infected with trichinae must be declared unfit for human consumption.

D. GLANDERS

1. Fresh meat of solipeds shall only be placed on the market if it was produced from equidae kept during the last 90 days prior to slaughter in a Member State of the EU or in a country authorised for entry into the Union of equidae.

2. In countries not meeting the criteria of the World Organisation for Animal Health for a glanders-free country, solipeds must be inspected for glanders by a careful examination of the mucous membranes of the trachea, larynx, nasal cavities and sinuses and their ramifications, after splitting the head in the median plane and excising the nasal septum.

3. Meat produced from horses in which glanders has been diagnosed must be declared unfit for human consumption.

[2] Commission Implementing Regulation (EU) 2015/1375 of 10 August 2015 laying down specific rules on official controls for Trichinella in meat (OJ L 212, 11.8.2015, p. 7).

E. TUBERCULOSIS

1. When animals have reacted positively or inconclusively to tuberculin, or there are other grounds for suspecting infection, they must be slaughtered separately from other animals, taking precautions to avoid the risk of contamination of other carcases, the slaughter line and staff present in the slaughterhouse.

2. All meat from animals in which post-mortem inspection has revealed localised tuberculous lesions in a number of organs or a number of areas of the carcase must be declared unfit for human consumption. However, when a tuberculous lesion has been found in the lymph nodes of only one organ or part of the carcase, only the affected organ or part of the carcase and the associated lymph nodes shall be declared unfit for human consumption.

F. BRUCELLOSIS

1. When animals have reacted positively or inconclusively to a brucellosis test, or there are other grounds for suspecting infection, they must be slaughtered separately from other animals, taking precautions to avoid the risk of contamination of other carcases, the slaughter line and staff present in the slaughterhouse.

2. Meat from animals in which post-mortem inspection has revealed lesions indicating acute infection with brucellosis must be declared unfit for human consumption. In the case of animals reacting positively or inconclusively to a brucellosis test, the udder, genital tract and blood must be declared unfit for human consumption even if no such lesion is found.

G. SALMONELLA

1. Without prejudice to the first paragraph of Article 1 of Regulation (EC) No 2073/2005, the competent authority shall verify the correct implementation by food business operators of points 2.1.3, 2.1.4 and 2.1.5 (process hygiene criterion for *Salmonella* on carcases of respectively cattle, sheep, goats and horses, pigs and broilers and turkeys) of Chapter 2 of Annex I to that Regulation by applying the following measures:

   (a) official sampling using the same method and sampling area as food business operators. At least 49[3] random samples shall be taken in each slaughterhouse each year. This number of samples may be reduced in small slaughterhouses based on a risk evaluation;

   (b) collecting all information on the total number and the number of *Salmonella* positive samples taken by food business operators in accordance with Article 5(5) of Regulation (EC) No 2073/2005, within the framework of points 2.1.3, 2.1.4 and 2.1.5 of Chapter 2 of Annex I thereto; or

   (c) collecting all information on the total number and the number of *Salmonella* positive samples taken within the framework of national control programmes in Member States or regions of Member States for which special guarantees have been approved in accordance with Article 8 of Regulation (EC) No 853/2004 as regards ruminant, equine, pork and poultry production.

2. If the process hygiene criterion is not complied with on several occasions, the competent authority shall require an action plan from the food business operator concerned and strictly supervise its outcome.

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3. The total number and the number of *Salmonella* positive samples, differentiating between samples taken under points 1(a), (b) and (c), when applied, shall be reported in accordance with Article 9(1) of Directive 2003/99/EC of the European Parliament and of the Council[4].

H. CAMPYLOBACTER

1. Without prejudice to the first paragraph of Article 1 of Regulation (EC) No 2073/2005, the competent authority shall verify the correct implementation by food business operators of point 2.1.9 (process hygiene criterion for *Campylobacter* on carcases of broilers) of Chapter 2 of Annex I to that Regulation by applying the following measures:

   (a) official sampling using the same method and sampling area as food business operators. At least 49 random samples shall be taken in each slaughterhouse each year. This number of samples may be reduced in small slaughterhouses based on a risk evaluation; or

   (b) collecting all information on the total number and the number of *Campylobacter* samples with more than 1 000 cfu/g taken by food business operators in accordance with Article 5(5) of Regulation (EC) No 2073/2005, within the framework of point 2.1.9 of Chapter 2 of Annex I thereto.

2. If the process hygiene criterion is not complied with on several occasions, the competent authority shall require an action plan from the food business operator concerned and strictly supervise its outcome.

3. The total number and the number of *Campylobacter* samples with more than 1 000 cfu/g, differentiating between samples taken under points 1(a) and (b), when applied, shall be reported in accordance with Article 9(1) of Directive 2003/99/EC.

[4] Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC (OJ L 325, 12.12.2003, p. 31).

ANNEX II

Official testing methods for detecting marine biotoxins in accordance with Article 13

Chapter I. PARALYTIC SHELLFISH POISON DETECTION METHOD

A. The paralytic shellfish poison (PSP) content of edible parts of live bivalve molluscs, namely the whole body or any part edible separately, shall be detected in accordance with the biological testing method or any other internationally recognised method.

B. If the results are challenged, the reference method shall be the above mentioned Lawrence method that may also be used as an alternative method for the detection of those toxins as published in AOAC International's Official Method 2005.06 (Paralytic Shellfish Poisoning Toxins in Shellfish J. of AOAC Internat. 88 (6), 1714-1732.)

Chapter II. AMNESIC SHELLFISH POISON DETECTION METHOD

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

However, for screening purposes, the 2006.02 ASP ELISA method as published in the AOAC Journal of June 2006 may also be used to detect the total content of ASP of edible parts of live bivalve molluscs.

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

Chapter III. LIPOPHILIC TOXIN DETECTION METHODS

A. Chemical methodology

1. The European Reference Laboratory Liquid Chromatography-Mass Spectrometry/Mass Spectrometry (EU-RL LC-MS/MS) method shall be the reference method for the detection of marine toxins as referred to in points 2(c), (d) and (e) of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004. This method shall determine at least the following compounds:

   (a) okadaic acid group toxins: OA, DTX1, DTX2 and DTX3 including their esters,

   (b) pectenotoxins group toxins: PTX1 and PTX2,

   (c) yessotoxins group toxins: YTX, 45 OH YTX, homo YTX and 45 OH homo YTX,

   (d) azaspiracids group toxins: AZA1, AZA2 and AZA3.

2. Total toxicity equivalence shall be calculated using toxicity equivalent factors (TEFs) as recommended by the European Food Safety Authority (EFSA).

3. If new analogues of public health significance are discovered, they shall be included in the analysis. Total toxicity equivalence shall be calculated using toxicity equivalent factors (TEFs) as recommended by the EFSA.

4. Methods other than those referred to in point 1, such as liquid chromatography (LC) mass spectrometry (MS) method, high-performance liquid chromatography (HPLC) with appropriate detection, immunoassays and

functional assays, such as the phosphatase inhibition assay, may be used as alternatives or supplementary to the EU-RL LC-MS/MS method, provided that:

(a) either alone or combined they can detect at least the analogues as identified in point 1 of Chapter III.A; more appropriate criteria shall be defined when necessary,

(b) they fulfil the method performance criteria stipulated by the EU-RL LC-MS/MS method. Such methods should be intra-laboratory validated and successfully tested under a recognised proficiency test scheme. The EU-RL LC-MS/MS method shall support activities toward inter-laboratory validation of the technique to allow for formal standardisation,

(c) their implementation provides an equivalent level of public health protection.

B. Biological methodology

The mouse bioassay shall be used only during the periodic monitoring of production areas and relaying areas for detecting new or unknown marine toxins on the basis of the national control programmes elaborated by the Member States.

ANNEX III

Practical arrangements of the health mark in accordance with Article 26(3)

1. The health mark must be an oval mark at least 6,5 cm wide by 4,5 cm high bearing the following information in perfectly legible characters:

   (a) the mark must indicate the name of the country in which the establishment is located, which may be written out in full in capitals or shown as a two-letter code in accordance with the relevant ISO code. In the case of Member States, however, these codes are BE, BG, CZ, DK, DE, EE, IE, GR, ES, FR, HR, IT, CY, LV, LT, LU, HU, MT, NL, AT, PL, PT, RO, SI, SK, FI, SE and UK;

   (b) the mark must indicate the approval number of the slaughterhouse; and

   When applied in an establishment located within the Union, the mark must be oval in shape and include the abbreviation CE, EC, EF, EG, EK, EO, EY, ES, EÜ, EK, EB, EZ or WE. Those abbreviations must not be included in marks applied on meat imported into the Union from slaughterhouses located outside the Union.

2. Letters must be at least 0,8 cm high and figures at least 1 cm high. The dimensions and characters of the mark may be reduced for health marking of lamb, kids and piglets.

3. The ink used for health marking must be authorised in accordance with Union rules on the use of colouring substances in foodstuffs.

4. The health mark may also include an indication of the official veterinarian who carried out the health inspection of the meat.

ANNEX IV

Testing methods for raw milk and heat-treated cow's milk in accordance with Article 28(1)

Chapter I. DETERMINATION OF PLATE COUNT AND SOMATIC CELL COUNT

A. When checking against the criteria laid down in Annex III, Section IX, Chapter I, Part III to Regulation (EC) No 853/2004, the following standards must be applied as reference methods:

1. EN/ISO 4833-1 for the plate count at 30 °C;
2. ISO 13366-1 for the somatic cell count.

B. The use of alternative analytical methods is acceptable:

1. For the plate count at 30 °C, when the methods are validated against the reference method mentioned in point 1(a) in accordance with the protocol set out in Standard EN ISO 16140–2, supplemented by Standard ISO 16297 for the specific case of plate count in raw milk.

   In particular the conversion relationship between an alternative method and the reference method mentioned in point 1(a) is established according to standard EN ISO 21187.

2. For the somatic cell count, when the methods are validated against the reference method mentioned in point 1(b) in accordance with the protocol set out in Standard EN ISO 8196-3 and when operated in accordance with Standard EN ISO 13366-2 or other similar internationally accepted protocols.

Chapter II . DETERMINATION OF ALKALINE PHOSPHATASE ACTIVITY IN COW's milk

A. When determining alkaline phosphatase activity in pasteurised cow's milk, Standard EN ISO 11816-1 must be applied as reference method.

B. The alkaline phosphatase activity in pasteurised cow's milk is expressed as milli units of enzyme activity per litre (mU/l). A unit of alkaline phosphatase activity is the amount of alkaline phosphatase enzyme that catalyses the transformation of 1 micromole of substrate per minute.

C. An alkaline phosphatase test is considered to give a negative result if the measured activity in cow's milk is not higher than 350 mU/l.

D. The use of alternative analytical methods is acceptable when the methods are validated against the reference method mentioned in point 1 in accordance with internationally accepted protocols and rules of good laboratory practices.

ANNEX V

Practical arrangements of official controls of fishery products in accordance with Article 30

CHAPTER I

GENERAL

A. ORGANOLEPTIC EXAMINATIONS

Random organoleptic checks must be carried out at all stages of production, processing and distribution. One aim of these checks is to verify compliance with the freshness criteria established in accordance with this Regulation. In particular, this includes verifying, at all stages of production, processing and distribution, that fishery products at least meet the baselines of freshness criteria established in accordance with this Regulation.

B. FRESHNESS INDICATORS

When the organoleptic examination reveals any doubt as to the freshness of the fishery products, samples may be taken and subjected to laboratory tests to determine the levels of total volatile basic nitrogen (TVB-N) and trimethylamine nitrogen (TMA-N) in accordance with the technical arrangements in Chapter II.

The competent authority must use the criteria laid down in this Regulation.

When the organoleptic examination gives cause to suspect the presence of other conditions which may affect human health, appropriate samples must be taken for verification purposes.

C. HISTAMINE

Random testing for histamine is to be carried out to verify compliance with the permitted levels laid down in Regulation (EC) No 2073/2005.

D. RESIDUES AND CONTAMINANTS

Monitoring arrangements must be set up to control the levels of residues and contaminants in accordance with Union legislation.

E. MICROBIOLOGICAL CHECKS

Where necessary, microbiological checks must be performed in accordance with the relevant rules and criteria laid down in Regulation (EC) No 2073/2005.

F. PARASITES

Random testing is to take place to verify compliance with Part D of Chapter III of Section VIII of Annex III to Regulation 853/2004 and Section I of Annex II to Regulation 2074/2005 .

G. POISONOUS FISHERY PRODUCTS

Checks must take place to ensure that:

1. fishery products derived from poisonous fish of the following families are not placed on the market: Tetraodontidae, Molidae, Diodontidae and Canthigasteridae;

2. fresh, prepared, frozen and processed fishery products belonging to the family Gempylidae, in particular Ruvettus pretiosus and Lepidocybium flavobrunneum, may only be placed on the market in wrapped/packaged form and must be appropriately labelled to provide information to the consumer on preparation/cooking methods and on the risk related to the presence of substances with adverse

gastrointestinal effects. The scientific names of the fishery products and the common names must appear on the label;

3. fishery products containing biotoxins such as ciguatera or other toxins dangerous to human health are not placed on the market. However, fishery products derived from live bivalve molluscs, echinoderms, tunicates and marine gastropods may be placed on the market if they have been produced in accordance with Section VII of Annex III to Regulation (EC) No 853/2004 and comply with the standards laid down in point 2 of Chapter V of that Section.

CHAPTER II

CONTROLS ON TOTAL VOLATILE BASIC NITROGEN (TVB-N)

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

1. Unprocessed fishery products shall be regarded as unfit for human consumption where organoleptic assessment has raised doubts as to their freshness and chemical checks reveal that the following TVB-N limits are exceeded:

   (a) 25 mg of nitrogen/100 g of flesh for the species referred to in point 1 of Section 2.G; [

   (b) 30 mg of nitrogen/100 g of flesh for the species referred to in point 2 of Section 2.G;

   (c) 35 mg of nitrogen/100 g of flesh for the species referred to in point 3 of Section 2.G;

   (d) 60 mg of nitrogen/100 g of whole fishery products used directly for the preparation of fish oil for human consumption as referred to in the second paragraph of point 1 of Chapter IV.B of Section VIII of Annex III to Regulation (EC) No 853/2004; however, where the raw material complies with points (a), (b) and (c) of the first paragraph of point 1 of Chapter IV.B of Section VIII of Annex III to Regulation (EC) No 853/2004, Member States may set limits at a higher level for certain species pending the establishment of specific Union legislation.

   The reference method to be used for checking the TVB-N limits involves distilling an extract deproteinised by perchloric acid as set out in Section 5.C.

2. Distillation as referred to in point 1 must be performed using apparatus which complies with the diagram in Section 5.D.

3. The routine methods which may be used to check the TVB-N limit are as follows:

   (a) microdiffusion method described by Conway and Byrne (1933);

   (b) direct distillation method described by Antonacopoulos (1968);

   (c) distillation of an extract deproteinised by trichloracetic acid (Codex Alimentarius Committee on Fish and Fishery Products (1968).

4. The sample must consist of about 100 g of flesh, taken from at least three different points and mixed together by grinding.

Member States shall recommend that official laboratories use, as a matter of routine, the methods referred to above. [Where the results are dubious or in the event of dispute regarding

the results of analysis performed by one of the routine methods, only the reference method may be used to check the results.

B. SPECIES CATEGORIES FOR WHICH TVB-N LIMIT VALUES ARE FIXED

TVB-N limit values are fixed for the following species categories:

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.

C. REFERENCE PROCEDURE FOR THE DETERMINATION OF THE CONCENTRATION OF TVB-N IN FISH AND FISHERY PRODUCTS

1. Purpose and area of application

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

2. Definitions

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

   'Solution' means an aqueous solution as follows:

   (a) perchloric acid solution = 6 g/100 ml;

   (b) sodium hydroxide solution = 20 g/100 ml;

   (c) hydrochloric acid standard solution 0,05 mol/l ((0,05 N). When using an automatic distillation apparatus, titration should take place with a hydrochloric acid standard solution of 0,01 mol/l ((0,01 N);

   (d) boric acid solution = 3 g/100 ml;

   (e) silicone anti-foaming agent;

   (f) 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.

3. Brief description

   The volatile nitrogenous bases are extracted from a sample using a solution of 0,6 mol perchloric acid. After alkalinisation the extract undergoes steam distillation and the volatile base components are absorbed by an acid receiver. The TVB-N concentration is determined by titration of the absorbed bases. The concentration shall be expressed in mg/100 g.

4. Chemicals

   Unless otherwise indicated, reagent-grade chemicals shall be used. The water used must be either distilled or demineralised and of at least the same purity.

5. The following instruments and accessories shall be used:

   (a) a meat grinder to produce a sufficiently homogenous fish mince;

(b) high-speed blender with a speed of between 8 000 and 45 000 revolutions/min;

(c) fluted filter, diameter 150 mm, quick-filtering;

(d) burette, 5 ml, graduated to 0,01 ml;

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

6. Execution of the reference procedure

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

(a) Preparing the sample

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

The extract thereby obtained can be kept for at least seven days at a temperature of between approximately 2 °C and 6 °C;

(b) Steam distillation

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

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

The pH of the end point should be 5,0 ± 0,1;

(c) Titration

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

(d) Blank

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

7. Calculation of TVB-N concentration

By titration of the receiver solution with hydrochloric acid standard solution, the TVB-N concentration is calculated using the following equation:

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

V1 = Volume of 0,01 mol hydrochloric acid standard solution in ml for sample

V0 = Volume of 0,01 mol hydrochloric acid standard solution in ml for blank

M = Weight of sample in g.

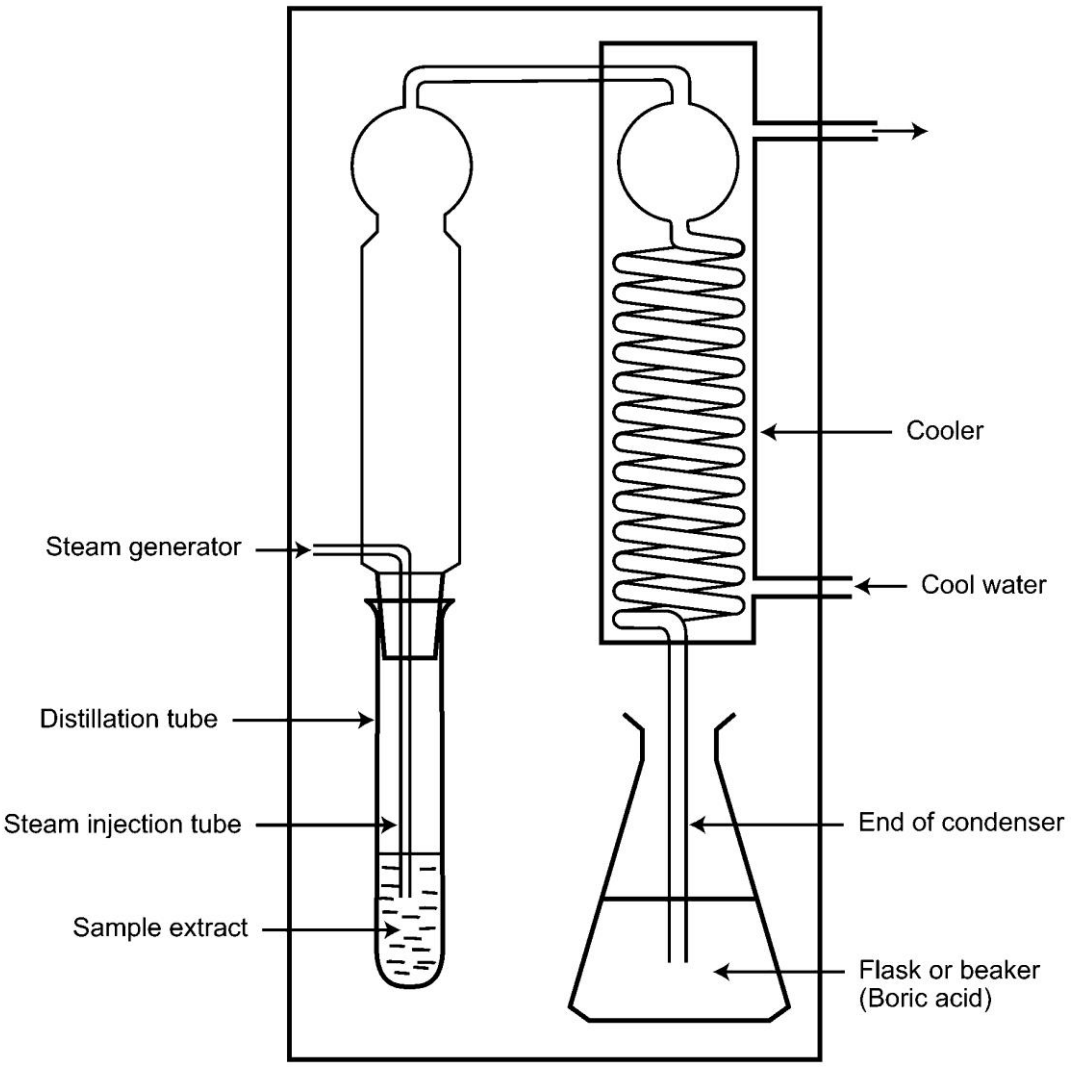
In addition, the following shall be required:

(a) Duplicate analyses. The applied method is correct if the difference between duplicates is not greater than 2 mg/100 g;

(b) Equipment check. The equipment shall be checked by distilling solutions of NH4Cl equivalent to 50 mg TVB-N/100 g;

(c) Standard deviations. The standard deviation of reproducibility SR = 1,20 mg/100 g and the standard deviation of comparability SR = 2,50mg/100 g shall be calculated.

D. TVB-N STEAM DISTILLATION APPARATUS



C.