EN

ANNEX I

Model document for communication with the holding of provenance in accordance with Article 39(5)

1. Identification details

1.1. Holding of provenance (owner or manager)
- Name/number
- Full address
- Telephone number
- Electronic address if available

1.2. Identification numbers of ……[please specify] or attach list
- Total number of animals (by species)
- Identification problems (if any)

1.3. Herd/flock/cage identification number (if applicable)

1.4. Animal species

1.5. Reference number of health certificate (if applicable)

2. Ante-mortem findings

2.1. Welfare
- Number of animals affected
- Type/class/age
- Observations

2.2. Animals were delivered dirty

2.3. Clinical findings of disease
- Number of animals affected
- Type/class/age
- Observations
- Date of inspection

2.4. Laboratory results[1]

3. Post-mortem findings

3.1. Macroscopic findings
- Number of animals affected
- Type/class/age
- Organ or site of animal(s) affected

[1] Microbiological, chemical, serological, etc. (include results as attached).

Date of slaughter

3.2. Disease (codes may be used[2])
Number of animals affected
Type/class/age
Organ or site of the animal(s) affected
Partially or totally condemned carcase (give reason)
Date of slaughter

3.3. Laboratory results[3]

3.4. Other results

3.5. Welfare findings

4. Additional information

5. Contact details of slaughterhouse (approval number)
Name
Full address
Telephone number
Electronic address if available

6. Official veterinarian (print name)
Signature and stamp

7. Date

8. Number of pages attached to this form:

[2] The competent authorities may introduce the following codes: code A for OIE-listed diseases; codes B100 and B200 for welfare issues and C100 to C290 for decisions concerning meat. The coding system can, if necessary, include further subdivisions (e.g. C141 for a mild generalised disease, C142 for a more severe disease, etc.). If codes are used, they should be readily available to the food business operator with a suitable explanation of their meaning.

[3] Microbiological, chemical, serological, etc. (include results as attached).

ANNEX II

Practical arrangements for the health mark in accordance with Article 48

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 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 approval number of the slaughterhouse; and

   (c) (when the mark is applied in an establishment located in the Union), the abbreviation CE, EC, EF, EG, EK, EO, EY, ES, EÜ, EB, EZ, KE or WE. Those abbreviations must not appear on 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 of the characters and the mark may be reduced for the 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 III

Testing methods for raw milk and heat-treated cow's milk in accordance with Article 50

CHAPTER I
DETERMINATION OF PLATE COUNT AND SOMATIC CELL COUNT

A. When verifying compliance with the criteria laid down in Part III of Section IX, Chapter I of Annex 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. EN 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, where the methods are validated against the reference method mentioned in point 1 of Part A in accordance with the protocol set out in standard EN ISO 16140-2, supplemented by standard EN 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 of Part A is established according to standard EN ISO 21187.

2. for the somatic cell count, where the methods are validated against the reference method mentioned in point 2 of Part A in accordance with the protocol set out in standard ISO 8196-3 and 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. To determine alkaline phosphatase activity in pasteurised cow's milk, standard EN ISO 11816-1 must be applied as the 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 where they are validated against the reference methods mentioned in Part A in accordance with internationally accepted protocols and rules of good laboratory practices.

ANNEX IV

Reference testing method for analysis of E. coli in live bivalve molluscs for classification of production and relaying areas in accordance with Article 52 (2)

The reference method for analysis of E. coli in live bivalve molluscs shall be the detection and 'most probable number' (MPN) technique specified in ISO 16649-3. Alternative methods may be used if they are validated against this reference method in accordance with the criteria in ISO 16140.

ANNEX V

Recognised methods for the detection of marine biotoxins in accordance with Article 61

CHAPTER I
PARALYTIC SHELLFISH POISON DETECTION METHOD

A. The paralytic shellfish poisoning (PSP) toxins content of the whole body or any part edible separately of bivalve molluscs shall be determined using AOAC official method OMA 2005.06, as published in *AOAC International Journal* 88(6), 1714-1732 (Lawrence method), the mouse bioassay or any other internationally recognised validated method.

B. If the results are challenged, the reference method shall be AOAC official method OMA 2005.06 as referred in point A.

CHAPTER II
AMNESIC SHELLFISH POISON DETECTION METHOD

A. The amnesic shellfish poisoning (ASP) toxins content of the entire body or any part edible separately of bivalve molluscs shall be determined using the high-performance liquid chromatography with ultraviolet detection (HPLC/UV) method or any other internationally recognised validated method.

B. However, for screening purposes, AOAC official method 2006.02, as published in *AOAC International Journal* 90, 1011-1027 (ASP enzyme-linked immunosorbent assay (ELISA) method), or any other internationally recognised validated method may also be used.

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

CHAPTER III
LIPOPHILIC TOXIN DETECTION METHODS

A. The reference method for the detection of marine toxins as referred to in points (c), (d) and (e) in Chapter V(2) of Section VII of Annex III to Regulation (EC) No 853/2004 shall be the EU reference laboratory liquid chromatography-mass spectrometry / mass spectrometry (EU-RL LC-MS/MS) method. This method shall determine at least the following compounds:

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

(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: AZA 1, AZA 2 and AZA 3.

If new analogues of the above toxins appear, for which a toxicity equivalent factor (TEF) has been established, they shall be included in the analysis.

Total toxicity equivalence shall be calculated using TEFs as recommended by the European Food Safety Authority (EFSA) in Journal (2008) 589, 1-62 or any updated EFSA advice.

B. Methods other than those referred to in point A, such as the LC-MS method, HPLC with appropriate detection, immunoassays and functional assays, such as the phosphatase inhibition assay, may be used as alternatives to, or as well as, the EURL LC-MS/MS method, provided that:

(a) either alone or combined they can detect at least the analogues identified in point A; more appropriate criteria shall be defined where necessary;

(b) they meet the method performance criteria stipulated by the EURL LC-MS/MS method. Such methods should be intra-laboratory validated and successfully tested under a recognised proficiency test scheme. The EURL 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.

CHAPTER IV
DETECTION OF NEW OR EMERGING MARINE TOXINS

Chemical methods, alternative methods with appropriate detection, or the mouse bioassay can be used during the periodic monitoring of production areas and relaying areas for detecting new or emerging marine toxins on the basis of the national control programmes elaborated by the Member States.

ANNEX VI

Practical arrangements for official controls on fishery products in accordance with Article 71

CHAPTER I
GENERAL

A. ORGANOLEPTIC EXAMINATIONS

Random organoleptic controls shall be carried out at all stages of production, processing and distribution. One aim of the controls 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 gives rise to 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 shall use the criteria laid down in this Regulation.

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

C. HISTAMINE

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

D. RESIDUES AND CONTAMINANTS

Monitoring arrangements shall be established in accordance with Directive 96/23/EC and Decision 97/747/EC to control compliance with the EU legislation on:

- maximum residue limits for pharmacologically active substances, in accordance with Regulations (EU) No 37/2010 and (EU) 2018/470;
- prohibited and non-authorised substances, in accordance with Regulation (EU) No 37/2010, Directive 96/22/EC and Decision 2005/34/EC;
- contaminants, in accordance with Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in food; and
- pesticide residues, in accordance with Regulation (EC) No 396/2005.

E. MICROBIOLOGICAL CHECKS

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

F. PARASITES

Risk-based testing shall take place to verify compliance with Part D of Chapter III of Section VIII of Annex III to Regulation (EC) No 853/2004 and Section I of Annex II to Regulation (EC) No 2074/2005.

G. POISONOUS FISHERY PRODUCTS

Controls shall 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 be placed on the market only in wrapped/packaged form and are appropriately labelled to inform the consumer about preparation/cooking methods and the risk related to the presence of substances with adverse gastrointestinal effects. The scientific names of the fishery products and the common names shall 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. 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 B of this Chapter; [

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

   (c) 35 mg of nitrogen/100 g of flesh for the species referred to in point 3 of Section B of this Chapter;

   (d) 60 mg of nitrogen/100 g of whole fishery product 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 that point, 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 C below.

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

3. The routine methods that 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 shall 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 DETERMINING 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. The 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 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 is expressed in mg/100 g.

4. Chemicals

Unless otherwise indicated, reagent-grade chemicals shall be used. The water used shall 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 8 000 to 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 shall 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 is ground carefully using a meat grinder as described in point 5(a). An amount of 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:

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

where:

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 is 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 is checked by distilling solutions of NH_4Cl equivalent to 50 mg TVB-N/100 g;

(c) standard deviations. The standard deviation for repeatability Sr = 1.20 mg/100 g and the standard deviation for reproducibility SR = 2.50 mg/100 g are calculated.

D. TVB-N STEAM DISTILLATION APPARATUS