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Subject: Draft COMMISSION DECISION of concerning a Community financial contribution towards a coordinated monitoring programme on the prevalence of *Listeria monocytogenes* in certain ready-to-eat foods to be carried out in the Member States

Delegations will find attached Commission document D005673/04.

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
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final

Draft

COMMISSION DECISION

of

concerning a Community financial contribution towards a coordinated monitoring programme on the prevalence of *Listeria monocytogenes* in certain ready-to-eat foods to be carried out in the Member States

Draft

COMMISSION DECISION

of

concerning a Community financial contribution towards a coordinated monitoring programme on the prevalence of *Listeria monocytogenes* in certain ready-to-eat foods to be carried out in the Member States

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules¹, and in particular Article 66 thereof,

Having regard to Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents², and in particular Article 5 thereof,

Whereas:

- (1) Regulation (EC) No 882/2004 lays down, among others, procedures governing a Community financial support to conduct measures necessary to ensure the application of the Regulation (EC) No 882/2004.
- (2) Reports on trends and sources of zoonoses, zoonotic agents and antimicrobial resistance in the Community were issued by the European Food Safety Authority (EFSA) and the European Centre for Disease Prevention and Control in 2006³ and 2007⁴ (EFSA-ECDC reports). According to those reports, a total of 1,588 cases of listeriosis (*Listeria monocytogenes*) in humans were registered in 25 Member States in 2006. In addition, 1,558 such cases were registered in 26 Member States in 2007. The reports further demonstrated a significant increase in the incidence of such cases in humans over the period 2001-2006. Illness is often severe and mortality is high.
- (3) The fact that *Listeria monocytogenes* is able to multiply in various foods at temperatures as low as 2 to 4 °C makes the occurrence of *Listeria monocytogenes* in ready-to-eat (RTE) foods with a relatively long shelf-life of particular concern.

¹ OJ L 165, 30.4.2004, p. 1.

² OJ L 325, 12.12.2003, p. 31.

³ *The EFSA Journal* (2007), 130.

⁴ *The EFSA Journal* (2009), 223.

- (4) Pursuant to Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs⁵, food business operators are to comply with *Listeria monocytogenes* food safety criteria for ready-to-eat foods within the framework of good hygiene practises and hazard analysis of critical control point (HACCP) programmes.
- (5) The EFSA-ECDC reports showed that the highest proportions of non-compliance with the *Listeria monocytogenes* criteria were registered in ready-to-eat cheese and in ready-to-eat fishery and heat treated meat products.
- (6) The exposure of humans to *Listeria monocytogenes* is mainly food-borne. Therefore the prevalence and level of *Listeria monocytogenes* contamination in ready-to-eat fishery products, cheeses and heat treated meat products should be estimated in a harmonised and comparable way by means of a coordinated monitoring programme at retail level in all Member States.
- (7) The growth of *Listeria monocytogenes* in a ready-to-eat product is influenced significantly by the pH, water activity and storage temperature of the product. A modelling can be used for the estimation of the growth of *Listeria monocytogenes* in a ready-to-eat product under various temperature conditions.
- (8) Where there are no relevant definitions in the Community legislation, the definitions in the Codex General Standard for Cheese (CODEX STAN 283-1978, amendment 2008) and in the Codex Group Standard for Unripened Cheese including Fresh Cheese (CODEX STAN 221-2001, amendment 2008) issued by the Codex Alimentarius Commission should be used to guarantee the harmonized approach in defining ready-to-eat cheeses.
- (9) Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents⁶ provides that coordinated monitoring programmes may be established, especially when specific needs are identified, to assess risks and to establish baseline values related to zoonoses and zoonotic agents.
- (10) In May 2009, the Task Force on Monitoring of Zoonoses Data Collection of EFSA adopted a Report on proposed technical specifications for a co-ordinated monitoring programme for *Listeria monocytogenes* in certain categories of RTE foods at retail in the EU⁷.
- (11) Given the importance of collecting comparable data on the prevalence of *Listeria monocytogenes* in ready-to-eat foods, a Community financial contribution for carrying out such coordinated monitoring programme should be granted.
- (12) It is appropriate to reimburse costs incurred on the laboratory testing, subject to a ceiling. All other costs incurred, such as costs for sampling, travel and administration should not be eligible for any Community financial contribution.

⁵ OJ L 338, 22.12.2005, p. 1.

⁶ OJ L 325, 12.12.2003, p. 31.

⁷ *The EFSA Journal* (2009) 300, 1-66.

- (13) A financial contribution from the Community should be granted insofar as the coordinated monitoring programme is carried out in accordance with this Decision and provided that the competent authorities furnish all the necessary information within the time limits provided for therein.
- (14) For reasons of administrative efficiency all expenditure presented for a financial contribution by the Community should be expressed in euro. In accordance with Council Regulation (EC) No 1290/2005 of 21 June 2005 on the financing of the common agricultural policy⁸, the conversion rate for expenditure in a currency other than euro should be the rate most recently set by the European Central Bank prior to the first day of the month in which the application for reimbursement is submitted by the Member State concerned.
- (15) The present Decision constitutes a financing Decision within the meaning of Article 75 of the Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities (Financial Regulation)⁹, Article 90 of the detailed rules for the implementation of the Financial Regulation, and Article 15 of the Internal Rules on the Implementation of the general budget of the European Communities.
- (16) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1
Subject matter

This Decision establishes a coordinated monitoring programme on the prevalence of *Listeria monocytogenes* in certain ready-to-eat food categories provided for in Article 2 at retail level, and lays down rules on a financial contribution from the Community to the Member States for its implementation.

Article 2
Scope and duration of the coordinated monitoring programme

1. The Member States shall carry out a coordinated monitoring programme to assess the prevalence of *Listeria monocytogenes* in the following ready-to-eat food categories in samples selected at random at retail level:
 - (a) packaged (not frozen) hot or cold smoked or gravad fish;
 - (b) soft or semi-soft cheeses, excluding fresh cheeses;
 - (c) packaged heat treated meat products.

⁸ OJ L 209, 11.8.2005, p. 1.

⁹ OJ L 248, 16.9.2002, p. 1.

2. The sampling for the coordinated monitoring programme provided for in paragraph 1 shall be carried out from 1 January 2010 to 31 December 2010 at the latest.

Article 3 *Definitions*

For the purposes of this Decision, the following definitions shall apply:

1. 'ready-to-eat food' means ready-to-eat food as defined in Article 2(g) of Regulation (EC) No 2073/2005.
2. 'shelf-life' means shelf-life as defined in Article 2(f) of Regulation (EC) No 2073/2005.
3. 'batch' means batch as defined in Article 2(e) of Regulation (EC) No 2073/2005.
4. 'retail' means retail as defined in Article 3(7) of Regulation (EC) No 178/2002 of the European Parliament and the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety¹⁰; however, for the purposes of this Decision, retail covers only shops, supermarkets and other similar outlets that sell directly to the final consumer; it does not include distribution terminals or centres, catering operations, institutional catering, factory canteens, restaurants and other similar food service operations and wholesale outlets.
5. 'processing' means processing as defined in Article 2(1)(m) of Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs¹¹.
6. 'meat products' means meat products as defined in point 7.1 of Annex I 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 origin¹².
7. 'country of production' means the country indicated on the identification mark as provided for in point 6 of part B of Section I of Annex II to Regulation (EC) No 853/2004.
8. 'packaged food' means food that has its entire surface covered in order to prevent direct contact of the food with the environment, either by permeable or impermeable wrapping.
9. 'modified atmosphere packaged food' means food that was packaged and hermetically sealed after the removal of air from the package and the replacement of that air with a strictly controlled gaseous mixture of carbon dioxide, oxygen, and/or nitrogen.

¹⁰ OJ L 31, 1.2.2002, p. 1.

¹¹ OJ L 139, 30.4.2004, p. 1.

¹² OJ L 139, 30.4.2004, p. 55.

10. 'vacuum packaged food' means food that was packaged and hermetically sealed after the removal of the air from the package.
11. 'smoked fish' means fish cured by smoking.
12. 'gravad fish' means fish that has been cured in salt and sugar without thermal treatment.
13. 'ripened cheeses' means cheeses which are not ready for consumption shortly after manufacture but which must be held for such time, at such temperature, and under such other conditions as will result in the necessary biochemical and physical changes characterizing the cheese in question.
14. "soft cheeses" means cheeses that have a percentage moisture, on a fat-free basis, higher than 67%.
15. "semi-soft cheeses" means cheeses that have a texture which is only slighter harder than the soft cheese category. These cheeses have a percentage moisture, on a fat-free basis, ranging from 62 to 67%. Semi-soft cheeses are characterized by their firm but elastic feel.
16. 'mould ripened cheeses' means cheeses in which the ripening has been accomplished primarily by the development of characteristic mould growth throughout the interior and/or on the surface of the cheese.
17. 'smear-ripened cheeses' means cheeses in which during or after ripening, the cheese rind is treated or naturally colonized with desired cultures of microorganisms, for instance *Penicillium candidum* or *Brevibacterium linens*. The resulting layer or smear forms a part of the rind.
18. 'brine matured cheeses' means cheeses matured and stored in brine until they are sold or packed.
19. 'fresh cheeses' means curd-style cheeses which do not undergo any ripening, for example cottage cheese, mozzarella, ricotta and quark. Fresh cheeses are not included in this coordinated monitoring programme.

Article 4

Sampling, analyses and recording of data by the Member States

1. Sampling shall be performed by the competent authority or under its supervision.
2. National reference laboratories for *Listeria monocytogenes* shall perform the *Listeria monocytogenes*, pH and water activity analyses.
3. The competent authority may designate other laboratories than the national reference laboratories which are accredited for and involved in official controls of *Listeria monocytogenes* to perform the *Listeria monocytogenes*, pH and water activity analyses.

4. The sampling and analyses provided for in paragraphs 1, 2 and 3, as well as recording of all relevant data, shall be performed in accordance with the technical specifications set out in Annex I.
5. The number of samples to be taken per ready-to-eat food category in each Member State is set out in Annex II.

Article 5

Collection, assessment, reporting and use of data at Community level

1. Member State shall collect and assess the results of the sampling and *Listeria monocytogenes*, pH and water activity analyses provided for in Article 4(1), (2) and (3) of this Decision.

Those results and their assessment, together with all relevant data, shall be included in a final report on the completion of the coordinated monitoring programme that shall be transmitted to the Commission before 31 May 2011.

2. The Commission shall establish by the 31 December 2009 the format of the Data Dictionary and data collection forms to be used in the drawing up of the report referred to in paragraph 1 by the competent authorities.
3. The Commission shall forward the final reports provided for in paragraph 1 to the European Food Safety Authority (EFSA), which shall examine them, develop predictive models for the compliance with the *Listeria monocytogenes* food safety criteria and for the microbial growth under various storage conditions and issue a Summary Report within six months.
4. Any use of the data submitted by the Member States for purposes other than the coordinated monitoring programme shall be subject to prior agreement of the Member States.
5. Data and results shall be made publicly available in a form that ensures confidentiality of the individual results.

Article 6

Conditions for granting a Community financial contribution

1. A Community financial contribution of a total amount of 1 555 300 euros from budget line 170402 towards the costs of the analyses provided for in Article 4(2) shall be granted to the Member States up to the maximum total amount for co-financing set out in Annex III.
2. The Community financial contribution provided for in paragraph 1 shall be paid to the Member States provided that the coordinated monitoring programme is carried out in accordance with the relevant provisions of Community law, including rules on competition and on the award of public contracts, and subject to compliance with the following conditions:

The final report on the completion of the coordinated monitoring programme must be submitted to the Commission before 31 May 2011; the report must contain:

- (i) all the information set out in Part D of Annex I;
 - (ii) supporting evidence for the costs incurred by the Member States for the analyses; that evidence must comprise at least the information set out in Annex IV.
3. In the case of late submission of the final report referred to in paragraph 2 the Community financial contribution shall be reduced by 25% on 1 July 2011, 50% on 1 August 2011 and 100% on 1 September 2011.

Article 7

Maximum amounts to be reimbursed

The maximum amounts of the Community financial contribution towards the costs to be reimbursed to the Member States for each analysis shall not exceed the following:

- (a) EUR 60 for each analysis for the detection of *Listeria monocytogenes*;
- (b) EUR 60 for each analysis for the enumeration of *Listeria monocytogenes*;
- (c) EUR 15 for each pH analysis;
- (d) EUR 20 for each water activity (a_w) analysis.

Article 8

Conversion rate for expenditure

Where a Member State's expenditure is in a currency other than euro, the Member State concerned shall convert it into euro by applying the most recent exchange rate set by the European Central Bank prior to the first day of the month in which the application is submitted by the Member State.

Article 9

Addressees

This Decision is addressed to the Member States.

Done at Brussels,

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX I

(referred to in Article 4(4))

PART A: SAMPLING FRAME

1. THE PRODUCTS TO BE SAMPLED

The following categories of ready-to-eat food shall be sampled at retail level:

1.1. Packaged (not frozen) hot or cold smoked or gravad fish

Products belonging to this category must be vacuum packaged or modified atmosphere packaged.

The fish may be sliced or not. The package may contain a whole fish, or half or a part of a fish. The skin of the fish may be present or absent.

1.2. Soft or semi-soft cheeses, excluding fresh cheeses

This category shall include cheese made from raw, thermised or pasteurised milk of any animal species. The cheese can be ripened, smear-ripened, mould-ripened or brine-matured.

The cheese may be packaged including wrapped in muslin, or may be unpackaged at retail but packaged at the point of sale for the consumer.

1.3. Packaged heat-treated meat products

1.3.1. Products belonging to this category must have undergone heat treatment and after that must have been handled and vacuum or modified atmosphere packaged.

1.3.2. Products belonging to this category cover both exposed meat products and meat products in a permeable skin that have been sliced or otherwise handled between heat treatment and packaging. Products may have been smoked after the heat treatment.

This category includes in particular:

(a) Cold, cooked meat products: meat products typically made with whole or large parts of anatomical or reformed structures (such as cooked sliced ham and cooked chicken fillet);

(b) sausages;

(c) pâtés.

1.3.3. This category does not include:

(a) meat products dried after heat treatment, such as jerky products;

(b) meat products heat-treated in an impermeable package which are not handled thereafter;

- (c) fermented meat products, including fermented sausages.

2. SAMPLING DESIGN

A proportionate stratified sampling scheme is used for the coordinated monitoring programme whereby the samples are allocated to every Member State proportionally to the size of the human population in that Member State.

2.1. Sampling plan

2.1.1. Each Member State must have a sampling plan, based on a multistage cluster design:

- (a) the first level is composed of the major cities/towns to be sampled ;
- (b) the second level is composed of the retail outlets to be sampled;
- (c) the third level is composed of the different food products within the three ready-to-eat food categories to be sampled.

2.1.2. The sampling plan must be drawn up by the competent authority and must include the following:

- (a) the cities/towns included in the coordinated monitoring programme;
- (b) the types of retail outlets covered and the percentage of samples taken from each category;
- (c) the timing of the sampling throughout the year.

2.1.3. Where relevant marketing data is available, the sampling plan must also include:

- (a) the types of products to be sampled within each of the three ready-to-eat food categories;
- (b) the number of samples to be taken from each type of product referred to in (a).

2.1.4. Member States shall draw up a sampling plan following the rules described below and based on the best marketing data available. These marketing data, or assistance with how to obtain the information, may often be available from a national trade association. In the absence of marketing data, the best estimate of market shares shall be used to inform the sampling plan at a central level. In the absence of any reliable marketing information it may be necessary for competent authorities to devolve the selection of the type of product to sample within a category to the sampler in the field.

2.2. Selection of the retail outlet categories to be targeted

The competent authorities shall choose the retail outlets from which samples are to be taken. Typical types of retail outlets that shall be included for sampling are: supermarkets, small shops, speciality delis, and street markets (such as farmers' or country markets).

If the biggest category of outlets (for example supermarkets) supply at least 80% of the market of a RTE category then samples only need to be taken from those outlets. Where that is not the case, the second largest outlet category shall be added until at least 80% of the market is covered.

When sampling is performed according to a sampling plan, the number of samples that shall be taken for each category of ready-to-eat food from each retail outlet type shall be proportionate to the market share of that outlet type within the targeted outlet types.

2.3. Selection of the cities or towns to be sampled

The sampling shall take place in large cities/towns. At least two large cities/towns in each Member State must be sampled.

The cities/towns in which sampling is performed must, taken together, cover at least 30% of the human population in the Member State. However, if the eight largest cities/towns are included in the plan, the human population coverage may be less than 30%.

2.4. Selection of sample timing

The contamination level of *Listeria monocytogenes* in ready-to-eat food may vary over the year. In order to ensure accurate results of the coordinated monitoring programme, its duration is divided in 12 periods of one month during which equal numbers of samples must be taken.

2.5. Selection of the ready-to-eat foods within the three main categories to be sampled

The ready-to-eat foods within the three ready-to-eat food categories to be sampled shall be selected based on the marketing data and detailed in the sampling plan.

However, the diverse nature of products within a category may not permit estimation of market share with a high degree of reliability. In this case, the competent authorities may choose to instruct samplers to select cheeses for sampling based upon an estimated contribution to market share, according to the national sampling plan. Such sampling may be informed by turnover details provided by local retail management, or more roughly by prominence in the marketplace, e.g. what is displayed at the retail outlet. With such an approach competent authorities should provide some direction on approximate market share of major types of food within categories to best approach a sample representative of market e.g. raw/pasteurised milk cheeses.

PART B: SAMPLE COLLECTION AND TRANSPORT

1. TYPE AND DETAIL OF SAMPLE

Samples shall be taken at random from the customer display and must weight at least 100 g each. It is possible to take more than one sample from each three ready-to-eat food category during the same visit to the retail outlet. However, no more than five batches from each category should be sampled at the same visit.

Only packaged and intact (sealed) packages, packaged by the manufacturer, shall be collected for sampling. However, in case of cheeses, products packaged at the retail outlet may also be collected for sampling.

The products collected for sampling must be labelled in order to make it possible to record information concerning the products. Information on the label shall include the following:

- (a) details of the country of production;
- (b) batch number;
- (c) durability date;
- (d) instructions on temperature storage conditions, if available;
- (e) other information which is normally on the label of packaged ready-to-eat food.

If not all the information referred to in points (a) to (d) is present on the label, the sampler shall ask the owner or manager of the retail outlet for the missing information on the product and labelling details and/or refer to the wholesale pack for that information.

If the label on the ready-to-eat food is not clear or is otherwise damaged, then the product shall not be collected for sampling. Two samples shall be collected from each batch of smoked or gravad fish sampled. Labelling information, such as batch numbers, date until which the product may be sold must be examined to ensure that the two samples are from the same batch. One of those two samples must be analysed on the day of receipt of the sample at the laboratory and the other at the end of shelf-life.

For soft and semi-soft cheeses and heat-treated meat products, only one sample is taken from a batch that must be analysed at the end of shelf-life.

The samples must be placed in a separate sampling bag and sent immediately to the laboratory for analysis

Precautions must be taken at all stages to ensure that the equipment used during sampling, transport and storage is not contaminated with *Listeria monocytogenes*.

2. SAMPLE INFORMATION

All relevant information available concerning the sample shall be recorded on a sampling form, the model of which shall be drawn up by the competent authority. The sampling form shall accompany the sample at all times. In the case of cheese samples packaged at the retail outlet, it may be necessary to ask for the information on the required product and labelling details and/or refer to the wholesale pack for this information.

When samples are collected, the surface temperature of the packaged samples shall be measured and recorded on the sampling form.

Each sample and its sample form shall be labelled with a unique number which shall be used from sampling to testing. The competent authority shall use for this purpose a unique numbering system.

3. TRANSPORT OF SAMPLES

The samples shall be transported in refrigerated containers and must be kept at between 2 to 8 °C and free from external contamination during transportation.

All ready-to-eat food samples must reach the laboratory within 24 hours of the time of sampling.

In exceptional circumstances the transportation time may exceed 24 hours. However, the transportation time shall not be longer than 48 hours and shall in no circumstances lead to testing being carried out after the sell by date of the product collected for sampling.

PART C: SAMPLE PREPARATION AND ANALYTICAL METHODS

1. RECEIPT OF SAMPLES

1.1. General rules

On receipt of the samples, laboratories shall check the information recorded by the sampler on the sampling form and complete the relevant sections of that form. All samples received shall be examined to ensure that the packaging used for transportation is intact before storing. Samples received at a temperature higher than 8°C shall be rejected unless the temperature at retail was higher than 8 °C.

Without prejudice to point 1.2, all samples are kept refrigerated until the end of their shelf-life.

In cases where samples must be stored until the end of their shelf-life, they shall be refrigerated:

- (a) at the storage temperature indicated on the label of the packaging. If the label indicates a temperature interval, the sample must be stored at the upper limit of the temperature interval;
- (b) if there is no specific storage temperature indicated on the label of the packaging, the sample must be kept at:
 - (i) the maximum refrigeration temperatures defined by the legislation or guidance in force in the Member State where the sample is collected, with a tolerance of ± 2 °C,
 - (ii) 8 °C (± 2 °C) where no such legislation or guidance exists.

If the shelf-life of the product sampled ends during a weekend or a national holiday, the sample must be analyzed on the last working day before the end of the shelf-life.

1.2. Special rules concerning smoked and gravad fish

One of the two samples is analyzed within 24 hours from the time of arrival at the laboratory. If that sample is not analysed immediately upon arrival, it must be kept refrigerated at 3 °C (± 2 °C) in the laboratory before analysis.

The second sample shall be kept refrigerated until the end of its shelf-life.

2. SAMPLE PREPARATION AND INITIAL SUSPENSION PREPARATION

Cross contamination between samples and from the surrounding environment shall be avoided at all stages. Samples are discarded once laboratory analyses have been initiated. If the analysis is stopped, for example due to unacceptable deviations in the analysis process, new samples must be obtained.

Either the entire product, or a representative test portion of 100 to 150 g, shall be taken to the initial dilution. Food shall be sampled to include surfaces reflecting the proportion that would be consumed (such as 20% rind/surface and 80% inside). When a packaged product is sliced, the respective sample is taken from more than one slice of the product. The test portion shall be cut in small pieces and placed into a stomacher bag, using a sterile instrument and an aseptic technique. From that mixture, a test portion of 10 g shall be taken for enumeration and a test portion of 25 g shall be taken for detection.

To the volume of the test portion (10g), 9 volumes (90 ml) of diluent are added and subsequently the mixture is homogenized using a stomacher or a pulsifier for 1 to 2 min.

Buffered peptone water, as described in EN ISO 11290-2 'Microbiology of food and animal feeding stuffs – Horizontal method for detection and enumeration of *Listeria monocytogenes* - Part 2: Colony-count technique', may be applied as a diluent for general use.

For the dilution of cheese, a sodium citrate solution, as described in EN ISO 6887-5 'Microbiology of food and animal feeding stuffs – Preparation of test samples, initial suspension and decimal dilutions for microbiological examination – Part 5: Specific rules for the preparation of milk and milk products' shall be used.

Detection and enumeration analyses of *Listeria monocytogenes* shall be performed in accordance with the following:

- (a) for smoked and gravad fish samples two sets of analyses must be carried out:
 - (i) immediately after sample collection at retail level and
 - (ii) at the end of shelf-life;
- (b) for soft and semi-soft cheese samples and heat-treated meat product samples the analyses must be carried out only at the end of shelf-life.

2.1. Detection of *Listeria monocytogenes*

Detection of *Listeria monocytogenes* shall be performed according to the amended version of EN ISO 11290-1:1996 "Microbiology of food and animal feeding stuffs -- Horizontal method for the detection and enumeration of *Listeria monocytogenes* -- Part 1: Detection method".

2.2. Enumeration of *Listeria monocytogenes*

The enumeration of *Listeria monocytogenes* shall be performed according to EN ISO 11290-2:1998 "Microbiology of food and animal feeding stuffs -- Horizontal method for the detection and enumeration of *Listeria monocytogenes* -- Part 2: Enumeration method" and its modification EN ISO 11290-2:1998/Amd 1:2004 "Modification of the enumeration medium".

If the sample is found to be contaminated, it is assumed that the majority of products would contain low contamination levels of *Listeria monocytogenes*. To enable the

estimation of low numbers in samples (between 10 and 100 cfu/g), 1 ml of the primary dilution shall be tested in duplicate as indicated in EN ISO 11290-2:1998/Amd 1:2004:

- (a) spread onto the surface of three 90-mm diameter plates, or
- (b) spread onto the surface of one 140-mm diameter plate.

Because of the possibility of higher contamination levels of *Listeria monocytogenes*, 0.1 ml of the primary dilution must be spread onto the surface of one plate to allow the enumeration of up to 1.5×10^4 cfu/g. This plating must be performed in single as provided in ISO 7218:2007 "Microbiology of food and animal feeding stuffs – General requirements and guidance for microbiological examinations".

3. PH AND WATER ACTIVITY (A_w) ANALYSES OF SMOKED AND GRAVAD FISH

3.1. Determination of the pH

The determination of the pH of the sample shall be performed according to EN ISO 2917:1999 "Meat and meat products – Measurement of pH – Reference method".

The analysis must be carried out on the sample tested on the arrival at the laboratory. The non-destructive technique listed in the ISO method is recommended for measuring the pH of the sample.

The result must be reported to the nearest 0.05 unit of pH.

3.2. Determination of the water activity (a_w)

The determination of the water activity (a_w) of the sample shall be performed according to EN ISO 21807:2004 "Microbiology of food and animal feeding stuffs – Determination of water activity".

The analysis must be carried out on the sample tested on the arrival at the laboratory. The method shall be able of operating in the range 0.999 to 0.9000 and the repeatability limit shall correspond to a standard deviation of 0.002.

The reported value should contain at least two significant figures.

4. STORAGE OF ISOLATES

One confirmed *Listeria monocytogenes* strain per positive sample shall be stored for possible further typing studies. If *Listeria monocytogenes* strains are recovered both from the detection and enumeration methods, only the isolates from the enumeration method shall be stored.

Isolates shall be stored by the national reference laboratories using appropriate methods for culture collection as long as it ensures viability of the strains for a minimum of two years for the typing.

PART D: REPORTING

1. GENERAL PROVISIONS

The information to be reported by Member States, as far as it is available or accessible, consists of two broad categories:

- (a) an overview of the coordinated monitoring programme and results; the overview must take the form of a textual account;
- (b) individual detailed data for each sample tested as part of the sampling plan; that information must be submitted in as raw data using the 'Data Dictionary' and the data collection forms provided for in Article 5(2).

2. INFORMATION TO BE INCLUDED IN THE OVERVIEW OF THE COORDINATED MONITORING PROGRAMME AND RESULTS

- (a) Member State name;
- (b) Date of start and end of the sampling and analysis;
- (c) Number of ready-to-eat food samples collected and analysed from retail outlets:
 - (i) soft and semi-soft cheeses,
 - (ii) packaged smoked and gravad fish,
 - (iii) packaged heat-treated meat products;
- (d) Overall results:

prevalence and proportion of samples exceeding the limit of 100 cfu/g of *Listeria monocytogenes* in soft and semi-soft cheeses, smoked and gravad fish as well as in heat-treated meat products covered by the coordinated monitoring programme;
- (e) Description of the markets in soft and semi-soft cheeses, smoked and gravad fish as well as in heat-treated meat products in the Member State:
 - (i) overall absolute market size (if available),
 - (ii) market share of different types of retail outlets, such as supermarket, small shops, speciality delis, street markets (if available),
 - (iii) market share of imported (intra-Community trade and imports from third countries) and domestic production (if available),
 - (iv) market share of different types of products, (if available);
- (f) Retail outlets sampled:

type of outlet categories covered: e.g. supermarkets, small shops etc.;

- (g) Geographical distribution of sampling – cities/towns covered (% of human population covered);
- (h) Description of randomisation procedure for retail sampling:
month randomisation;
- (i) Comment on overall representativeness of the sampling programme;
- (j) Preparation of test sample used for pH measurement;
- (k) Analytical method used for water activity (a_w) determination.

3. INFORMATION TO BE INCLUDED IN THE INDIVIDUAL DETAILED DATA FOR EACH SAMPLE

- (a) Type of sample:
 - (i) packaged soft and semi-soft cheeses,
 - (ii) packaged smoked and gravad fish,
 - (iii) packaged heat-treated meat products;
- (b) Subtype of the sample:
 - (i) cheeses made from raw/thermised/pasteurised milk,
 - (ii) cheeses made from cow / goat / sheep / buffalo / mixed milk,
 - (iii) smear-ripened, mould-ripened, brine-matured or other ripened cheeses,
 - (iv) sliced and non-sliced products,
 - (v) cold/hot smoked or gravad fish,
 - (vi) species of the fish;
- (c) Preservatives used in smoked or gravad fish (as indicated in the label);
- (d) Cheese rind included in the specimen analyses (yes/no, if yes then also proportion if available);
- (e) Code of the laboratory involved in initial analysis;
- (f) Date of sample collection;
- (g) Use by date of the sampled product;
- (h) Production / packaging date (if available);

- (i) Surface temperature of the sample in the retail outlet;
- (j) Storage temperature in the laboratory up to the end of shelf-life;
- (k) Analysis immediately after sampling (only for smoked and gravad fish) / end of shelf-life;
- (l) Date of beginning of the analysis at the laboratory;
- (m) Detection of *Listeria monocytogenes*:
qualitative results (absence/presence in 25g);
- (n) Quantification of *Listeria monocytogenes*:
quantitative results (cfu/g);
- (o) pH (only smoked and gravad fish);
- (p) Water activity (a_w) (only smoked and gravad fish);
- (q) Code of the city/town;
- (r) Code of the outlet;
- (s) Type of retailer:
 - (i) supermarket,
 - (ii) small shop/independent retailer,
 - (iii) speciality delis,
 - (iv) street market/farmers' market;
- (t) Country of production:
as ascertained with reference to the identification mark on packaging or commercial documentation;
- (u) Pre-packaged:
 - (i) modified atmosphere packaged,
 - (ii) vacuum packaged,
 - (iii) packed at retail level (only for cheeses);
- (v) Organoleptic quality of the sample.

ANNEX II

Number of samples to be taken per ready-to-eat food category in the Member States (referred to in Article 4(5))

Member State	Population on 1.1.2008 (EUROSTAT data)		Harmonized stratified sample size	
	N (Million)	%	Per food category and analysis stage*	Total sample size
Belgium – BE	10.7	2.1	60	240
Bulgaria – BG	7.6	1.5	60	240
Czech Republic – CZ	10.4	2.1	60	240
Denmark – DK	5.576	1.1	60	240
Germany – DE	82.2	16.5	400	1 600
Estonia – EE	1.3	0.3	30	120
Ireland – IE	4.4	0.9	30	120
Greece – EL	11.2	2.3	60	240
Spain – ES	45.3	9.1	200	800
France – FR	63.8	12.8	400	1 600
Italy – IT	59.6	12.0	400	1 600
Cyprus – CY	0.8	0.2	30	120
Latvia – LV	2.3	0.5	30	120
Lithuania – LT	3.4	0.7	30	120
Luxembourg – LU	0.5	0.1	30	120
Hungary – HU	10.0	2.0	60	240
Malta – MT	0.4	0.1	30	120
Netherlands – NL	16.4	3.3	60	240
Austria – AT	8.3	1.7	60	240
Poland – PL	38.1	7.7	200	800
Portugal – PT	10.6	2.1	60	240
Romania – RO	21.5	4.3	60	240
Slovenia – SI	2.0	0.4	30	120
Slovakia – SK	5.4	1.1	60	240
Finland – FI	5.3	1.1	60	240
Sweden – SE	9.2	1.8	60	240
United Kingdom – UK	61.2	12.3	400	1 600
Total EU	497.5	100.0	3 020	12 080

- * For smoked and gravad fish: two samples are collected from each batch. One of these samples is analysed on the day of receipt at the laboratory and the other one is analysed at the end of the shelf-life. (see point 1.2 of part C of Annex I)

ANNEX III

Maximum Community financial contribution to the Member States

Member State	Maximum total amount for co-financing of analyses for the (EUR)				
	<i>Listeria mono-cytogenes</i> detection	<i>Listeria mono-cytogenes</i> enumeration	pH	Water activity	Total
Belgium – BE	14 400	14 400	900	1 200	30 900
Bulgaria – BG	14 400	14 400	900	1 200	30 900
Czech Republic – CZ	14 400	14 400	900	1 200	30 900
Denmark – DK	14 400	14 400	900	1 200	30 900
Germany – DE	96 000	96 000	6 000	8 000	206 000
Estonia – EE	7 200	7 200	450	600	15 450
Ireland – IE	7 200	7 200	450	600	15 450
Greece – EL	14 400	14 400	900	1 200	30 900
Spain – ES	48 000	48 000	3 000	4 000	103 000
France – FR	96 000	96 000	6 000	8 000	206 000
Italy – IT	96 000	96 000	6 000	8 000	206 000
Cyprus – CY	7 200	7 200	450	600	15 450
Latvia – LV	7 200	7 200	450	600	15 450
Lithuania – LT	7 200	7 200	450	600	15 450
Luxembourg – LU	7 200	7 200	450	600	15 450
Hungary – HU	14 400	14 400	900	1 200	30 900
Malta – MT	7 200	7 200	450	600	15 450
Netherlands – NL	14 400	14 400	900	1 200	30 900
Austria – AT	14 400	14 400	900	1 200	30 900
Poland – PL	48 000	48 000	3 000	4 000	103 000
Portugal – PT	14 400	14 400	900	1 200	30 900
Romania – RO	14 400	14 400	900	1 200	30 900
Slovenia – SI	7 200	7 200	450	600	15 450
Slovakia – SK	14 400	14 400	900	1 200	30 900
Finland – FI	14 400	14 400	900	1 200	30 900
Sweden – SE	14 400	14 400	900	1 200	30 900
United Kingdom – UK	96 000	96 000	6 000	8 000	206 000
Total EU	724 800	724 800	45 300	60 400	1 555 300

ANNEX IV

Certified financial report on the implementation of a coordinated monitoring programme of *Listeria monocytogenes* in selected categories of ready-to-eat foods

Reporting period:..... to.....

Statement on costs incurred on the coordinated monitoring programme and eligible for Community financial contribution:

Reference number of Commission Decision providing a Community financial contribution:

Costs incurred related to	Number of tests	Total costs of analysis incurred during reporting period (national currency)
Analyses for the detection of <i>Listeria monocytogenes</i>		
Analyses for the enumeration of <i>Listeria monocytogenes</i>		
Analyses for the determination of the pH		
Analyses for the water activity (a_w)		

Declaration by the beneficiary

I certify that

- the above costs are genuine and have been incurred in carrying out the tasks laid down in Decision .../.../EC [*please complete with the correct serial number reference of this Decision, once that is known*]and were essential for the proper performance of those tasks;
- all supporting documents supporting for the costs are available for audit purposes;
- no other Community contribution was requested for this coordinated monitoring programme.

Date:.....

Person financially responsible:.....

Signature:.....