
Changes to legislation: There are currently no known outstanding effects for the Commission Decision of 5 November 2010 concerning a financial contribution from the Union 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 (notified under document C(2010) 7516) (2010/678/EU), ANNEX I. (See end of Document for details)

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

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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 data, 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 ready-to-eat food 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.

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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 1 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.

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. The competent authorities should also 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 and meat products, 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

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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:

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- (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 analysed 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 analysed 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 (10 g), 9 volumes (90 ml) of diluent are added and subsequently the mixture is homogenised 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' may be used instead of buffered peptone water.

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

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- (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 $1,5 \times 10^4$ 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.

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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 2 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 (trade within the Union and imports from third countries) and domestic production (if available),

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- (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) Date of sample collection;
- (f) Use by date of the sampled product;
- (g) Production/packaging date (if available);
- (h) Surface temperature of the sample in the retail outlet;
- (i) Storage temperature in the laboratory up to the end of shelf-life;
- (j) Analysis immediately after sampling (only for smoked and gravad fish)/end of shelf-life;
- (k) Date of beginning of the analysis at the laboratory;

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

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