

II

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is not obligatory)

DECISIONS

COMMISSION DECISION

of 28 September 2007

concerning a financial contribution from the Community towards a survey on the prevalence of *Salmonella* spp. in herds of breeding pigs to be carried out in the Member States

(notified under document number C(2007) 4434)

(2007/636/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

April 2007 a Report on a proposal for technical specifications for a baseline study on the prevalence of *Salmonella* in breeding pigs ⁽³⁾ (the EFSA report).

Having regard to the Treaty establishing the European Community,

Having regard to Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field ⁽¹⁾, and in particular Article 20 thereof,

Whereas:

(1) Decision 90/424/EEC lays down procedures governing a financial contribution by the Community towards specific veterinary measures, including technical and scientific measures. It provides for the Community to undertake, or assist Member States in undertaking, the technical and scientific measures necessary for the development of Community veterinary legislation and for the development of veterinary education or training.

(2) Under Article 4 and Annex I of Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of *Salmonella* and other specified food-borne zoonotic agents ⁽²⁾, a Community target is to be established for reducing the prevalence of *Salmonella* in populations of herds of breeding pigs.

(3) The Task Force on Zoonoses Data Collection of the European Food Safety Authority (EFSA) adopted on 30

(4) In order to set the Community target, comparable data on the percentage of *Salmonella* infected holdings of breeding pigs in the Member States needs to be available. Such information is not available and a special survey should therefore be carried out to monitor the prevalence of *Salmonella* in breeding pigs over a suitable period in order to take account of possible seasonal variations. The survey should be based on the EFSA report.

(5) The EFSA report also recommends additional sampling for the estimation of within-holding prevalence. Such sampling should be carried out by a number of Member States geographically representing the different situations in the Community.

(6) The survey is to provide technical information necessary for the development of Community veterinary legislation. Given the importance of collecting comparable data on the prevalence of *Salmonella* in breeding pigs in the Member States, they should be granted a Community financial contribution for implementing the specific requirements of the survey. It is appropriate to reimburse 100 % of the costs incurred on the laboratory testing, subject to a ceiling. All other costs incurred such as sampling, travel, administration, etc. should not be eligible for any Community financial contribution.

⁽¹⁾ OJ L 224, 18.8.1990, p. 19. Decision as last amended by Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).

⁽²⁾ OJ L 325, 12.12.2003, p. 1. Regulation as last amended by Regulation (EC) No 1791/2006.

⁽³⁾ The EFSA Journal (2007) 99, pp. 1-28.

- (7) The financial contribution from the Community should be granted provided that the survey is carried out in accordance with the relevant provisions of Community law and subject to compliance with certain other conditions.
- (8) The financial contribution from the Community should be granted insofar as the actions provided for are effectively carried out and provided that the competent authorities furnish all the necessary information within the time limits provided for.
- (9) 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 policy ⁽¹⁾, 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 is submitted by the Member State concerned.
- (10) 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 and scope

This Decision lays down rules on the financial contribution from the Community towards a baseline survey to be carried out in the Member States to assess the prevalence of *Salmonella* spp. across the Community in breeding pigs sampled at farm level (the survey).

The results of the survey shall be used to set a Community target as provided for in Article 4 of Regulation (EC) No 2160/2003 and to consider the best approach to evaluate in the future the achievement of such target.

Article 2

Definition

For the purposes of this Decision, 'competent authority' shall be the authority or authorities of a Member State as designated pursuant to Article 3 of Regulation (EC) No 2160/2003.

⁽¹⁾ OJ L 209, 11.8.2005, p. 1. Regulation as last amended by Regulation (EC) No 378/2007 (OJ L 95, 5.4.2007, p. 1).

Article 3

Scope of the survey

1. The Member States shall carry out a survey to assess the prevalence of *Salmonella* spp. in breeding pigs sampled at farm level in accordance with Annex I.
2. The survey shall cover a one-year period commencing on 1 January 2008.

Article 4

Performance of sampling and analyses

Sampling and analysis shall be performed by the competent authority or under its supervision, in accordance with the technical specifications set out in Annex I.

Article 5

Conditions for granting a Community financial contribution

1. The financial contribution from the Community towards the costs of analyses shall be granted to the Member States up to the maximum total amount for co-financing set out in Annex II for the duration of the survey.
2. The financial contribution from the Community provided for in paragraph 1 shall be granted to the Member States provided that the survey is implemented in accordance with the relevant provisions of Community law, including the rules on competition and on the award of public contracts, and subject to compliance with the following conditions:
 - (a) the national laws, regulations and administrative provisions required to implement the survey must enter into force by 1 January 2008 at the latest;
 - (b) a progress report containing the information listed in point 5.1 of Annex I and covering the period from 1 January 2008 to 31 March 2008 must be submitted to the Commission by 31 May 2008 at the latest;
 - (c) a final report on the implementation of the survey, together with supporting evidence for the costs incurred by the Member States for the analyses and the results attained during the period from 1 January 2008 to 31 December 2008 must be submitted to the Commission by 28 February 2009 at the latest;
 - (d) the survey must be implemented effectively.

The supporting evidence for the costs incurred as referred to in paragraph 2(c) shall comprise at least the information set out in Annex III.

3. Failure to submit the final report referred to in paragraph 2(c) shall entail a progressive reduction of the financial contribution to be paid by the Community, amounting to 25 % of the total amount by 31 March 2009, 50 % by 30 April 2009 and 100 % by 31 May 2009.

Article 6

Maximum amounts to be reimbursed

The maximum amounts of the financial contribution from the Community towards the costs to be reimbursed to the Member States for analyses covered by the survey shall not exceed the following:

- (a) EUR 20 per test for bacteriological detection of *Salmonella* spp.;
- (b) EUR 30 for serotyping of the relevant isolates.

Article 7

Collection of data, assessment and reporting

1. The competent authority responsible for preparing the yearly national report pursuant to Article 9(1) of Directive 2003/99/EC of the European Parliament and of the Council ⁽¹⁾ shall collect and assess the results of the survey.

2. The Commission shall forward the national data and the assessment referred to in paragraph 1 to the European Food Safety Authority, which shall examine them.

3. National data and results shall be made publicly available in a form that ensures confidentiality.

Article 8

Conversion rate for expenditure

Where a Member State's expenditure is in a currency other than the 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 for the financial contribution from the Community is submitted by the Member State.

Article 9

Application

This Decision shall apply from 1 January 2008.

Article 10

Addressees

This Decision is addressed to the Member States.

Done at Brussels, 28 September 2007.

For the Commission

Markos KYPRIANOU

Member of the Commission

⁽¹⁾ OJ L 325, 12.12.2003, p. 31.

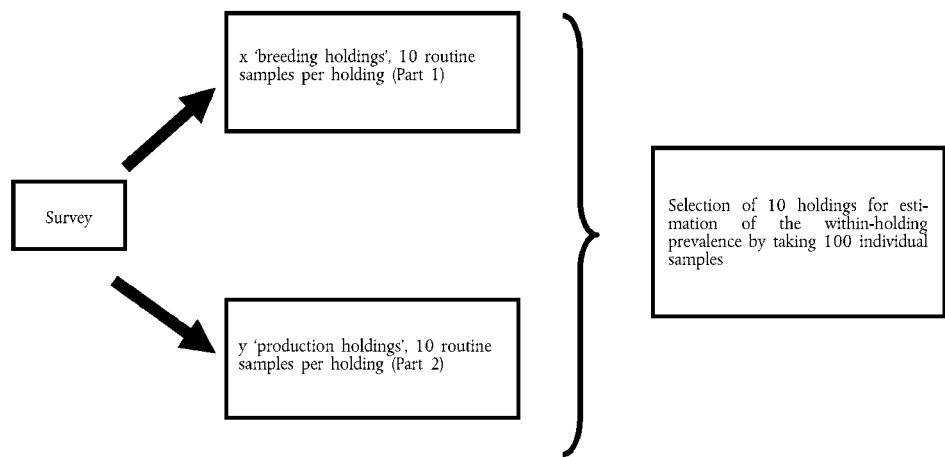
ANNEX I

Technical specifications referred to in Articles 3(1), 4 and 5(2)(b)

1. OVERVIEW OF THE SURVEY

The survey shall be performed according to the overview in Figure 1.

Figure 1: overview of the survey



2. SAMPLING FRAME

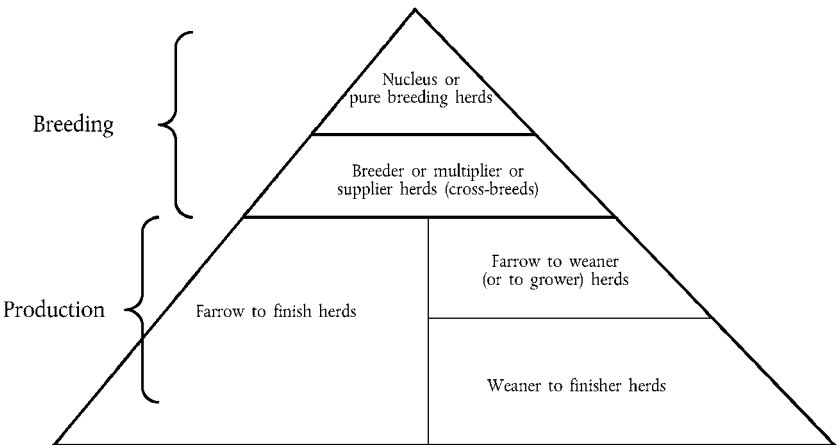
2.1. The delineation of the population

The survey shall be carried out on holdings harbouring at least 80 % of the breeding pig population in a Member State. Preferentially holdings having 50 breeding pigs or more shall be sampled. However, if those holdings having 50 breeding pigs or more do not contain 80 % of the national herd of breeding pigs, then smaller holdings with less than 50 breeding pigs shall also be sampled.

Holdings with breeding pigs shall be classified either as 'breeding holdings' or as 'production holdings'. Breeding holdings sell gilts and/or boars for breeding purposes. Typically, they sell 40 % or more of the gilts that they rear for breeding whilst the remainder are sold for slaughter. In contrast, production holdings mainly sell pigs for fattening or slaughter.

The *Salmonella* prevalence must be measured separately in breeding holdings (part 1 of the survey) and in production holdings (part 2 of the survey), representing the herds as indicated in Figure 2, but excluding weaner to finisher herds.

Figure 2: overview of holdings



2.2. The sample and the sampling strategy

Both parts of the survey shall have a similar two-stage sampling design. In the first stage, a random sample of holdings shall be selected in every Member State from the breeding holdings and a second random sample shall be selected from the production holdings group. The number of holdings required is discussed in section 2.3. In the second stage, a number of pens shall be selected for sampling within every selected holding (see section 2.2.2).

2.2.1. First stage: selection of holdings

Each Member State must create two sampling frames. The first shall list all eligible breeding holdings (usually, those holdings with at least 50 breeding pigs — see section 2.1) and the second shall list all eligible production holdings. The required number of holdings for each part of the survey will then be selected at random from each list. A random sample is intended to ensure that the survey includes holdings with a range of herd sizes and from all regions of a Member State where pig keeping is practised. It is recognised that in some Member States, there may be a few holdings (e.g. fewer than 10 % of all eligible holdings) with a very large herd size. Thus, random selection may by chance result in none of these very large herds being selected. A Member State may use a stratification criterion prior to holding selection — for example, to define a stratum containing the 10 % of largest herds and to allocate 10 % of the required sample size to this stratum. Similarly, a Member State may stratify the sample across administrative regions according to the proportion of eligible herds within each region. Any stratification that is considered should be described in the report that a Member State submits to the Commission in accordance with paragraph 5(1).

If a selected holding cannot be sampled (for example, if it no longer exists when sampling is carried out) a new holding shall be selected at random from the same sampling frame. If any stratification (e.g. on herd size or region) was in operation, then the new holding should be selected from the same stratum.

The primary sample size (number of holdings to be sampled) shall be approximately equally distributed over the year to cover the different seasons, as far as possible. Samples shall be taken from approximately one twelfth of the number of holdings each month.

Outdoor holdings must be included in the survey but there shall be no mandatory stratification on this production type.

2.2.2. Second stage: sampling on the holding

In each selected breeding herd and production herd the pens, yards or groups of breeding pigs over six months of age to be sampled will be randomly selected.

The number of pens, yards or groups to be sampled must be proportionally allocated according to the numbers of breeding pigs in the different stages of production (pregnant, non-pregnant and other categories of breeding pigs). The exact age categories to be sampled are not prescribed, but this information shall be collected during the sampling.

Breeding pigs that have arrived recently to the herd and are held in quarantine shall not be included in the survey.

2.3. The sample size calculation

2.3.1. Primary sample size (first-stage sample size)

A regular primary sample size calculation shall be conducted for the breeding holdings and a second regular primary sample size calculation shall be conducted for the production holdings. The primary sample size shall be the number of breeding holdings to be sampled and the number of production holdings to be sampled in each Member State and it shall be determined taking into account the following criteria, assuming simple random sampling:

- (a) the total number of breeding holdings (breeding holdings, part 1 of the survey);
- (b) the total number of production holdings (production holdings, part 2 of the survey);
- (c) annual expected prevalence (p): 50 %;

(d) desired confidence level (Z): 95 %, corresponding to a Z_{α} value of 1,96;

(e) accuracy (L): 7,5 %;

(f) using these values and the formula: $n_{\infty} = \frac{(Z_{\alpha})^2 p(1-p)}{L^2}$

The calculation shall be conducted firstly, for the breeding holdings and secondly, for the production holdings. In each case, the assumptions in steps (c)-(e) above are the same.

For practical purposes, if there are 100 000 or more holdings in either the breeding herds sampling frame or the production herds sampling frame then that population can be considered to be infinite and the number of holdings to be randomly selected from that sampling frame is 171 (see Table 1). Where the number of breeding herds or production herds is less than 100 000 a finite population correction factor is applied and fewer holdings need to be sampled as shown in Table 1.

As an example, if there are in a Member State 1 000 holdings belonging to the production holding group and 250 holdings belonging to the breeding holding group, 147 holdings must be sampled in the production holding group and 102 holdings must be sampled in the breeding holding group.

Table 1

Number of holdings with breeding pigs to sample in either part of the survey as a function of the finite population size (total number of holdings with breeding pigs in the Member States)

Number of holdings with breeding pigs (N)	Sample size (n) for finite population size 7,5 % accuracy
100 000	171
10 000	169
5 000	166
2 000	158
1 000	147
500	128
250	102
150	80
125	73
100	64
90	59
80	55
70	50
60	45
50	39
40	33
30	26
20	18
10	10

Non-response shall be anticipated, e.g. by increasing the sample size in each group by 10 %. Any unsuitable holding shall be replaced in the process of the survey (see Section 2.2.1).

In case an estimation of the number of 'breeding holdings' is not possible prior to the start of the survey, a number of holding shall be selected for sampling as in Table 1 based on the total number of holdings with sows (X holdings). The number of holdings to be sampled shall be increased by at least 30 % ((X + 30 %) holdings). Prior to the survey, the competent authority shall identify a number of breeding holdings, equal to at least this additional 30 %. While visiting the farms, the holding will be classified as breeding or production holding according to the definitions above.

2.3.2. *Secondary sample size (second-stage sample size)*

In each selected holding routine faecal samples (see section 3.1) shall be collected from 10 randomly chosen pens, yards or groups of breeding pigs. If necessary (for example, in farrowing accommodation or where sows are kept in small groups of less than 10 individuals), a group can consist of more than one pen. At least 10 individual breeding pigs should contribute to each routine sample.

However, where on small holdings or holdings with large numbers of breeding pigs kept outdoors in paddocks, the number of pens, yards or groups is less than 10, sampling of the same pen, yard or group shall be required so that a total of 10 routine samples are submitted.

3. **SAMPLE COLLECTION IN THE HERDS**

3.1. **Type and detail of the routine sample**

The material collected for bacteriological analysis shall be freshly voided faeces representing the whole holding, which is the unit of interest. Since every holding is unique, it shall be decided, before starting the sampling, which pens, yards or groups within the holding are sampled. The sample collected shall be placed in a separate container avoiding cross contamination and sent to the laboratory.

Each pooled sample shall total at least 25 g and two approaches may be employed to collect these pooled faeces samples:

- (1) where there is an accumulation of mixed faeces within an area of a pen or yard, a large swab (e.g. 20 cm × 20 cm) can be used to pass through the faecal mass, ensuring that at least 25 g of mixed material is collected. This may be achieved by for example, moving the swab along a two-metre zig-zag path such that it is well coated with faecal material. If necessary, for example due to hot weather or on slatted flooring then the swab may be moistened with an appropriate liquid such as drinking water;
- (2) where there is no such accumulation, for example in a field, a large yard, a farrowing house, or pens or other accommodation with low numbers of pigs per group, then individual pinches shall be selected from individual fresh faecal masses or places so that a minimum of 10 individuals, contribute to a total sample volume of at least 25 g. The sites from which these pinches are collected should be distributed in a representative manner across the area concerned.

Approach 1 shall be preferred where practical. In this approach at least 10 individual pigs must contribute to each sample taken, otherwise approach 2 shall be applied.

3.2. **Additional sampling for the within-holding prevalence study**

Together, 10 holdings, selected at random from the overall sample of breeding holdings and of production holdings are subjected to more intensive sampling. On these holdings 10 routine samples shall be collected in the same manner as described previously (section 3.1). In addition, 10 individual samples of at least 30 g shall be collected in each selected pen and shall be identified in such a manner that these 10 individual samples can be associated with the routine sample from that pen. Thus in total, 10 routine samples and 100 (10 × 10) individual samples shall be collected from each of these 10 holdings. The processing of these samples is described in section 4.3.1.

This sampling should be applied in the Czech Republic, Denmark, Romania, Slovenia, Sweden and the United Kingdom.

3.3. **Sample information**

All relevant information available from the sample shall be recorded on a sampling form produced by the competent authority to enable the data requirements in Part 5 to be fulfilled.

Each sample and its sample form shall be labelled with a unique number which shall be used from sampling to testing, and with the code of the pen. The competent authority must arrange for the issue and use of a unique numbering system.

3.4. Transport of samples

Samples shall be preferably kept at between + 2 to + 8 °C and free of external contamination during transportation. The samples shall be sent to the laboratory as quick as possible within 36 hours by fast mail or courier and shall reach the laboratory no later than 72 hours after sampling.

4. LABORATORY ANALYTICAL METHODS

4.1. Laboratories

Analysis and serotyping shall take place at the National Reference Laboratory (NRL). Where the NRL does not have the capacity to perform all analyses or if it is not the laboratory that performs detection routinely, the competent authorities may decide to designate a limited number of other laboratories involved in official control of *Salmonella* to perform the analyses. These laboratories shall have proven experience of using the required detection method and have a quality assurance system complying with ISO standard 17025 and be submitted to the supervision of the NRL.

4.2. Receipt of samples

At the laboratory, samples shall be kept refrigerated until bacteriological examination, which shall preferably be carried out within 24 hours after receipt but in any case no later than 96 hours after the sample was collected.

4.3. Sample analysis

Member States shall guarantee that all involved parties have been sufficiently trained to carry out the analyses.

4.3.1. Preparation

In the laboratory, routine samples shall be mixed carefully and thoroughly before 25 g are collected for analysis.

For evaluation of the within-holding prevalence in accordance with paragraph 3.2, each of the individual collected samples (30 g) needs to be divided into two parts. One part, weighing at least 25 g, shall be mixed carefully and thoroughly and subsequently cultured individually. The remaining second part is to be used to prepare an artificially pooled sample from the 10 individual samples in the selected pen, group or yard. This latter part shall be prepared by adding 10 times 2,5 g of the individual samples to create an artificially pooled sample of 25 g. The artificially pooled samples are mixed carefully and thoroughly before analysis. In total, 10 routine samples, 10 artificially pooled sample and 100 individual samples shall be analysed from each of the 10 holdings selected for the estimation of the within-holding prevalence.

4.3.2. Detection and identification methods

4.3.2.1. Detection of *Salmonella*

The method recommended by the Community Reference Laboratory (CRL) for *Salmonella* in Bilthoven, the Netherlands, shall be used. This method is described in the Annex D of ISO 6579: 'Detection of *Salmonella* spp. in animal faeces and in samples of the primary production stage'. The latest version of Annex D shall be used.

4.3.2.2. Serotyping of *Salmonella*

All strains isolated and confirmed as *Salmonella* spp. shall be serotyped according to the Kaufmann-White scheme, by the NRL for *Salmonella*.

For quality assurance, 16 typable strains and 16 non-typable isolates shall be sent to the CRL for *Salmonella*. A proportion of these isolates shall be sent to the CRL on a quarterly basis. If fewer strains have been isolated all shall be sent.

4.3.2.3. Phage typing of *Salmonella*

In case isolates of *Salmonella* Enteritidis and *Salmonella* Typhimurium are phage typed (optional), the methods described by the WHO reference centre for phage typing of *Salmonella* of the Health Protection Agency (HPA) Colindale, London, shall be used.

5. REPORTING FROM THE MEMBER STATES

5.1. Overall description on the implementation of the survey

A report in text format shall include at least:

- (a) Member State;
- (b) description of the population of holdings with breeder pigs:
 - (1) breeding holdings:
 - (i) total number of breeder holdings;
 - (ii) total number of nucleus holdings;
 - (iii) total number of multiplier holdings;
 - (iv) number of breeder holdings planned to be sampled, and number of breeder holdings actually sampled; number of holdings planned for sampling but not sampled and the reason therefor;
 - (v) comments on the overall representativeness of the breeding holdings sampling programme;
 - (2) production holdings:
 - (i) total number of production holdings;
 - (ii) total number of farrow to weaner/grower holdings;
 - (iii) total number of farrow to finish holdings;
 - (iv) number of production holdings planned to be sampled, and number of production holdings actually sampled; number of holdings planned for sampling but not sampled and the reason therefor;
 - (v) possible comments on overall representativeness of the production holdings sampling programme;
- (c) number of samples obtained and analysed:
 - (i) from breeding holdings;
 - (ii) from production holdings;
 - (iii) from holdings sampled for within-holding prevalence study;
- (d) overall results:
 - (i) prevalence of breeding holdings and of production holdings infected with *Salmonella*, and serovars of *Salmonella*;
 - (ii) outcome of within-holding prevalence study;
- (e) list of laboratories responsible in the baseline study for *Salmonella*:
 - (i) detection;
 - (ii) serotyping;
 - (iii) phage typing (if carried out).

5.2. Complete data on each holding sampled and corresponding tests results

The Member States shall submit the results of the investigation electronically in the form of raw data using a data dictionary and data collection forms provided by the Commission. This dictionary and forms shall be established by the Commission.

5.2.1. *The following information shall be collected in Member States for each holding selected for sampling:*

- (a) code of the holding;
- (b) holding production type;
 - (i) indoor versus 'any stage of the production kept outdoors';
 - (ii) nucleus, multiplier, farrow to weaner, farrow to finish and farrow to grower;
- (c) holding size: the number of breeding pigs present at the time of sampling (adult inventory);
- (d) replacement policy: all replacement breeding pigs purchased; some replacement breeding pigs homebred or all replacement breeding pigs homebred;
- (e) (voluntarily) clinical symptoms of diarrhoea: were there symptoms of diarrhoea within the three months before the sampling?

5.2.2. *The following information shall be collected in Member States for each sample sent to the laboratory:*

- (a) code of the sample;
- (b) code of the laboratory involved in initial analysis;
- (c) date of sample collection;
- (d) date laboratory analysis begun;
- (e) detection of *Salmonella*: qualitative result (positive/negative);
- (f) serotyping of *Salmonella*: serovar(s) detected (may be more than one);
- (g) age of the pigs: all gilts versus mixed age breeding pigs;
- (h) sex: only sows; sows and boars or only boars;
- (i) production stage: maternity; mating, gestation (other?);
- (j) housing: slatted floor (fully/partly); solid floor; deep straw or other;
- (k) diet: are pigs in this pen, yard or group fed compound feed exclusively?;
- (l) feed supplement: is there any *Salmonella* reducing substance added to the feed (like organic acid, a probiotic)?;
- (m) systematic use of antibiotics: are antibiotics used in all animals of this group by any route of administration;
- (n) the last date of administration of antimicrobials to the animals (within the last four weeks).

5.2.3. *The following additional information shall be collected in Member States for each individual sample sent to the laboratory within the frame of the sampling for the within-holding prevalence:*

- (a) code of the pooled sample;
 - (b) detection of *Salmonella* in each individual sample: qualitative result (positive/negative);
 - (c) serotyping of *Salmonella* in each individual sample: serovar(s) detected (may be more than one).
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ANNEX II

Maximum Community financial contribution to the Member States referred to in Article 5

Member State	Maximum total amount for co-financing of analyses (EUR)
Belgium — BE	59 800
Bulgaria — BG	52 260
Czech republic — CZ	102 960
Denmark — DK	98 280
Germany — DE	57 980
Estonia — EE	9 360
Ireland — IE	43 420
Greece — EL	39 260
Spain — ES	82 680
France — FR	82 680
Italy — IT	79 300
Cyprus — CY	20 020
Latvia — LV	3 380
Lithuania — LT	13 780
Luxembourg — LU	11 960
Hungary — HU	74 360
Malta — MT	0
Netherlands — NL	87 100
Austria — AT	59 020
Poland — PL	85 020
Portugal — PT	54 860
Romania — RO	107 900
Slovenia — SI	81 120
Slovakia — SK	54 080
Finland — FI	64 740
Sweden — SE	81 120
United Kingdom — UK	102 960
Total	1 609 400

ANNEX III

Certified financial report on the implementation of the baseline survey on the prevalence of *Salmonella* spp. in herds of breeding pigs

Reporting period: to

Statement on costs incurred on the survey and eligible for Community financial contribution:

Reference number of Commission Decision providing Community financial contribution:

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Costs incurred related to functions at/by	Number of tests	Total costs of testing incurred during reporting period (national currency)
Bacteriology for <i>Salmonella</i> spp.		
Serotyping <i>Salmonella</i> isolates		

Declaration by the beneficiary

We certify that:

- the above costs are genuine and have been incurred in carrying out the tasks laid down in this Decision and were essential for the proper performance of those tasks,
- all supporting documents for the costs are available for audit purposes,
- no other Community contribution was requested for this survey.

Date:

Person financially responsible:

Signature:
