II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 29 September 2006

concerning a financial contribution from the Community towards a baseline survey on the prevalence of *Salmonella* in slaughter pigs to be carried out in the Member States

(notified under document number C(2006) 4306)

(2006/668/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

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) Pursuant to Decision 90/424/EEC the Community is to undertake or assist the Member States in undertaking the technical and scientific measures necessary for the development of veterinary legislation and for the development of veterinary education or training.

(2) Under Article 4 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 slaughter pigs by the end of 2007.

(3) The Scientific Panel on Biological Hazards of the European Food Safety Authority (EFSA) adopted an opinion on the request from the Commission related to 'Risk assessment and mitigation options of *Salmonella* in pig production', during its meeting of 16 March 2006. The opinion proposes technical specifications for a baseline study on the prevalence of *Salmonella* in fattening pigs in the EU.

(4) In order to set the Community target, comparable data on the prevalence of *Salmonella* in populations of slaughter pigs in the Member States needs to be available. Such information is not at hand and a special survey should therefore be carried out to monitor the prevalence of *Salmonella* in slaughter pigs over a suitable period in order to take account of possible seasonal variations.

(5) The EFSA opinion recommends slaughterhouse sampling by taking ileocaecal lymph nodes to reflect the *Salmonella* status of the pig sent to slaughter. Such sampling should therefore be used as a tool to monitor the prevalence of *Salmonella* in slaughter pigs. It is opportune to use this baseline survey also to evaluate the effect of contamination of the pigs during transport and lairage, and contamination of the carcase during the slaughter process by taking carcase swabs. In addition, serological methods have been developed to assess the *Salmonella* status of a pig and may be used for monitoring *Salmonella* in pigs within the frame of national control programmes to be implemented in accordance with Article 5 of Regulation (EC) No 2160/2003.

(6) A number of Member States volunteered to carry out the additional analyses by taking carcase swabs or carrying out serology on meat juice.

[1] OJ L 224, 18.8.1990, p. 19. Decision as last amended by Decision 2006/53/EC (OJ L 29, 2.2.2006, p. 37).

[2] OJ L 325, 12.12.2003, p. 1. Regulation as amended by Commission Regulation (EC) No 1003/2005 (OJ L 170, 1.7.2005, p. 12).

(7) 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 slaughter 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 such as sampling, travel, administration, etc should not be eligible for any Community financial contribution.

(8) A 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.

(9) A financial contribution from the Community should be granted in so far as the actions provided for are effectively carried out and provided that the authorities furnish all the necessary information within the time limits provided for.

(10) There is a need to clarify the rate to be used for the conversion of payment applications submitted in national currencies as defined in Article 1(d) of Council Regulation (EC) No 2799/98 of 15 December 1998 establishing agrimonetary arrangements for the euro ([1]).

(11) 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

Objective of the survey and general provisions

1. A survey shall be carried out to assess the prevalence of *Salmonella* spp. across the Community in slaughter pigs sampled in the slaughter house. The survey shall also be used to collect at the same time information on contamination of carcases in slaughterhouses and on the relation between bacteriological and serological tests.

2. The results of the survey shall be used to set Community targets 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 the target.

3. The survey shall cover a one-year period commencing on 1 October 2006.

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

Article 2

Technical specifications

The survey in slaughter pigs shall be organised by the Member States and shall be performed from 1 October 2006 in slaughterhouses. Sampling and analysis shall be performed by the competent authority or under its supervision.

Sampling and analysis shall be performed in accordance with the provisions in Annex I.

Article 3

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 ([2]) shall collect and assess the results achieved pursuant to Article 2 of this Decision and shall report all necessary data and its assessment to the Commission.

2. The Commission shall forward the results to the European Food Safety authority, which shall examine them.

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

Article 4

Scope of the Community financial contribution

1. The Community shall provide financial contribution for the costs incurred by the Member States on laboratory testing, i.e. bacteriological detection of *Salmonella* spp., serotyping of the relevant isolates and serology.

2. The maximum financial contribution from the Community shall be EUR 20 per test for bacteriological detection of *Salmonella* spp., EUR 30 for serotyping of the relevant isolates and EUR 10 for serology on meat juice.

3. The financial contribution from the Community shall not exceed the amounts set out in Annex II for the duration of the survey.

Article 5

Conditions for granting a Community financial contribution

1. The financial contribution provided for in Article 4 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:

([1]) OJ L 349, 24.12.1998, p. 1.

([2]) OJ L 325, 12.12.2003, p. 31.

(a) by 1 October 2006, the laws, regulations and administrative provisions required to implement the survey shall come into force;

(b) a progress report covering the first three months of the survey shall be forwarded by 28 February 2007. The progress report should contain all information requested in Annex III of the Opinion of the Scientific Panel on Biological Hazards on the request from the Commission related to 'Risk assessment and mitigation options of *Salmonella* in pig production'.

(c) a final report shall be forwarded by 31 October 2007 at the latest on the technical execution of the survey, together with supporting evidence for the costs incurred and the results attained during the period 1 October 2006 to 30 September 2007; the evidence as to costs incurred shall comprise at least the information set out in Annex III;

(d) the survey shall be implemented effectively.

2. An advance of 50 % of the total amount referred to in Annex II may be paid at the request of the Member State concerned.

3. Failure to comply with the time limit in paragraph 1(c) shall entail a progressive reduction of the financial contribution to be paid, amounting to 25 % of the total amount by 15 November 2007, 50 % by 1 December 2007 and 100 % by 15 December 2007.

Article 6

Conversion rate for applications in national currencies

The conversion rate for applications submitted in national currencies in month 'n' shall be that for the 10th day of month 'n+1' or the first day before that day for which a rate is quoted.

Article 7

Application

This Decision shall apply from 1 October 2006.

Article 8

Addressees

This Decision is addressed to the Member States.

Done at Brussels, 29 September 2006.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX I

Technical specifications in accordance with Article 2

1. **Sampling frame**

A minimum number of pigs, kept during at least the preceding three months in the Member State, shall be ad random sampled in accordance with Table 1.

Table 1

Minimum sample size

Number of pigs present in the population	Minimum sample size (1)
> 20 000 000	2 400
10 to 20 000 000	1 067
2 to 10 000 000	600
< 2 000 000	384

(1) Based on an infinite population (> 100 000 per year), an estimated prevalence of 50 %, a confidence level of 95 % and a accuracy of 2, 3, 4 and 5 % respectively.

Member States shall take a 10 % extra number of samples, to be analyzed in case some samples would be excluded from the study for various reasons.

Samplings shall be stratified by month to ensure to cover the different seasons.

Sampling shall be stratified by slaughterhouses that participate and proportional to slaughterhouse capacity. Each Member State shall rank all slaughterhouses according to their fattening pigs throughput in the previous year. Thus, each Member State shall identify those plants that accounted for at least 80 % of all slaughtered fattening pigs.

The total number of pigs and carcases to be sampled in each of the slaughterhouses included in the study shall be estimated by multiplying the sample size (e.g. 2 400) by the proportion of fattening pigs processed in the previous year. For example, if one slaughterhouse accounted for 25 % of fattening pigs slaughtered in the selected slaughterhouses (those representing at least 80 % of all fattening pigs slaughtered in the Member State), then (2 400 × 0,25) 600 pigs shall be sampled. These shall be evenly divided so that 50 pigs were sampled in every month, for 12 months. A further example is shown in Table 2.

Naturally, if a slaughterhouse is no longer in production, if a new facility has been opened or there is predicted to be a significant change in plant throughput during the survey, then the estimated throughput shall be adjusted accordingly.

Table 2

Weighing of slaughterhouses for the purpose of allocating the number of fattening pigs to be sampled from each slaughterhouse; calculation of sampled animals per slaughterhouse

Slaughterhouse ID	Number of fattening pigs processed previous year	Percent of total slaughter included in the study	Number of samples per slaughterhouse	Samples per month (/12)
AXD	88 000	17,6	0,176 × 2 400 = 422,4	422,4:12 = 36
SVH	25 000	5,0		
TPB	75 000	15,0		
MLG	100 000	20,0		
GHT	212 000	42,4		
Total	500 000 (1)	100,0		

(1) This number should represent at least 80 % of slaughtered fattening pigs in a Member State.

For each slaughterhouse each month, a number between 1 and 31 shall be selected at random. If the randomly selected number is a slaughtering day, for that month, then that day is selected for sampling. If not, then a new number is selected randomly. This process is performed once a month and repeated so many times as there are samples to be collected at the slaughterhouse. For example, in the slaughterhouse AXD the process shall be repeated at least 36 times to select at least 36 working days randomly. Naturally, it might be more than one carcase to be sampled on the same day.

As the number of animals slaughtered on a specific day may vary enormously, the random selection of the individual animal shall take place at the slaughterhouse at the day randomly selected for sampling. The given day, the total number of animals is known, and the personnel of the slaughterhouse shall then randomly select a carcase or carcases using the randomisation sheet which has been provided to them and which has been generated using a maximum that exceeds the highest possible number of fattening pigs slaughtered on any given day in any slaughterhouse in the Member State.

A randomisation table may then look as shown in Table 3.

Table 3

Randomisation table

Slaughterhouse	Day of the month	Identity of carcase ([1])
AXD	19	5
	4	2
	12	124
	12	2
	8	59

([1]) i.e. the fifth carcase to be processed on the 19th day of that month should be sampled for the survey.

The following animals shall be excluded from the baseline study:

— animals with a live weight of less than 50 kg or more than 170 kg,

— animals that have undergone emergency slaughter,

— any carcase that is totally condemned.

2. **Samples**

2.1. *Sampling in general*

The following samples shall be collected:

— the aggregate of ileocaecal lymph nodes or at least five individual ileocaecal lymph nodes of all selected pigs. If possible, at least 25 grams of lymph nodes without fat or connective tissues shall be collected,

— a sponge swabbed at four sites in accordance with paragraph 2(3), per carcase, from a total of at least 384 pigs, randomly selected from the selected pigs. The sponge sampling method shall be used in accordance with the most recent edition of standard ISO 17604. This sampling shall be carried out in Belgium, the Czech Republic, Denmark, France, Ireland, Cyprus, Latvia, Lithuania, Austria, Poland, Slovenia, Sweden and the United Kingdom,

— a muscle sample for serology on meat juice or blood (if equivalent to the method on meat juice) from all selected pigs. Sufficient neck or diaphragm muscle shall be taken to yield enough meat juice to allow a portion to be frozen and stored for later comparative studies. This sampling shall be carried out in Denmark, Germany, France, Ireland, Cyprus, Lithuania, the Netherlands, Slovenia, Sweden and the United Kingdom.

Records shall be kept at the slaughterhouse on the muscle which is sampled, time and date of sampling of each sample and the time and date and name of the courier that takes delivery of the samples.

2.2. *Details on sampling of ileocaecal lymph nodes*

The mesenterium between the caecum and the part of the ileum that is closest to the caecum shall be torn and the ileocaecal lymph nodes are presented at the surface of the torn-open area. Without a knife, but with gloved fingers, the lymph nodes shall be bluntly 'harvested' from such opened mesenterium if individual lymph nodes are collected. The lymph nodes or the aggregate shall be placed in a plastic bag which is marked with date, time, slaughterhouse identification and sample identification code.

2.3. *Details on carcase sampling by surface swabs-sampling*

Sampling of the carcase shall be performed after evisceration and before chilling. A surface of about 100 cm^2 per site shall be swabbed using one single abrasive sponge for all the following sites as indicated and numbered below in accordance with Annex A of standard ISO 17604:

— hind limb, medial (9),

— abdomen, lateral (belly, 3),

— mid-dorsal region (mid-back, 4),

— jowl (7).

Two sites shall be swabbed with one side of the sponge, which shall then be turned over for the remaining two sites, and a scrubbing action shall be used. Enough pressure shall be used to push the lower part of the carcase slightly (2 to 5 mm) away from the sampler. The sponge shall be wiped over each sampling site for a total of approximately 10 times in the vertical and 10 times in the horizontal direction. If templates are used, precautions shall be taken to avoid cross-contamination between carcases.

The sample shall be kept at max. 7 °C during storage and transportation. The plastic bag is marked with the date, time, slaughterhouse identification and sample identification code.

3. **Transport**

Samples shall be sent within 36 hours by fast mail or courier and shall reach the laboratory no later than 72 hours after sampling. Samples arriving later than within 72 hours after sampling shall be discarded unless analysis is initiated within 96 hours after sampling and the cold chain was not interrupted.

4. **Analysis of samples**

Analysis and serotyping shall take place at the National Reference Laboratory (NRL). In case that 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 should 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.

At the laboratory, samples shall be kept refrigerated until bacteriological examination, which shall be carried out within 24 hours after receipt and so that analysis is initiated no later than 96 hours after the sample was collected.

The muscle sample for serology shall be kept frozen until analysis, which shall be carried out immediately after thawing.

4.1. *Sample preparation for bacteriology*

Lymph nodes shall be surface de-contaminated before analysis by dipping into absolute alcohol and drying by air.

All lymph nodes shall be pooled and closed in a plastic bag and banged with a hammer or so on the plastic bag smashing the lymph nodes.

The homogenised lymph nodes shall be weighed and placed in a sterile container with pre-warmed buffered peptone water (BPW) in dilution 1:10. Containers shall be incubated for a total of (18 ± 2) hours at (37 ± 1) °C.

Regarding swabs sample, at the laboratory, 100 ml of BPW shall be added for pre-enrichment. The sample shall be incubated at 37 °C overnight and examined for *Salmonella* using the modified semi-solid Rappaport-Vassiladis medium (MRSV) method (draft Annex D of the ISO 6579:2002(E).

4.2. *Detection method for bacteriology*

The method recommended by the Community Reference Laboratory (CRL) for *Salmonella* in Bilthoven, the Netherlands, shall be used. This method is described in the current version of draft Annex D of ISO 6579:2002: 'Detection of *Salmonella* spp. in animal faeces and in samples of the primary production stage.' In this method, MSRV shall be used as the single selective enrichment medium.

4.3. *Serotyping*

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

For quality assurance, 16 typable strains and 16 non-typable isolates shall be sent to the CRL. If less strains have been isolated, all shall be sent.

4.4. *Phage typing*

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

4.5. *Testing of anti-microbial susceptibility*

In case of testing for anti-microbial susceptibility (optional), a validated and controlled method for testing shall be used, such as those recommended by the National Committee for Clinical Laboratory Standards (NCCLS, since 1 January 2005: 'Clinical and Laboratory Standards Institute' — CLSI).

Both agar diffusion and broth dilution methods are acceptable. Results shall be reported both as quantitative data (MIC for dilution methods and inhibition zone diameter for diffusion methods) and as qualitative data (proportion resistant isolates). Qualitative data shall be based on interpretation according to epidemiological cut-off values presented by the European Committee on Antimicrobial Susceptibility Testing (EUCAST) at: http://www.eucast.org

The isolates shall be tested for the susceptibility to the antimicrobial substances listed below:

— Ampicillin or Amoxicillin,

— Tetracycline,

— Chloramphenicol,

— Florfenicol,

— Nalidixic acid,

— Ciprofloxacin (preferably) or Enrofloxacin,

— Sulphonamide (preferably Sulfametoxazole),

— Sulphonamide/Trimethoprim or Trimethoprim,

— Gentamicin,

— Streptomycin,

— Kanamycin (preferably) or Neomycin,

— third generation Cephalosporin, (preferably Cefotaxime),

— Colistin (optional).

Before initiation of the study Member States are encouraged to organise training for the involved parties.

5. **Records and sample storage**

Records of bacteriology shall be kept on all samples processed in a format like or comparable to the example given in Table 4.

All strains isolated shall be stored at the NRLs of the different Member States as long as it ensures integrity of the strains for a minimum of five years.

All samples of meat juice for serology shall be stored frozen for two years.

Table 4

Example of records to be taken on all processed samples

Sample				Receipt					Analysis			
Sample ID + type [1]	Slaughterhouse ID	Name	Date	Time	Name	Date	Time	Positive or Negative	Serovar	Phagetype	Antibiogram	Storage ID
1 S	EU012	PW	3-10-06	12:00	AB	3-10	14:00	Neg				
2 L	EU023	PW	4-10	12:30	AB	4-10	14:00	Pos	Typh	DT104	ASTSu	(IDnr)
3 L	EU083	PW	8-10	16:30	AB	9-10	9:00	Pos	Agona	n.a. [2]	ASTE	(IDnr)

[1] Type of sample: L = lymph nodes, S = swab, MJ = meat juice.
[2] n.a. = not applicable (phage typing is only done after *Salmonella typhimurium* and *Salmonella enteritidis* isolation).

6. **Reporting from Member States**

The competent authority responsible for the preparation of the yearly national report on the monitoring of *Salmonella* in animals pursuant to Article 9 of Directive 2003/99/EC shall collect and evaluate the results and report to the Commission.

Reports shall be made including at least the following information:

6.1. *Overall description on the implementation of the programme*

— description of the population under study stratified according to slaughterhouses capacity,

— description of randomisation procedure, including notification system,

— sample size calculated,

— details of authorities and laboratories involved in sampling/testing/typing,

— overall results of the study (samples analysed by bacteriology and serology, number of positive, serovar, phage type and antibiotic resistance testing).

6.2. *Complete data on each animal sampled and corresponding tests results:*

The Member States shall submit the results of the investigation 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:

— reference of the slaughterhouse,

— capacity of the slaughterhouse,

— date and time of sampling,

— reference of the samples (e.g. number),

— type of samples taken: lymph nodes, carcase swab,

— date of shipment to the laboratory.

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

— ID of the laboratory (in case several laboratories are involved),

— means of transport of samples,

— date of reception by the laboratory,

— when testing lymph nodes, weight of the specimen,

— result for the individual sample tested: 'negative' or in case positive for *Salmonella* spp., also the results of serotyping '*Salmonella* serovar' or 'untypable',

— results for strains subject to antimicrobial susceptibility testing and/or phagetyping results.

ANNEX II

Maximum Community financial contribution to the Member States

(in EUR)

Member State	Amount
Belgium — BE	25 584
Czech Republic — CZ	25 584
Denmark — DK	48 396
Germany — DE	86 400
Estonia — EE	9 984
Greece — EL	9 984
Spain — ES	62 400
France — FR	48 396
Ireland — IE	23 808
Italy — IT	15 600
Cyprus — CY	23 808
Latvia — LV	19 968
Lithuania — LT	23 808
Luxembourg — LU	9 984
Hungary — HU	15 600
Malta — MT	9 984
Netherlands — NL	38 412
Austria — AT	25 584
Poland — PL	37 726
Portugal — PT	15 600
Slovenia — SI	23 808
Slovakia — SK	9 984
Finland — FI	9 984
Sweden — SE	23 808
United Kingdom — UK	31 584
Total	675 778

ANNEX III

Certified financial report on the implementation of a baseline survey on the prevalence of *Salmonella* spp. in herds of fattening 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 *Salmonella* spp.		
Serotyping *Salmonella* isolates		
Serology meat juice		

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 supporting for the costs are available for audit purposes.

Date: .....

Person financially responsible: .....

Signature: .....