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COMMISSION OF THE EUROPEAN COMMUNITIES

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Draft

**COMMISSION REGULATION**

**implementing Regulation (EC) No 853/2004 as regards salmonella additional guarantees for consignments to Finland and Sweden of meat from bovine and porcine animals, of meat from poultry and of eggs**

**(Text with EEA relevance)**

(Memorandum from Mr M. KYPRIANOU)

Draft

## COMMISSION REGULATION

### **Implementing Regulation (EC) No 853/2004 as regards salmonella additional guarantees for consignments to Finland and Sweden of meat from bovine and porcine animals, of meat from poultry and of eggs**

**(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard 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 origin<sup>1</sup>, and in particular Article 8 and Article 9 thereof,

Whereas:

- (1) At the time of their accession, Finland and Sweden were granted additional salmonella guarantees by certain Directives modified by the Act of Accession for Austria, Finland and Sweden, i.e. as regards food: Directive 64/433/EEC on health conditions for the production and marketing of fresh meat<sup>2</sup>, Directive 71/118/EEC of 15 February 1971 on health problems affecting the production and placing on the market of fresh poultrymeat<sup>3</sup> and Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens Directive 90/425/EEC<sup>4</sup>. These additional guarantees cover trade of fresh meat from bovine and porcine animals, fresh poultrymeat and table eggs. These guarantees were extended to minced meat by Directive 94/65/EC<sup>5</sup>.
- (2) The operational programmes submitted by Finland and Sweden regarding salmonella controls were approved by Commission Decisions 94/968/EC<sup>6</sup> and 95/50/EC<sup>7</sup>. Those programmes contain specific measures in particular for meat from bovine and porcine animals, for meat from poultry and for eggs.

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<sup>1</sup> OJ L 226, 25.6.2004, p. 22.

<sup>2</sup> OJ P 121, 29.7.1964, p. 2012

<sup>3</sup> OJ L 55, 8.3.1971, p.23.

<sup>4</sup> OJ L 62, 15.3.1993, p. 49.

<sup>5</sup> OJ L 368, 31.12.1994, p. 10

<sup>6</sup> OJ L 371, 31.12.1994, p. 36.

<sup>7</sup> OJ L 53, 9.3.1995, p. 31.

- (3) Commission Decision 95/168/EC<sup>8</sup> and Council Decisions 95/409/EC<sup>9</sup> and 95/411/EC<sup>10</sup> establish additional guarantees, as regards salmonella, for consignments of eggs intended for human consumption, of fresh beef and veal and pigmeat and of fresh poultry meat,
- (4) As from 1 January 2006, Directives 64/433/EEC, 71/118/EEC, and 94/65/EC will be repealed and Directive 92/118/EEC will be amended by Directive 2004/41/EC of the European Parliament and of the Council on 21 April 2004 repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC<sup>11</sup>,
- (5) As from 1 January 2006, Regulation (EC) No 853/2004 will establish new rules concerning special guarantees for food, in respect of salmonella,
- (6) There is therefore a need to revise as appropriate the provisions foreseen in Commission Decision 95/168/EC and in Council Decisions 95/409/EC and 95/411/EC, pursuant to the new provisions of Regulation (EC) No 853/2004. It is furthermore appropriate to gather all the provisions in one single Commission Decision and then to repeal the above Decisions.
- (7) The implementation of microbiological tests by an establishment constitutes one of the additional guarantees to be given to Finland and Sweden and provides equivalent guarantees to those obtained under the Finnish and Swedish operational programmes as recognized by the relevant Commissions Decisions.
- (8) The rules relating to such microbiological tests by sampling should be drawn up laying down the sampling method, the number of samples to be taken and the microbiological method to be used for examining the samples.
- (9) As far as the sampling methods are concerned, it is appropriate to make a distinction, for meat from bovine and porcine animals, between carcasses and half carcasses, on the one hand and quarters, cuts and smaller pieces on the other; and, for meat from poultry, between whole carcasses, on the one hand, and parts of carcasses and offal on the other.
- (10) As additional guarantees for minced meat were not foreseen in the initial Decisions and as there were no sampling methods appropriated for minced meat, there is a need to provide for such a sampling method. The number of samples to be taken and the microbiological methods to be used shall be the same as for fresh meat.
- (11) It is appropriate to take into account international methods for the microbiological examination of samples, as reference methods, while allowing the use of certain

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<sup>8</sup> OJ L 109, 16.5.1995, p. 44. Decision as amended by Commission Decision 97/278/EC (OJ L 110, 26.4.1997, p. 77)

<sup>9</sup> OJ L 243, 11.10.1995, p. 21. Decision as last amended by Council Decision 98/227/EC (OJ L 87, 21.3.1998, p. 14)

<sup>10</sup> OJ L 243, 11.10.1995, p. 29. Decision as last amended by Council Decision 98/227/EC (OJ L 87, 21.3.1998, p. 14)

<sup>11</sup> OJ L 195, 2.6.2004, p. 12.

alternative methods that have been validated and certified to provide equivalent guarantees.

- (12) Consignments of meat or eggs shall be accompanied by a document stating that the guarantees are fulfilled.
- (13) Those guarantees should not be applicable to any consignment that is subject to a programme recognised as equivalent to that implemented by Finland and Sweden.
- (14) Finland and Sweden shall apply to consignments from third countries import requirements at least as stringent as those laid down in this Decision.
- (15) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee for the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

### *Article 1*

#### *Meat from bovine animals*

1. Without prejudice to Article 8 (2) (c) and (d) of Regulation No (EC) 853/2004, the sampling of meat from bovine – including minced meat but excluding meat preparations and Mechanically Separated Meat (MSM) – intended for Finland and Sweden, as referred to in Article 8 (2) (a) shall be carried out as laid down in Annex I. Concerning minced meat, the sampling shall be carried out using the ‘destructive method’, as laid down in paragraph 3, section A of Annex I.
2. The microbiological testing for salmonella shall be carried out as laid down in Article 5.

### *Article 2*

#### *Meat from porcine animals*

1. Without prejudice to Article 8 (2) (c) and (d) of Regulation No (EC) 853/2004, the sampling of meat from porcine animals – including minced meat but excluding meat preparations and MSM – intended for Finland and Sweden, as referred to in Article 8 (2) (a) shall be carried out as laid down in Annex I. Concerning minced meat, the sampling shall be carried out using the ‘destructive method’, as laid down in paragraph 3, section A of Annex I.
2. The microbiological testing for salmonella shall be carried out as laid down in Article 5.

### Article 3

#### *Meat from poultry*

1. Without prejudice to Article 8 (2) (c) and (d) of Regulation No (EC) 853/2004, the sampling of meat from poultry – including minced meat but excluding meat preparations and MSM – intended for Finland and Sweden, as referred to in Article 8 (2) (a) shall be carried out as laid down in Annex II. Concerning minced meat, the sampling shall be carried out using the ‘destructive method’ laid down in paragraph 3, section A of Annex II.
2. The microbiological testing for salmonella shall be carried out as laid down in Article 5.

### Article 4

#### *Eggs*

1. Without prejudice to Article 8 (2) (c) and (d) of Regulation No (EC) 853/2004, the flocks of origin of the eggs intended for Finland and Sweden shall be subjected to a microbiological test as referred to in Article 8 (2) (b).
2. The sampling shall be carried out as laid down in Annex III.
3. The microbiological testing for salmonella shall be carried out as laid down in Article 5 (1).

### Article 5

#### *Microbiological methods for the examination of the samples*

1. Microbiological testing of the samples for salmonella shall be carried out in accordance with the most recent edition of the standard of the International Organisation for Standardisation (ISO) EN/ISO 6579<sup>12</sup>, or by the most recent edition of method No 71 described by the Nordic Committee on Food Analysis (NMKL)<sup>13</sup>.

Where the results of analyses are contested between Member States, the most recent edition of EN/ISO 6579 standard should be regarded as the reference method.

2. For samples of meat from bovine and porcine animals and meat from poultry, the following alternative analytical methods, which shall have been validated by the use of meat samples in the validation studies, are authorised:

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<sup>12</sup> EN/ISO 6579: Microbiology of food and animal feeding stuffs – Horizontal method for the detection of *Salmonella spp.*

<sup>13</sup> NMKL method No 71: Salmonella. Detection in food.

- methods, which have been validated against the most recent editions of EN/ISO 6579 standard or of NMKL method No 71 and certified by a third party in accordance with the protocol set in the latest edition of EN/ISO 16140 standard,
- pending the experience gained from the application of EN/ISO 16140 standard, methods, which have been validated against the above-mentioned analytical methods and certified to provide equivalent guarantees in accordance with protocols described by Association Française de Normalisation (AFNOR), Nordic System for Validation of Alternative Microbiological Method (NordVal) or Association of Official Analytical Chemists (AOAC).

#### *Article 6*

##### *Documentation*

1. Pursuant to Article 8 (2) (e) of Regulation No (EC) 853/2004, consignments of meat from bovine or porcine animals or meat from poultry -including minced meat but excluding meat preparations and Mechanically Separated Meat (MSM)- intended for Sweden or Finland shall be accompanied by a trade document complying with the model in Annex IV.
2. Pursuant to Article 8 (2) (f) of Regulation No (EC) 853/2004, the eggs must be accompanied by a certificate as set out in Annex V.

#### *Article 7*

1. Commission Decisions 95/168/EC and 2003/470/EC are hereby repealed.
2. Council Decisions 95/409/EC and 95/411/EC are hereby repealed.

#### *Article 8*

This Regulation shall enter into force on the twentieth day following that of its publication in the Official journal of the European Union.

It shall apply from 1 January 2006.

This regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, [...]

*For the Commission*  
*Markos Kyprianou*  
*Member of the Commission*

## **ANNEX I**

### **Sampling rules applicable to meat or minced meat from bovine and porcine animals when intended for Finland and Sweden.**

#### **SECTION A**

##### **SAMPLING METHOD**

**1. CARCASSES, HALF-CARCASSES AND QUARTERS OBTAINED FROM THE SLAUGHTERHOUSE OF ORIGIN ('SWAB TECHNIQUE')**

The non-destructive sampling method as described in ISO 17604 standard, including the rules for storage and transport of samples should be used.

For beef carcasses, three sites shall be sampled (leg, flank and neck). For pork carcasses, two sites shall be sampled (leg and brisket). An abrasive sponge sampling method shall be used. The sampling area shall cover a minimum of 100 cm<sup>2</sup> per site selected. Samples from the different sampling sites on the carcass shall be pooled before examination.

Each sample is duly marked and identified.

**2. QUARTER CUTS OBTAINED FROM AN ESTABLISHMENT OTHER THAN THE SLAUGHTERHOUSE OF ORIGIN OF THE CARCASS, CUTS AND SMALLER PIECES ('DESTRUCTIVE METHOD')**

Pieces of tissue are obtained by punching a sterile cork borer into the meat surface or cutting a slice of tissue of approximately 25 cm<sup>2</sup> with sterile instruments. The samples are aseptically transferred into a sample container or plastic dilution bag and then homogenized (peristaltic stomacher or rotary blender (homogenizer)). Samples of frozen meat remain frozen during transport to the laboratory. Samples from chilled meat are not frozen but kept refrigerated. Separate samples of the same consignment may be pooled as established in ISO 6579 standard, up to a maximum of 10.

Each sample is duly marked and identified.

**3. MINCED MEAT ('DESTRUCTIVE METHOD')**

Pieces of meat are obtained by sampling of approximately 25 g with sterile instruments. The samples are aseptically transferred into a sample container or plastic dilution bag and then homogenized (peristaltic stomacher or rotary blender (homogenizer)). Samples of frozen meat remain frozen during transport to the laboratory. Samples from chilled meat are not frozen but kept refrigerated. Separate samples of the same consignment may be pooled as established in ISO 6579 standard, up to a maximum of 10.

Each sample is duly marked and identified.

## SECTION B

### NUMBER OF SAMPLES TO BE TAKEN

**1. CARCASSES, HALF-CARCASSES, HALF-CARCASSES CUT INTO A MAXIMUM OF THREE PIECES AND QUARTERS REFERRED TO UNDER A (1)**

The number of carcasses or half-carcasses (units) in a consignment of which separate random samples are to be taken is as follows:

<i>Consignment (number of packing units)</i>	<i>Number of packing units to be sampled</i>
1 – 24	Number equal to the number of units, with a maximum of 20
25 – 29	20
30 – 39	25
40 – 49	30
50 – 59	35
60 – 89	40
90 – 199	50
200 – 499	55
500 or more	60

**2. QUARTERS, CUTS AND SMALLER PIECES AS REFERRED TO UNDER A (2) AND MINCED MEAT AS REFERRED TO UNDER A (3)**

The number of packing units in the consignment of which separate random samples are to be taken is as follows:

<i>Consignment (number of packing units)</i>	<i>Number of packing units to be sampled</i>
1 – 24	Number equal to the number of packing units, with a maximum of 20
25 – 29	20
30 – 39	25
40 – 49	30
50 – 59	35
60 – 89	40
90 – 199	50
200 – 499	55
500 or more	60

Depending on the weight of the packing units, the number of packing units to be sampled can be reduced using the following multiplication factors:

Weight of packing units	> 20 kg	10 – 20 kg	< 10 kg
Multiplication factors	× 1	× $\frac{3}{4}$	× $\frac{1}{2}$

## **ANNEX II**

### **Sampling rules applicable to meat or minced meat from poultry when intended for Finland and Sweden.**

#### **SECTION A**

##### **SAMPLING METHOD**

**1. CARCASSES (WITH THE NECK SKIN STILL ATTACHED)**

Random samples are evenly distributed through the whole consignment. Sampling consists of pieces of about 10 g of neck skin to be removed aseptically with a sterile scalpel and tweezers. Samples should be kept refrigerated until examination. Samples may be pooled as established in ISO 6579 standard, up to a maximum of 10.

Samples are duly marked and identified.

**2. CARCASSES WITHOUT NECK SKIN, CARCASS PARTS AND OFFAL ('DESTRUCTIVE METHOD')**

Pieces of tissue of about 25 g are obtained by punching a sterile cork borer into the meat surface or cutting a slice of tissue with sterile instruments. Samples should be kept refrigerated until examination. Samples may be pooled as established in ISO 6579 standard, up to a maximum of 10.

Samples are duly marked and identified.

**3. MINCED MEAT ('DESTRUCTIVE METHOD')**

Pieces of meat are obtained by sampling of approximately 25 g with sterile instruments. Samples should be kept refrigerated until examination. Samples may be pooled, up to a maximum of 10.

Samples are duly marked and identified.

## SECTION B

### NUMBER OF SAMPLES TO BE TAKEN

The number of packing units in the consignment of which separate random samples are to be taken is as follows:

<i>Consignment (number of packing units)</i>	<i>Number of packing units to be sampled</i>
1 – 24	Number equal to the number of packing units, with a maximum of 20
25 – 29	20
30 – 39	25
40 – 49	30
50 – 59	35
60 – 89	40
90 – 199	50
200 – 499	55
500 or more	60

Depending on the weight of the packing units, the number of samples can be reduced by using the following multiplication factors:

Weight of packing units	> 20 kg	10 – 20 kg	< 10 kg
Multiplication factors	× 1	× $\frac{3}{4}$	× $\frac{1}{2}$

## **ANNEX III**

### **Sampling rules applicable to flocks when eggs are intended for Finland and Sweden.**

#### **SECTION A**

##### **SAMPLING METHOD**

In the case of hens raised on perches or free-range, composite samples of faeces, each sample consisting of separate samples of fresh faeces, each weighing at least 1 gram, are to be taken at random at a number of points in the building in which the hens are kept or, where such hens have free access to more than one building on a given farm, such samples shall be taken in each group of farm buildings in which the hens are kept.

In the case of laying hens in cages, such samples are to be taken from scrapers or from surface droppings in the pit.

#### **SECTION B**

##### **NUMBER OF SAMPLES TO BE TAKEN**

60 faeces samples shall be taken in the building or group of farm buildings.

#### **SECTION C**

##### **SAMPLING FREQUENCY**

The flock must be sampled within a period of two weeks before the beginning of laying and thereafter at least once every 25 weeks.

## ANNEX IV

### Notes

<p>(a) Commercial documents shall be produced, according to the layout of the model appearing in this Annex. It shall contain, in the numbered order that appears in the model, the attestations that are required for the transportation of meat from bovine or porcine animals or meat from poultry -including minced meat.</p> <p>(b) It shall be drawn up in one of the official languages of the EU Member State of origin or the EU Member State of destination, as appropriate. However, it may also be drawn up in other EU languages, if accompanied by an official translation or if previously agreed by the competent authority of the Member State of destination.</p> <p>(c) The commercial document must be produced at least in triplicate (one original and two copies). The original must accompany the consignment to its final destination. The receiver must retain it. The producer must retain one of the copies and the carrier the other.</p> <p>(d) The original of each commercial document shall consist of a single page, both sides, or, where more text is required it shall be in such a form that all pages needed are part of an integrated whole and indivisible.</p> <p>(e) If for reasons of identification of the items of the consignment, additional pages are attached to the document, these pages shall also be considered as forming part of the original of the document by the application of the signature of the responsible person, in each of the pages.</p> <p>(f) When the document, including additional pages referred to in e), comprises more than one page, each page shall be numbered <i>-(page number) of (total number of pages)-</i> at the bottom and shall bear the code number of the document that has been designated by the responsible person at the top.</p>	<p>(g) The original of the document must be completed and signed by the responsible person.</p> <p>(h) The colour of the signature of the responsible person shall be different to that of the printing.</p>
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*Commercial document for the transportation within the European Community of meat from bovine or porcine animals or meat from poultry, including minced meat*

<p><b>1. Consignor</b> (name of despatching establishment and address in full and, if appropriate approval number of the despatching establishment)</p> <p>.....</p> <p>.....</p>	<p><b>Document reference number</b><sup>(1)</sup> .....</p> <p><b>Total number of pages of this document:</b> .....</p> <p><b>Date (on which the material was taken from the premises):</b></p> <p>.....</p>
<p><b>2. Consignee</b> (receiver's name and address in full and, if appropriate approval number of the establishment of destination of the product)</p> <p>.....</p> <p>.....</p>	<p><b>3. Place of loading for dispatch</b> (address in full if different from point 1)</p> <p>.....</p> <p>.....</p>
<p><b>4. Carrier, means of transport, quantity and identification of consignment</b></p> <p>4.1. Carrier (name and address in full):</p> <p>.....</p> <p>.....</p> <p>4.2. Lorry, Rail-wagon, Ship or Aircraft<sup>(2)</sup></p> <p>4.3. Registration number(s), ship name or flight number:</p> <p>.....</p>	<p>4.5. Nature of packaging</p> <p>.....</p> <p>4.6. Number of packages per category of products:</p> <p>.....</p> <p>.....</p> <p>4.7. Net weight (kg):.....</p> <p>4.8. Container number if applicable</p> <p>.....</p>
<p><b>5. Description of the products</b></p> <p>5.1. Type of products <sup>(3)</sup>: .....</p> <p>5.2. Condition of products <sup>(4)</sup>: .....</p>	
<p><b>6. Declaration by the consignor</b></p> <p>I, the undersigned, declare that:</p> <p>The checks referred to in Decision Commission [...] have been carried out with negative results and a statement from the laboratory concerning the analyses performed on the consignment or the results of such analyses are attached to this document. <sup>(2)</sup></p> <p>The meat is intended for an establishment for the purposes of pasteurisation, sterilisation or treatment having a similar effect. <sup>(2)</sup></p> <p>The meat comes from an establishment that is subject to a control programme recognised as equivalent to that approved for Sweden and Finland. <sup>(2)</sup></p>	
<p><b>Signature</b></p> <p>Done at ..... on .....</p> <p style="text-align: center;">(place) (date)</p> <p style="text-align: center;">.....</p> <p style="text-align: center;">(signature of the responsible person/consignor) <sup>(5)</sup></p> <p style="text-align: center;">.....</p> <p style="text-align: center;">(name, in capital letters)</p>	

**Notes**

- |     |   |
|-----|---|
| (1) | Reference number issued by the responsible person for purpose of traceability.  |
| (2) | Delete as appropriate.  |
| (3) | Describe the type of product (e.g. meat from bovine animals, meat from porcine animals, meat from poultry, minced meat) |
| (4) | Describe the condition of product: chilled or frozen  |
| (5) | The signature must be in a different colour to that of the printing   |

ANNEX V

**Model certificate for the consignment to Finland and Sweden of eggs intended for human consumption**

<b>1. Consignor</b> (name and address in full) ..... ..... ..... .....	<b>CERTIFICATE</b> <b>for the consignment to Finland and Sweden of eggs</b> <b>intended for human consumption</b> No ..... ORIGINAL
<b>2. Consignee</b> (name and address in full) ..... ..... ..... .....	<b>3. Origin of the eggs</b> 3.1 Member State of origin: ..... .....
<b>5. Identification of egg consignment</b> 5.1 Quality grading: ..... 5.2 Weight category: ..... 5.3 Number of units or packs: ..... 5.4 Date of minimum durability: ..... 5.4 Net weight: .....	<b>4. Competent Authority</b> 4.1 Ministry: ..... 4.2 Service: ..... ..... 4.3 Local/Regional level: ..... ..... .....
<b>7. Means of transport and consignment identification<sup>(1)</sup></b> 7.1 Lorry, Rail-wagon, Ship, or Aircraft <sup>(2)</sup> 7.2 Registration number(s), ship name or flight number: ..... ..... 7.3 Consignment identification details <sup>(3)</sup> : ..... ..... .....	<b>6. Address(es) and approval No(s) of packing centre(s):</b> ..... ..... ..... ..... ..... .....
<b>8. Attestation</b>  I, the undersigned, hereby certify that:  (i) The eggs described above originate from a flock which has been subjected, with negative results, to the provisions laid down in Commission Decision [...]. <sup>(2)</sup>  (ii) The eggs are destined to be used for the manufacture of processed products by a process that guarantees the elimination of salmonella. <sup>(2)</sup>	
<b>Official stamp and signature</b>  Done at ..... on.....  <div style="text-align: right;">(signature of the competent authority)<sup>(4)</sup></div> <div style="text-align: right;">(stamp)<sup>(4)</sup></div> <div style="text-align: right;">(name in capital letters)</div>	

**Notes**

- (1) The registration number(s) of rail-wagon or lorry and the name of the ship should be given as appropriate. If known, the flight number of the aircraft.  
In case of transport in containers or boxes, the total number, their registration and seal numbers, if present, should be indicated under point 7.3.
- (2) Keep as appropriate.
- (3) Complete if appropriate.
- (4) The signature and the stamp must be in a colour different to that of the printing.