

EN

Deleted: 2008-4

SANCO/745/2008r5

EN

EN



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
C(2008)

WORKING DOCUMENT

Draft

GUIDANCE DOCUMENT

On the minimum requirements for *Salmonella* control programmes to be recognised equivalent to those approved for Sweden and Finland in respect of meat and eggs of *Gallus gallus*

This document has been presented on the meeting of the Standing Committee on the Food Chain and Animal Health on 18 June 2008. It was supported by the delegates of all Member States [except ... because...].

EN

EN

This document has been established for information purposes only. It has not been adopted or in any way approved by the European Commission.

The European Commission does not guarantee the accuracy of the information provided, nor does it accept responsibility for any use made thereof. Users should therefore take all necessary precautions before using this information, which they use entirely at their own risk.

PURPOSE OF THIS DOCUMENT

This document is mainly directed at Member States who consider a request to be granted special guarantees as regards *Salmonella* at import of certain products of animal origin in accordance with the provisions in Article 8(3)(b) of 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.

1. INTRODUCTION AND PURPOSE

At their accession special guarantees have been granted with regard to *Salmonella* for consignments to Finland and Sweden of certain meat, eggs, laying hens, breeding poultry and day-old chicks. The special guarantees for broiler meat and eggs are currently laid down in Commission Regulation (EC) No 1688/2005 of 14 October 2005 implementing Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards special guarantees concerning *Salmonella* for consignments to Finland and Sweden of certain meat and eggs¹. They include the absence of *Salmonella* using a strict sampling protocol, prior to the dispatch of the products to Finland or Sweden. The special guarantees also apply at dispatch to Norway. The reason for granting special guarantees was the favourable epidemiological situation in Finland and Sweden and the strict measures they apply within their national control programmes.

According to Regulation 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin² and in particular Article 8, point 3 (b) thereof, the rules concerning special guarantees may be extended, in whole or in part, to any Member State, or any region of a Member State, that has a control programme recognised as equivalent to that approved for Sweden and Finland in respect to the food of animal origin concerned.

This document aims to provide guidance on the minimum requirements expected to be addressed by the control programmes referred to in Regulation (EC) No 853/2004 to be considered equivalent. As this is a guidance documents, there is some flexibility on the minimum requirements if the applicant Member State or region clearly demonstrates equivalence to the proposed minimum requirements. The application of the minimum requirements shall not replace a case by case evaluation, preferably based on a risk assessment if sufficient information is available, of each control programme in order to evaluate the equivalence with the programme in Sweden and Finland.

Considering a control programme equivalent to the one in Sweden and Finland does not necessarily result in the granting of special guarantees. These guarantees can only be obtained by the procedure referred to in Article 12(2) of Regulation (EC) No 853/2004 (comitology procedure).

This document has no formal legal status and in the event of a dispute, ultimate responsibility for the interpretation of the law lies with the Court of Justice.

2. MINIMUM REQUIREMENTS

A *Salmonella* control programme may be recognised as equivalent to the Swedish and Finnish programme if the three minimum requirements below are fulfilled. The requirements are for programmes concerning the granting of special guarantees for table eggs and broiler meat. It

¹ OJ L 271, 15.10.2005, p. 17.

² OJ L 139, 30.4.2004, p. 20 as corrected by OJ L 226, 25.6.2004, p. 22.

might be extended in future to similar requirements for special guarantees for other poultry products. Minimum requirements for programmes in cattle and pigs are not addressed in this document.

2.1. Coverage of all *Salmonella* serotypes

The control programme should cover all *Salmonella* serotypes, and the measures taken after *Salmonella* is detected are the same for all serotypes. The only exception might be some animal species specific pathogenic serotypes (*S. Gallinarum*, *S. Pullorum*) which are covered by the Community animal health legislation.

2.2. Minimum requirements for sampling, analysing and control measures

It is obvious that all control programmes should be in line with the provisions which are mandatory in all Member States. These provisions are laid down in different acts. For clarity purposes, reference is made to the relevant acts where the details can be consulted. Differences to be granted special guarantees are clarified and all serotypes should be considered in line with point 2.1.

2.2.1. Sampling of flocks

2.2.1.1. Adult breeding hens

The frequency, sample size, protocol, methods for official sampling and sampling by the food business operator shall be

- As regards adult breeding flocks, in accordance with Commission Regulation (EC) No 1003/2005 of 30 June 2005 implementing Regulation (EC) No 2160/2003 as regards a Community target for the reduction of the prevalence of certain *Salmonella* serotypes in breeding flocks of *Gallus gallus* and amending Regulation (EC) No 2160/2003³.
- As regards adult laying flocks, in accordance with Commission Regulation (EC) No 1168/2006 of 31 July 2006 implementing Regulation (EC) No 2160/2003 as regards a Community target for the reduction of the prevalence of certain *Salmonella* serotypes in laying hens of *Gallus gallus* and amending Regulation (EC) No 1003/2005⁴.
- As regards flocks for rearing of breeding and laying hens, in accordance with Part B of Annex II to 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 agents⁵.

³ OJ L 170, 1.7.2005, p. 1. Regulation as amended by Regulation (EC) No 1168/2006 (OJ L 211, 1.8.2006, p. 4).

⁴ OJ L 211, 1.8.2006, p. 4.

⁵ OJ L 325, 12.12.2003, p. 1. Regulation as last amended by Commission Regulation (EC) 1237/2007 (OJ L 280, 24.10.2007, p. 5).

- As regards broilers, in accordance with according to Commission Regulation (EC) No 646/2007 of 12 June 2007 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Community target for the reduction of the prevalence of *Salmonella* Enteritidis and *Salmonella* Typhimurium in broilers and repealing Regulation (EC) No 1091/2005⁶.

However,

- As regards laying hens, the sampling by the competent authority in accordance with Point 2(1) of the Annex to Regulation (EC) No 1168/2006 should occur at least once a year
 - in all flocks
 - in any case on holdings that deliver eggs to an egg packing centre and on holdings comprising at least 1000 birds.
- As regards broilers, the derogation provided for in Point 1 (c) of the Annex to Regulation (EC) No 646/2007 should not be used.

2.2.2. Confirmation sampling

Official confirmation sampling after an initial *Salmonella* positive result may be allowed for all flocks if:

- No target for reduction in accordance with Regulation (EC) No 2160/2003 has been set for the detected serotype;
- The original positive detection shall be taken into account when estimating the prevalence in flocks.
- Official trade restrictions on products and animals are set immediately after an initial positive result; the trade restrictions may only be lifted after 2 consecutive negative results by official sampling with at least 2 weeks interval;
- Confirmation sampling is carried out according to Commission Regulation (EC) No 1237/2007 of 23 October 2007 amending Regulation (EC) No 2160/2003 of the European Parliament and of the Council and Decision 2006/696/EC as regards the placing on the market of eggs from *Salmonella* infected flocks of laying hens⁷. In particular, five faecal and two dust samples should be analysed individually as laid down in Point 4 (b) (i) of Annex I of the Regulation;
- There is no indication that products have been used which may hamper the detection of *Salmonella* at confirmatory sampling.
- The competent authority has verified the absence of the use of antimicrobials in accordance with the sampling method described under Point 2.2.2.2(b) of the Annex to Regulation (EC) No 1003/2005.

2.2.3. Measures after *Salmonella* detection

- Official trade restrictions on the animals and their products should be applied to the infected flock.
- Live animals from the infected flock should not leave the holding except for slaughter.

⁶ OJ L 151, 13.6.2007, p. 21.

⁷ OJ L 280, 24.10.2007, p. 5.

- The positive flock should be slaughtered at the end of the working day or on a separate line. The slaughterhouse should be thoroughly cleaned and disinfected afterwards.
- The meat of the positive flock should be heat treated in an establishment approved according to Regulation (EC) No 853/2004 before placing on the market.
- Hatching or table eggs should not leave the holding except for destruction or to an establishment producing egg products.
- If the eggs from a positive flock are used as egg products for human consumption they should be heat treated in an establishment approved according to Regulation (EC) No 853/2004 before placing on the market.
- The premises of the infected flock should be cleaned and disinfected. Restocking should only be allowed after a favourable official environmental sampling
- If *Salmonella* spp are detected in a flock of breeding and laying hens, all other flocks in the same holding should be officially sampled at the earliest convenience.
- ~~Once these special guarantees have been granted, if *Salmonella* is found in a batch of broiler meat, it shall be withdrawn from the market and submitted to a treatment to eliminate *Salmonella* under the supervision of the competent authorities or destroyed or returned to the country of origin and subjected to notification to the RASFF system~~
- Official epidemiological investigation should be carried out to try to find the origin of the *Salmonella* infection. Possible further spreading of the infection from the positive holding should also be investigated. If a flock is tested positive other animals at the holding should be tested when appropriate.

Deleted: if

Deleted: once these special guarantees have been granted

2.2.4. Preventive measures

- Good farming practices and strict bio-security measures should be applied at the holdings. A procedure should be in place to avoid contamination from other poultry or other production animals on the holding. These measures should be checked by the competent authority at least once a year during a visit at the holding. Once agreed on, the Community guides to good practice for hygiene referred to in Article 9 of Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs⁸, should be applied to the relevant poultry population.
- Vaccination against *Salmonella* should be prohibited in breeding flocks of *Gallus gallus*. In other poultry vaccination with live *Salmonella* strains should also be prohibited.
- Antibiotics shall not be used as a specific method to control *Salmonella* except under clearly defined exceptional circumstances as laid down in Commission Regulation (EC) No 1177/2006 of 1 August 2006 implementing Regulation (EC) No 2160/2006 of the European Parliament and of the Council as regards requirements for the use of specific control methods in the framework of national programmes for the control of *Salmonella* in poultry⁹. If antimicrobials are used for other purposes, sampling for *Salmonella* should only occur after the withdrawal period.

⁸ OJ L 226, 25.6.2004, p. 3.

⁹ OJ L 212, 2.8.2006, p. 3.

2.2.5. Feed control

Salmonella control of feedingstuffs should cover all serotypes. Some aspects should be included to the feed control programmes, such as surveillance of the processing line in the feed mill and a suitable number of samples in feed materials used or in feedstuffs. Other measures, such as heat treatment, careful selection of raw materials and microbiological criteria on certain feedstuffs (e.g. for breeders), are recommended.

Due to the lack of harmonised rules in Community legislation and the partly different approach of measures in the control programmes of Finland and Sweden, feed control measures must be assessed case by case.

2.2.6. Monitoring and control of foodstuffs

There should be a monitoring system in place to evaluate the occurrence of *Salmonella* in meat. The sampling shall be representative of the whole population and can take place in slaughterhouses or cutting plants. The sampling can be carried out by food business operators but details on the verification of this monitoring by the competent authorities should be included in the programme. Where relevant, the sampling should be done according to the provisions in Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs¹⁰.

2.2.7. Analysing methods

- Samples from flocks should be analysed according to ISO 6579:2002/MSRV.
- Samples from meat should be analysed according to ISO 6579:2002 or NMKL No 71:1999.
- Alternative methods may be used in accordance with the provisions in Article 12 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 agents¹¹ and Article 11 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 24 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules¹².

2.2.8. Laboratory requirements

- Laboratories carrying out analyses on official samples shall comply with the provisions in Article 12 of Regulation (EC) No 882/2004.
- Laboratories carrying out analyses on samples taken by the food business operators, including samples of food, shall comply with the provisions in Article 12 of Regulation (EC) No 2160/2003.

¹⁰ OJ L 338, 22.12.2005, p. 1. Regulation as amended by Regulation (EC) No 1447/2007 (OJ L 322, 7.12.2007, p. 12)

¹¹ OJ L 325, 12.12.2003, p. 1. Regulation as last amended by Commission Regulation (EC) 1237/2007 (OJ L 280, 24.10.2007, p. 5).

¹² OJ L 165, 30.4.2004, p. 1, as corrected by OJ L 191, 28/5/2004, p. 1; Regulation as amended by Regulation (EC) No 776/2006 (OJ L 136, 24.5.2006, p. 3)

2.2.9. Notification

All *Salmonella* spp. should be notified to the competent authority in animals, foodstuffs, feed and humans, including *Salmonella* spp detected in environmental sampling within the frame of HACCP based procedures put in place by food and feed business operators in feed and food establishments.

2.3. *Salmonella* prevalence

The prevalence of *Salmonella* spp. in flocks should be below 1.0 % for domestically produced foodstuffs and in each poultry population involved. The foodstuffs/populations involved should be adult breeding flocks, broiler flocks and broiler meat if special guarantees are requested for broiler meat, and adult breeding flocks and layer flocks if special guarantees for eggs are requested. The verification of the achievement of the target in flocks should be done according to Regulations (EC) No 1003/2005, 1168/2006 and 646/2007 but all serotypes should be taken into account. The target prevalence should have been achieved at least in two consecutive years before the equivalence is recognised.

The control programmes of Member States or regions having a prevalence up to 2.0 % in flocks of breeding hens, broilers and laying hens, may be considered, based on a case by case evaluation, equivalent to the programmes in Sweden and Finland if this higher prevalence is compensated by a specified increased surveillance, resulting in an equivalent exposure of *Salmonella* to the consumer by the relevant products. If there are less than 50 flocks of a population in a Member State or a region, maximum 1 per year may be infected over the last 5 years period. However the defined target prevalence of the programme should still be 1%.

Deleted: The prevalence in foodstuffs should be evaluated on a case by case basis.

Deleted: and

