Control of Salmonella and other zoonotic agents in the European Community – current status of legislation –

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Introduction

For the Commission of the European Communities the protection of human health against diseases and infections transmissible directly or indirectly between animals and humans (zoonoses) is of paramount importance. This will be a major issue until complete implementation 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“ in 2013.

In 1992, the European Union adopted a directive to monitor and control Salmonella infections in breeding flocks of domestic fowl (Council Directive 92/117/EC of 17 December 1992 concerning measures for protection against specified zoonoses and specified zoonotic agents in animals and products of animal origin in order to prevent outbreaks of food-borne infections and intoxication’s provided for the establishment of monitoring systems for certain zoonoses and controls on salmonella in certain poultry flocks.) This directive laid down specific minimum measures to control infections with Salmonella enteritidis and Salmonella typhimurium in breeding stocks of Gallus gallus.

In recent years, the Scientific Committee on Veterinary Measures relating to Public Health considered that the measures in place to control food-borne zoonotic infections were insufficient at that time. It further considered that the epidemiological data collected by Member States were incomplete and not fully comparable.

As a consequence, the Committee recommended to improve the existing control systems for specific zoonotic agents and in November 2003 the following legislation was implemented for


The purpose of Regulation (EC) No 2160/2003 is to ensure that proper and effective measures are taken to detect and control salmonella and other zoonotic agents at all relevant stages of production, processing and distribution, particularly at the level of primary production, in order to reduce their prevalence and the risk they pose to public health. The Regulation covers:

- the adoption of targets for the reduction of the prevalence of specified zoonoses
- the approval of specific control programs established by Member States
- the adoption of specific rules concerning certain control methods
- the adoption of rules concerning intra-Community trade and imports

Therefore, Regulation (EC) No 2160/2003 and especially its Annex I, is the basis for the co-ordinated control of zoonoses (Salmonella at the moment) within the European Community and gives a detailed time frame in which the prevalence have to be evaluated, targets have to be established and national control programs have to be prepared, approved by the European Community and implemented (see Table 1).
Table 1: Annex 1 of Regulation (EC) No 2160/2003, specified with dates and targets already defined

<table>
<thead>
<tr>
<th>Zoonosis or zoonotic agent</th>
<th>Animal population</th>
<th>Stage of food chain</th>
<th>Date by which target must be established</th>
<th>Date from which testing must take place</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Salmonella serotypes with public health significance</td>
<td>Breeding flocks of Gallus gallus</td>
<td>Primary production</td>
<td>Com. Reg. (EC) 1003/2005 Target less than 1%</td>
<td>01.01.2007</td>
</tr>
<tr>
<td>All Salmonella serotypes with public health significance</td>
<td>Laying hens</td>
<td>Primary production</td>
<td>Com. Reg. (EC) 1168/2005 Reduction by 10-40% dep. on prevalence</td>
<td>01.02.2008</td>
</tr>
<tr>
<td>All Salmonella serotypes with public health significance</td>
<td>Broilers</td>
<td>Primary production</td>
<td>March/April 2007</td>
<td>Presumably: 01.01.2009</td>
</tr>
<tr>
<td>All Salmonella serotypes with public health significance</td>
<td>Turkeys</td>
<td>Primary production</td>
<td>March/April 2008</td>
<td>Presumably: 01.01.2010</td>
</tr>
<tr>
<td>All Salmonella serotypes with public health significance</td>
<td>Herds of slaughter pigs</td>
<td>Slaughter</td>
<td>March/April 2008</td>
<td>Presumably: 01.01.2010</td>
</tr>
<tr>
<td>All Salmonella serotypes with public health significance</td>
<td>Breeding herds of pigs</td>
<td>Primary production</td>
<td>March/April 2009</td>
<td>Presumably: 01.01.2011</td>
</tr>
</tbody>
</table>

1. Breeding flocks of Gallus gallus:

1.1 Prevalence study

Based on the data collection in accordance with Council Directive 92/117/EC the data from the year 2004 have been used as a basis for the prevalence estimation of Salmonella in breeding flocks of Gallus gallus in the member states. The report on results of monitoring / control of salmonella in breeding flocks of Gallus gallus in the European Union and Norway (Sanco/1143/2005) shows, that over all production lines and age groups the prevalence of Salmonella enteritidis in the European Union is 1.5 % and for Salmonella typhimurium is 0.2 %. For the “Top 5” (S. enteritidis, S. hadar, S. infantis, S. typhimurium and S. virchow) the prevalence is 2.8 %, varying from 0.0 to 28.0 %. The prevalence rates of the Top 5 Salmonella serotypes in the Member States is shown in Figure 1.

1.2 Targets for the reduction of Salmonella

On 30 June 2005 Commission Regulation (EC) No 1003/2005 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 2160/2003 was implemented. For a transitional period of three years the Community target for breeding flocks of Gallus gallus covers the five most frequent salmonella serotypes in humans, which are Salmonella enteritidis, Salmonella hadar, Salmonella infantis, Salmonella typhimurium and Salmonella virchow. The target in breeding flocks of Gallus gallus shall be a reduction of the maximum percentage of adult breeding flocks remaining positive to 1 % or less by 31 December 2009.

The testing scheme to verify the achievement of the Community target is set out in Annex I of the Regulation. This includes Monitoring in breeding flocks by sampling at the initiative of the operator and official control sampling. At the initiative of the operator sampling shall take place every two weeks in agreement with the competent authority either at the hatchery or the holding.

The Official control sampling depends on the sampling of the operator. If sampling at the initiative of the operator takes place at the hatchery:
Figure 1: Prevalence of the Top 5 Salmonella serotypes in Gallus gallus breeding flocks

(a) routine sampling every 16 weeks at the hatchery, which shall on that occasion replace the corresponding sampling at the initiative of the operator;

(b) routine sampling at the holding on two occasions during the production cycle, the first one being within four weeks following moving to laying phase or laying unit and the second one being towards the end of the laying phase, not earlier than eight weeks before the end of the production cycle;

(c) confirmatory sampling at the holding, following detection of relevant salmonella from sampling at the hatchery.

If sampling at the initiative of the operator takes place at the holding, routine sampling shall be carried out on three occasions during the production cycle:

(a) within four weeks following moving to laying phase or laying unit;

(b) towards the end of the laying phase, not earlier than eight weeks before the end of the production cycle;

(c) during the production, at any time sufficiently distant from the samples referred to in points (a) and (b).

Type and size of sampling material, examination methods to be used and reporting of results are also specified in the Annex.

According to Council Regulation 2160/2003/EC specific requirements concerning breeding flocks of Gallus gallus must be followed. In case results of examined samples indicate the presence of Salmonella Enteritidis or Salmonella Typhimurium in a breeding flock of Gallus gallus non-incubated eggs from the flock must be destroyed. However, such eggs may be used for human consumption if they are treated in a manner that guarantees the elimination of Salmonella Enteritidis and Salmonella Typhimurium in accordance with Community legislation on food hygiene. All birds, including day-old chicks, in the flock must be slaughtered or destroyed so as to reduce as much as possible the risk of spreading salmonella. Slaughtering must be carried out in accordance with Community legislation on food
hygiene. Products derived from such birds may be placed on the market for human consumption in accordance with Community legislation on food hygiene. If not destined for human consumption, such products must be used or disposed of in accordance with Regulation No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption. Where eggs for hatching from flocks in which Salmonella Enteritidis or Salmonella Typhimurium is present are still present in a hatchery, they must be destroyed or treated in accordance with Regulation No 1774/2002.

1.3 Rules for certain control methods


However, the use of antimicrobials might be permitted in animals presenting salmonella infection with clinical signs in a way likely to cause undue suffering of the animals, salvaging of valuable genetic material in breeding flocks or on a case by-case basis for purposes other than salmonella control in a flock suspect of salmonella infection.

Live Salmonella vaccines should not be used if the manufacturer does not provide appropriate methods to distinguish bacteriologically wild-type strains of salmonella from vaccine strains.


1.4 National control program

In order to achieve the Community target established by Commission Regulation (EC) No 1003/2005 for the reduction of the prevalence of the top 5 salmonella serotypes in breeding flocks of Gallus gallus each Member State had to establish national control programs for the control of salmonella in breeding flocks of Gallus gallus. These control programs have been approved by Commission Decision 2006/759/EC of 8 November 2006 approving certain national programs for the control of salmonella in breeding flocks of Gallus gallus and have to be applied since 1 January 2007.

2. Laying hens

2.1 Prevalence study

In order to set the target, comparable data on the prevalence of salmonella in the populations of laying hens in Member States should be available. Such information was not available and therefore a special study was carried out in order to monitor the prevalence of salmonella in laying hens during an appropriate period of time in order to take into account possible seasonal variations (Commission Decision 2004/665/EC of 22 September 2004 concerning a baseline study on the prevalence of salmonella in laying flocks of Gallus gallus).

The Preliminary Report was published on 7 April 2006 by the European Food Safety Authority (EFSA). The study was conducted on large-scale laying hen holdings with at least 1,000 laying hens per flock in a period of 1 October 2004 to 30 September 2005. From each flock five pooled samples of faeces and two pooled samples of dust were collected during the last nine weeks of the production period.

The EU weighted prevalence for salmonella spp. in laying hens was 30.7 %, ranging from 0.0 % in countries like Sweden and Luxembourg to 79.5 % in Portugal. The EU weighted prevalence of laying flocks being positive for S. enteritidis or S. typhimurium or both was 20.3 % ranging again from countries with 0.0 % to 62.5 % in Czech Republic. This demonstrates that in most Member States
the majority of laying hens is infected with either S. enteritidis or S. typhimurium or both. The prevalence rates of S. enteritidis/S. typhimurium in the Member States is shown in Figure 2.

Figure 2: Prevalence of the S.e./S.tm. in Laying hens

2.2 Targets for the reduction


The Community target for the reduction of S. enteritidis and S. typhimurium in adult Laying hens of Gallus gallus depend on the prevalence in the preceding year:

An annual minimum percentage of reduction of positive flocks of adult laying hens equal to at least:

(i) 10 % if the prevalence in the preceding year was less than 10 %;
(ii) 20 % if the prevalence in the preceding year was between 10 and 19 %;
(iii) 30 % if the prevalence in the preceding year was between 20 and 39 %;
(iv) 40 % if the prevalence in the preceding year was 40 % or more;

This target should be achieved in 2008 and is based on the results of the prevalence study carried out under Decision 2004/665/EC.

The sampling scheme including frequency, sampling protocols, transport of samples, examination methods and reporting are specified in the Annex. Sampling shall take place at the initiative of the operator at least every 15 weeks, starting at the age of 24 ± 2 weeks. Sampling by the competent authorities shall take place at least in one flock per year per holding or in case of suspicion or detection of S. enteritidis or S. typhimurium.
2.3 Rules for certain control methods


However, the use of antimicrobials might be permitted in animals presenting salmonella infection with clinical signs in a way likely to cause undue suffering of the animals, salvaging of valuable genetic material in breeding flocks or on a case by-case basis for purposes other than salmonella control in a flock suspect of salmonella infection.

Live Salmonella vaccines should not be used if the manufacturer does not provide appropriate methods to distinguish bacteriologically wild-type strains of salmonella from vaccine strains. They also should not be used in laying hens during production unless the safety of the use has been demonstrated. At the latest from 1 January 2008 in Member States which did not demonstrate a prevalence below 10 % vaccination programs against Salmonella enteritidis shall be applied at least during the rearing period to all laying hens.

2.4 National control program

In order to achieve the Community target established by Commission Regulation (EC) No 1168/2006 for the reduction of the prevalence of Salmonella enteritidis and Salmonella typhimurium in laying flocks of Gallus gallus each Member State had to establish national control programs for the control of salmonella. Those had to be submitted to the European Union until 31 December 2006 and should be approved by the mid of 2007. They have to be applied from 1 February 2008.

2.5 Intra-Community Trade, export and import of eggs

The Commission of the European Communities is working on a Commission Regulation introducing restrictions on the intra-community trade, export and import of eggs from salmonella infected flocks of laying hens (SANCO/1188/).

According to the draft of this Commission Regulation, intra-community trade and export of eggs, classed A in accordance to Regulation (EEC) No 1907/1990 shall only be authorized if derived from holdings applying the monitoring laid down in the Annex of Regulation (EC) 1168/2006 and which are not suspected of having or infected by Salmonella enteritidis or Salmonella typhimurium. Imported eggs shall only be authorized if derived from flocks providing similar guarantees as stated in a declaration by the competent authority of the country of production.

These restrictions for trade will be implemented either from 1 February 2008 or 1 January 2009. Eggs from laying hens infected with Salmonella enteritidis or Salmonella typhimurium will result in class B eggs with a “S” identification.

3. Broilers

3.1 Prevalence study

In order to provide the scientific basis for setting of the Community target for reduction of the prevalence of salmonella in boiler flocks of Gallus gallus, an European-Union wide study was carried out in order to determine the prevalence of salmonella in boiler flocks (Commission Decision 2005/636/EC of 1 September 2005 concerning a baseline survey on the prevalence of Salmonella spp. in broiler flocks of Gallus gallus).

The Report was published on 28 March 2007 by the European Food Safety Authority (EFSA). The study was conducted on commercial holdings with at least 5.000 birds on the holding in a period of 1
October 2005 to 30 September 2006. From each flock five pooled samples of faeces (by boot swabs or sock samples).

The EU weighted prevalence for salmonella spp. in broilers was 23.7 %, ranging from 0.0 % in Sweden to 68.2 % in Hungary. The EU weighted prevalence of broiler flocks being positive for S. enteritidis or S. typhimurium or both was 11.0 % ranging again from countries with 0.0 % to 39.3 % in Portugal. The Community weighted observed flock prevalence for the 5 most frequently reported Salmonella serotypes was:

- S. enteritidis 10.9 %
- S. typhimurium 0.5 %
- S. infantis 2.2 %
- S. mbandaka 0.4 %
- S. hadar 1.1 %
- Others 6.5 %

The prevalence rates of S. spp. and S. enteritidis/S. typhimurium in broiler flocks in the Member States is shown in Figure 3 and 4.

**Figure 3:** Prevalence of the S. spp. in broiler flocks

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**3.2 Targets for the reduction**

For a transitional 3 year period Regulation (EC) No 2160/2003 foresees the reduction of the Salmonella prevalence in broiler flocks only for two Salmonella serotypes, S. enteritidis and S. typhimurium, the two most frequently reported Salmonella serotypes in human salmonellosis.

As the prevalence study in broilers demonstrates that in most Member States Salmonella serotypes others than Salmonella enteritidis and Salmonella typhimurium are more frequently found, the targets might be extended to other serotypes either by the Member States within their national control programs or after risk-benefit analysis also later by the European Union.

Targets for the reduction of the prevalence of Salmonella enteritidis and Salmonella typhimurium in broiler flocks are still to be established in April 2007.
3.3 National control programs

In order to achieve the Community target for the reduction of the prevalence of Salmonella enteritidis and Salmonella typhimurium in broiler flocks of Gallus gallus each Member State have to establish national control programs for the control of salmonella. Those have to be send to the European Union until 31 December 2007 and should be approved by the mid of 2008. Presumably they have to be applied from 1 January 2009.

4. Turkeys

In turkeys, both breeder and meat turkey flocks, the prevalence study started on 1 October 2006 and will end on 30 September 2007 (Commission Decision 2006/622/EC of 29 September 2006 concerning a financial contribution from the Community towards a baseline survey on the prevalence of Salmonella in turkeys to be carried out in the Member States). The report on this study is expected in the beginning of 2008. Targets for the reduction of Salmonella in turkey flocks have to be established until March / April 2008 and the national control programs have to be sent to the European Union until 31 December 2008.

The approval of national control programs is expected in early 2009 and they should be applied as of 1 January 2010, focusing on Salmonella enteritidis and Salmonella typhimurium.

5. Slaughter Pigs

Also in herds of slaughter pigs, the prevalence study started on 1 October 2006 and will end on 30 September 2007. The report on this study is expected in the beginning of 2008. Targets for the reduction of Salmonella in slaughter pigs have to be established until March / April 2008 and the national control programs have to be sent to the European Union until 31 December 2008.

The approval of national control programs is expected again in early 2009 and they should be applied as of 1 January 2010. On which Salmonella serotypes these control programs have to focus is not clear at the moment and depend on risk-benefit analysis done by the European Union.
6. Breeding pigs

In breeding pigs, the prevalence study will start on 1 October 2007 and will end on 30 September 2008. The report on this study is expected in the beginning of 2009. Targets for the reduction of Salmonella in pig breeding herds have to be established until March / April 2009 and the national control programs have to be sent to the European Union until 31 December 2009.

The approval of national control programs is expected in early 2010 and they should be applied as of 1 January 2011. On which Salmonella serotypes these control programs have to focus is again not clear at the moment and depend on risk-benefit analysis done by the European Union.

7. Discussion

The complete implementation 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 will only be achieved in 2013 at the earliest. The current status of implementing this regulation in the primary poultry production is summarized in Table 2.

In breeding flocks of Gallus gallus the Community target for the Top 5 salmonella serotypes shall be a reduction of the maximum percentage of adult breeding flocks remaining positive to 1 % or less by 31 December 2009. According to the prevalence evaluation in 2004, this Community target was reached under the conditions of Council Directive 92/117/EC already by 9 Member States. This may change to some degree as the sampling frame under Commission Regulation (EC) No 1003/2005 is much more sensitive as compared to sampling under Council Directive 92/117/EC.

In several countries, this Community target might only be achieved with the intensive use of vaccines against Salmonella. For those Salmonella serotypes of the Top 5, where licensed vaccines are not available, the use of autogenous vaccines might be necessary.

In Laying flocks of Gallus gallus the prevalence study has shown that the EU weighted prevalence of laying flocks being positive for S. enteritidis or S. typhimurium or both was 20.3 %. This means that every 5th flock of laying hens in the Community will be affected at the latest when the Commission Regulation regarding intra-community trade and export of eggs will be in place. These restrictions will be implemented either from 1 February 2008 or 1 January 2009. Latest from this date, eggs from laying hens infected with Salmonella enteritidis or Salmonella typhimurium could not be marketed anymore. This will have dramatic effects for the egg industry.

The prevalence study in broilers has demonstrated that the EU weighted prevalence for salmonella spp. was 23.7 % and for Salmonella enteritidis or Salmonella typhimurium or both was 11.0 %. As the Community target in broilers focus only on Salmonella enteritidis and Salmonella typhimurium, in most Member states the targets to be achieved under Regulation (EC) No 2160/2003 will affect the prevalence only partially. But on the other hand Annex II (E) of Regulation (EC) No 2160/2003 defines specific requirements concerning fresh meat. With the effect from 84 months after entry into force of this Regulation (e.g. in 2010), fresh poultry meat from animals listed in Annex I (see table 1) may not be placed on the market for human consumption unless it meets the following criterion: ‘Salmonella: absence in 25 grams’. By this criterion the poultry meat industry is not only challenged in regard to the presence of Salmonella enteritidis and Salmonella typhimurium, but must focus on any type of Salmonella.

Although measure related to the implementation of Regulation (EC) No 2160/2003 might be co-financed with 50% by the European Commission this most probably will be handled by the Member States completely different depending on methods of compensation and reserve-funds available. Therefore, implementation of Regulation (EC) No 2160/2003 remains and continues to be of major economic importance for the poultry industry in the European Community.

Zusammenfassung

Stand der EU-Gesetze zur Kontrolle von Salmonellen und anderen Zoonosen


Table 2: REGULATION (EC) No 2160/2203 on the control of Salmonella and other specified food-borne zoonotic agents

<table>
<thead>
<tr>
<th>Animal population</th>
<th>Prevalence Study</th>
<th>Community Target</th>
<th>Rules for Control Methods</th>
<th>National control programs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laying hens</td>
<td>Council Decision 2004/665/EC 01.10.2004-30.09.2005 Report: EFSA preliminary report 'Analysis of Salmonella in laying hens', 7 April 2006 Se/Stm: EU weighted prevalence 20.3 %</td>
<td>Comm. Reg.(EC) No 1177/2006 An annual minimum percentage of reduction of positive flocks of adult laying hens equal to at least: (v) 10 % if the prevalence was less than 10 %; (vi) 20 % if the prevalence was between 10 and 19 %; (vii) 30 % if the prevalence was between 20 and 39 %; (viii) 40 % if the prevalence was 40 % or more;</td>
<td>Comm. Reg.(EC) No 1168/2006 No use of antimicrobials Requirements for use of live vaccines From 1 January 2008 vaccination against S. enteritidis in countries with prevalence &gt; 10 %</td>
<td>Submitted since 31 December 2007 Approval expected mid 2007 To be applied from 1 February 2008</td>
</tr>
<tr>
<td>Broilers</td>
<td>Council Decision 2005/636/EC 01.10.2005-30.09.2006 Report: EFSA baseline study on the prevalence of Salmonella in broiler flocks Se/Stm: EU weighted prevalence 11.0 %</td>
<td>To be established in April 2007</td>
<td>To be established</td>
<td>To be submitted until 31 December 2007 Presumably to be applied from 1 January 2009</td>
</tr>
<tr>
<td>Turkeys</td>
<td>Council Decision 2006/622/EC 01.10.2006-30.09.2007</td>
<td>To be established in March/April 2008</td>
<td>To be established</td>
<td>To be submitted until 31 December 2008 Presumably to be applied from 1 January 2010</td>
</tr>
</tbody>
</table>

References


Commission Decision 2005/636/EC of 1 September 2005 concerning a financial contribution from the Community towards a baseline survey on the prevalence of Salmonella spp. in broiler flocks of Gallus gallus to be carried out in the Member States. *Official Journal of the European Union* 2005, L 228/14, 03.09.2005


Commission Regulation introducing restrictions on the intra-community trade, export and import of eggs from salmonella infected flocks of laying hens (SANCO/1188/2006)