

## COMMISSION REGULATION (EU) No 517/2011

of 25 May 2011

implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of certain *Salmonella* serotypes in laying hens of *Gallus gallus* and amending Regulation (EC) No 2160/2003 and Commission Regulation (EU) No 200/2010

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard 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 agents<sup>(1)</sup>, and in particular the second subparagraph of Article 4(1), and Article 13(1), thereof,

Whereas:

- (1) The purpose of Regulation (EC) No 2160/2003 is to ensure that 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.
- (2) Regulation (EC) No 2160/2003 provides for Union targets to be established for the reduction of the prevalence of the zoonoses and zoonotic agents listed in Annex I thereto in the animal populations listed therein. It also lays down certain requirements for those targets. Such reduction is important in view of the strict measures which have to be applied to infected flocks in accordance with Regulation (EC) No 2160/2003. In particular, eggs originating from flocks with unknown *Salmonella* status, that are suspected of being infected or from infected flocks, may be used for human consumption only if treated in a manner that guarantees the elimination of *Salmonella* serotypes with public health significance in accordance with Union legislation on food hygiene.
- (3) Annex I to Regulation (EC) No 2160/2003 refers to all *Salmonella* serotypes with public health significance in laying flocks of *Gallus gallus*. Those laying flocks may

spread *Salmonella* infection via their eggs to the consumer. Therefore, a reduction in the prevalence of *Salmonella* in laying flocks contributes to the control of that zoonotic agent in eggs, which is an important public health risk.

- (4) 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 1003/2005<sup>(2)</sup> provides for a Union target for the reduction of the prevalence of *Salmonella Enteritidis* and *Salmonella Typhimurium* in adult laying hens of *Gallus gallus*. The Union target for each Member State is an annual minimum percentage of reduction of positive flocks of adult laying hens by 10 to 40 % depending on the prevalence in the preceding year. Alternatively, a reduction of the maximum percentage to 2 % or less.
- (5) Regulation (EC) No 2160/2003 provides that experience gained under existing national measures and information forwarded to the Commission or to the European Food Safety Authority ('EFSA') under existing Union requirements, in particular in the framework of information provided for in Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC<sup>(3)</sup>, and in particular Article 5 thereof, is to be taken into account when setting the Union target.
- (6) The Community Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks in the European Union in 2008<sup>(4)</sup> showed that *Salmonella Enteritidis* and *Salmonella Typhimurium* are the serovars most frequently associated with human illness. Human cases caused by *S. Enteritidis* decreased markedly in 2008, while an increase in *S. Typhimurium* cases was observed. In accordance with the requirements of Regulation (EC) No 2160/2003, the EFSA has been consulted on the setting of a permanent Union target for laying flocks of *Gallus gallus*.

<sup>(2)</sup> OJ L 211, 1.8.2006, p. 4.

<sup>(3)</sup> OJ L 325, 12.12.2003, p. 31.

<sup>(4)</sup> The EFSA Journal 2010; 8(1):1496.

<sup>(1)</sup> OJ L 325, 12.12.2003, p. 1.

- (7) On 10 March 2010, the Panel on Biological Hazards of EFSA adopted on a request from the Commission a Scientific Opinion on a quantitative estimation of the public health impact of setting a new target for the reduction of *Salmonella* in laying hens<sup>(1)</sup>. It concludes that *Salmonella Enteritidis* is the most successful vertically transmitted zoonotic *Salmonella* serotype in poultry. It also concludes that Union control measures in laying hens have successfully contributed to the control of *Salmonella* infections in production stock and to the reduction of human health risks from poultry.
- (8) Monophasic strains of *Salmonella Typhimurium* have rapidly become one of the most commonly found *Salmonella* serotypes in several species of animals and in clinical isolates of humans. According to the Scientific Opinion on monitoring and assessment of the public health risk of 'Salmonella Typhimurium-like strains'<sup>(2)</sup>, adopted by the Panel on Biological Hazards of EFSA on 22 September 2010, monophasic *Salmonella Typhimurium* strains with the antigenic formula 1,4,[5],12:i:- are considered as variants of *Salmonella Typhimurium* and pose a public health risk comparable to that of other *Salmonella Typhimurium* strains.
- (9) Accordingly, for the purposes of clarity of Union legislation, it is appropriate to amend Regulation (EC) No 2160/2003 and Commission Regulation (EU) No 200/2010 of 10 March 2010 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of *Salmonella* serotypes in adult breeding flocks of *Gallus gallus*<sup>(3)</sup> in order to provide that *Salmonella Typhimurium* include monophasic strains with the antigenic formula 1,4,[5],12:i:-.
- (10) Taking into account the Scientific Opinion of 22 September 2010 and considering that more time is needed to assess the trend of *Salmonella* in flocks after the introduction of national control programmes, it is appropriate to provide for a Union target for the reduction of *Salmonella* in adult laying flocks of *Gallus gallus* similar to the Union target provided for in Regulation (EC) No 1168/2006.
- (11) In order to ascertain progress in the achievement of the Union target, it is necessary to provide for repeated sampling of flocks of adult laying hens of *Gallus gallus*.
- (12) The technical amendments introduced in the Annex to this Regulation are directly applicable and harmonised in Member States, therefore possible adaptations of national control programmes in accordance with this Regulation do not require reapproval by the Commission.
- (13) National control programmes for the achievement of the Union target for 2011 for flocks of adult laying hens of *Gallus gallus* have been submitted for Union co-financing
- in accordance with Council Decision 2009/470/EC of 25 May 2009 on expenditure in the veterinary field<sup>(4)</sup>. Those programmes were based on Regulation (EC) No 1168/2006 and approved in accordance with Commission Decision 2010/712/EU of 23 November 2010 approving annual and multiannual programmes and the financial contribution from the Union for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2011 and following years<sup>(5)</sup>.
- (14) Regulation (EC) No 1168/2006 should be repealed and replaced by this Regulation. The technical provisions in the Annex to Regulation (EC) No 1168/2006 achieve the same results as the Annex to this Regulation. Therefore, Member States would be able to apply the latter immediately without the need of a transitional period.
- (15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

#### Article 1

##### Target

1. The Union target referred to in Article 4(1) of Regulation (EC) No 2160/2003 for the reduction of the prevalence of *Salmonella Enteritidis* and *Salmonella Typhimurium* in adult laying hens of *Gallus gallus* ('Union target') shall be as follows:
- (a) an annual minimum percentage of reduction of positive flocks of adult laying hens equal to at least:
- (i) 10 % where the prevalence in the preceding year was less than 10 %;
  - (ii) 20 % where the prevalence in the preceding year was more than or equal to 10 % and less than 20 %;
  - (iii) 30 % where the prevalence in the preceding year was more than or equal to 20 % and less than 40 %;
  - (iv) 40 % where the prevalence in the preceding year was more than or equal to 40 %;
- or
- (b) a reduction of the maximum percentage equal to 2 % or less of positive flocks of adult laying hens; however, for Member States with less than 50 flocks of adult laying hens, not more than one adult flock may remain positive.

<sup>(1)</sup> The EFSA Journal 2010; 8(4):1546.

<sup>(2)</sup> The EFSA Journal 2010; 8(10):1826.

<sup>(3)</sup> OJ L 61, 11.3.2010, p. 1.

<sup>(4)</sup> OJ L 155, 18.6.2009, p. 30.

<sup>(5)</sup> OJ L 309, 25.11.2010, p. 18.

The Union target shall be achieved every year based on the monitoring of the previous year. As regards the target to be achieved in 2011, the results of the year 2010 based on the monitoring carried out in accordance with Article 1 of Regulation (EC) No 1168/2006 shall be used as reference.

As regards monophasic *Salmonella Typhimurium*, serotypes with the antigenic formula 1,4,[5],12:i:- shall be included in the Union target.

2. The testing scheme necessary to verify progress on the achievement of the Union target is set out in the Annex ('testing scheme').

#### Article 2

##### Review of the Union target

The Union target shall be reviewed by the Commission taking into account the information collected in accordance with the testing scheme and the criteria laid down in Article 4(6)(c) of Regulation (EC) No 2160/2003.

#### Article 3

##### Amendment to Regulation (EC) No 2160/2003

In Annex II to Regulation (EC) No 2160/2003, in Part C, the following subparagraph is inserted:

- '6. All references in this section to '*Salmonella Typhimurium*' shall also include monophasic *Salmonella Typhimurium* with the antigenic formula 1,4,[5],12:i:-.'

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

Done at Brussels, 25 May 2011.

#### Article 4

##### Amendment to Regulation (EU) No 200/2010

In Article 1(1), the first subparagraph is replaced by the following:

- '1. From 1 January 2010, the Union target, as referred to in Article 4(1) of Regulation (EC) No 2160/2003, for the reduction of *Salmonella* spp. in breeding flocks of *Gallus gallus* ("the Union target") shall be a reduction to 1 % or less of the maximum percentage of adult breeding flocks of *Gallus gallus* remaining positive for *Salmonella Enteritidis*, *Salmonella Infantis*, *Salmonella Hadar*, *Salmonella Typhimurium*, including monophasic *Salmonella Typhimurium* with the antigenic formula 1,4,[5],12:i:-, and *Salmonella Virchow* (the relevant *Salmonella* serotypes).'

#### Article 5

##### Repeal of Regulation (EC) No 1168/2006

Regulation (EC) No 1168/2006 is repealed.

References to Regulation (EC) No 1168/2006 shall be construed as references to this Regulation.

#### Article 6

##### Entry into force and applicability

This Regulation shall enter into force on the third day following its publication in the *Official Journal of the European Union*.

For the Commission

The President

José Manuel BARROSO

## ANNEX

**Testing scheme necessary to verify the achievement of the Union target for the reduction of *Salmonella* Enteritidis and *Salmonella* Typhimurium in adult laying hens of *Gallus gallus*, as referred to in Article 1(2)**

## 1. SAMPLING FRAME

The sampling frame shall cover all flocks of adult laying hens of *Gallus gallus* ('laying flocks') within the framework of the national control programmes provided for in Article 5 of Regulation (EC) No 2160/2003.

## 2. MONITORING IN LAYING FLOCKS

## 2.1. Frequency and status of sampling

Laying flocks shall be sampled at the initiative of the food business operator and by the competent authority.

Sampling at the initiative of the food business operator shall take place at least every 15 weeks. The first sampling shall take place at the flock-age of 24 +/- 2 weeks.

Sampling by the competent authority shall take place at least:

- (a) in one flock per year per holding comprising at least 1 000 birds;
- (b) at the age of 24 +/- 2 weeks in laying flocks housed in buildings where the relevant *Salmonella* was detected in the preceding flock;
- (c) in any case of suspicion of *Salmonella* infection when investigating food-borne outbreaks in accordance with Article 8 of Directive 2003/99/EC or any cases where the competent authority considers it appropriate, using the sampling protocol laid down in point 4(b) of Part D to Annex II to Regulation (EC) No 2160/2003;
- (d) in all other laying flocks on the holding in case *Salmonella* Enteritidis or *Salmonella* Typhimurium is detected in one laying flock on the holding;
- (e) in cases where the competent authority considers it appropriate.

A sampling carried out by the competent authority may replace one sampling at the initiative of the food business operator.

## 2.2. Sampling protocol

In order to maximise the sensitivity of the sampling, and to ensure the correct application of the sampling protocol, the competent authority or the food business operator shall ensure that samples are taken by trained persons.

## 2.2.1. Sampling by the food business operator

- (a) In cage flocks, 2 × 150 grams of naturally pooled faeces shall be taken from all belts or scrapers in the house after running the manure removal system; however, in the case of step cage houses without scrapers or belts 2 × 150 grams of mixed fresh faeces must be collected from 60 different places beneath the cages in the dropping pits.
- (b) In barn or free-range houses, two pairs of boot swabs or socks shall be taken.

Boot swabs used must be sufficiently absorptive to soak up moisture. The surface of the boot swab must be moistened using appropriate diluents.

The samples must be taken while walking through the house using a route that produces representative samples for all parts of the house or the respective sector. This shall include littered and slatted areas provided that slats are safe to walk on. All separate pens within a house must be included in the sampling. On completion of the sampling in the chosen sector, boot swabs must be removed carefully so as not to dislodge adherent material.

### 2.2.2. Sampling by the competent authority

At least one sample must be collected using the sampling protocol in addition to samples referred to under point 2.2.1. Further samples shall be taken in order to ensure representative sampling if required by the distribution or the size of the flock.

In the case of sampling referred to in point 2.1(b), (c), (d) and (e), the competent authority shall satisfy itself by conducting further checks, namely by laboratory tests and/or documentary checks as appropriate to ensure that the results of examinations for *Salmonella* in birds are not affected by the use of antimicrobials in the flocks.

Where the presence of *Salmonella Enteritidis* and *Salmonella Typhimurium* is not detected but antimicrobials or bacterial growth inhibitory effects are detected it shall be considered and accounted for as an infected laying flock for the purpose of the Union target.

The competent authority may decide to allow replacement of one faecal sample or one pair of boot swabs by a dust sample of 100 grams collected from multiple places throughout the house from surfaces with a visible presence of dust. As an alternative one or several moistened fabric swab(s) of at least 900 cm<sup>2</sup> surface area in total may be used instead to gather dust from multiple surfaces throughout the house, ensuring that each swab is well coated with dust on both sides.

The competent authority may decide to increase the minimum number of samples in order to ensure representative sampling on a case-by-case evaluation of epidemiological parameters, namely the biosecurity conditions, the distribution or size of the flock or other relevant conditions.

## 3. EXAMINATION OF THE SAMPLES

### 3.1. Transport and preparation of the samples

Samples shall preferably be sent by express mail or courier to the laboratories referred to in Articles 11 and 12 of Regulation (EC) No 2160/2003, within 24 hours after collection. If they are not sent within 24 hours, they shall be stored refrigerated. The samples may be transported at ambient temperature provided that excessive heat (namely over 25 °C) or exposure to sunlight is avoided. At the laboratory the samples shall be kept refrigerated until examination, which must be started within 48 hours following receipt and within 4 days after sampling.

Separate preparations shall be made of the boot swabs and dust or the fabric dust swab in the case of samples by the competent authority, but as regards samples by food business operators the different sample types may be combined in one test.

#### 3.1.1. Boot and fabric swab samples

(a) The two pairs of boot swabs (or 'socks') or dust swabs shall be carefully unpacked to avoid dislodging adherent faecal material, pooled and placed in 225 ml of Buffered Peptone Water (BPW) which has been pre-warmed to room temperature, or the 225 ml of diluent must be added directly to the two pairs of boot swabs in their container as received in the laboratory. The boot/socks or fabric swab shall be fully submersed in BPW to provide sufficient free liquid around the sample for migration of *Salmonella* away from the sample and therefore more BPW may be added if necessary.

(b) The sample shall be swirled to fully saturate it and culture shall be continued by using the detection method set out in point 3.2.

#### 3.1.2. Other faecal and dust material

(a) The faeces samples shall be pooled and thoroughly mixed and a 25-gram sub-sample shall be collected for the culture.

(b) The 25-gram sub-sample (or 50 ml of suspension containing 25 grams of the initial sample) shall be added to 225 ml of BPW which has been pre-warmed to room temperature.

(c) Culture of the sample shall be continued by using the detection method set out in point 3.2.

If ISO standards on the preparation of relevant samples for the detection of *Salmonella* are agreed on, they shall be applied and replace those set out in points 3.1.1 and 3.1.2.

### 3.2. Detection method

The detection of *Salmonella* shall be carried out according to Amendment 1 of EN/ISO 6579-2002/Amd1:2007 'Microbiology of food and animal feeding stuffs – Horizontal method for the detection of *Salmonella* spp. – Amendment 1: Annex D: Detection of *Salmonella* spp. in animal faeces and in environmental samples from the primary production stage' of the International Organization for Standardization.

After incubation the samples in BPW shall not be shaken, swirled or otherwise agitated.

### 3.3. Serotyping

At least one isolate from each positive sample taken by the competent authority shall be serotyped, following the Kaufmann-White-LeMinor scheme. In isolates taken by the food business operators, at least the serotyping for *Salmonella Enteritidis* and *Salmonella Typhimurium* must be carried out.

### 3.4. Alternative methods

With regard to samples taken on the initiative of the food business operator, alternative methods may be used instead of the methods for the preparation of samples, detection methods and serotyping set out in points 3.1, 3.2 and 3.3 of this Annex, if validated in accordance with the most recent version of EN/ISO 16140.

### 3.5. Testing for antimicrobial resistance

The isolates shall be tested for antimicrobial resistance in accordance with Article 2 of Commission Decision 2007/407/EC <sup>(1)</sup>.

### 3.6. Storage of strains

The competent authority shall ensure that at least one isolated strain of the relevant *Salmonella* serotypes from sampling as part of official controls per house and per year is stored for possible future phagetyping or antimicrobial susceptibility testing, using the normal methods for culture collection, which must ensure integrity of the strains for a minimum period of 2 years.

If the competent authority so decides, isolates from sampling by food business operators shall also be stored for these purposes.

## 4. RESULTS AND REPORTING

### 4.1. A laying flock shall be considered positive for the purpose of ascertaining the achievement of the Union target where:

(a) the presence of the relevant *Salmonella* serotypes (other than vaccine strains) has been detected in one or more samples taken in the flock, even if the relevant *Salmonella* serotype is only detected in the dust sample or dust swab; or

(b) antimicrobials or bacterial growth inhibitors have been detected in the flock.

This rule shall not apply in exceptional cases described in Annex II D point 4 of Regulation (EC) No 2160/2003, where the initial *Salmonella* positive result has not been confirmed by that respective sampling protocol.

### 4.2. A positive laying flock shall only be counted once regardless of:

(a) how often the relevant *Salmonella* serotype has been detected in this flock during the production period;

or

(b) whether the sampling was carried out at the initiative of the food business operator or by the competent authority.

However, if sampling during the production period is spread over 2 calendar years, the result of each year shall be reported separately.

<sup>(1)</sup> OJ L 153, 14.6.2007, p. 26.

**4.3. Reporting shall include:**

- (a) the total number of adult laying flocks which were tested at least once during the year of reporting;
- (b) the results of the testing including:
  - (i) the total number of laying flocks positive with any *Salmonella* serotype in the Member State;
  - (ii) the number of laying flocks positive at least once with *Salmonella Enteritidis* and *Salmonella Typhimurium*;
  - (iii) the number of positive laying flocks for each *Salmonella* serotype or for *Salmonella* unspecified (isolates that are untypable or not serotyped);
- (c) explanations of the results, in particular concerning exceptional cases or any substantial changes in number of flocks tested and/or found positive.

The results and any additional relevant information shall be reported as part of the report on trends and sources provided for in Article 9(1) of Directive 2003/99/EC.

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