COMMISSION REGULATION (EU) No 200/2012

of 8 March 2012

concerning a Union target for the reduction of *Salmonella enteritidis* and *Salmonella typhimurium* in flocks of broilers, as provided for in Regulation (EC) No 2160/2003 of the European Parliament and of the Council

(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 [1] and, in particular the second subparagraph of Article 4(1), the second subparagraph of Article 8(1) and the second paragraph of Article 13 thereof;

Whereas:

(1) Regulation (EC) No 2160/2003 aims to ensure that appropriate and effective measures are taken to detect and control, amongst others, *salmonella* at all relevant stages and in particular at the level of primary production, i.e. in flocks, in order to reduce the prevalence of food-borne zoonotic pathogens and thus the risk they pose to public health.

(2) Article 4 (5) of Regulation (EC) No 2160/2003 provides for Union targets to be established for the reduction of the prevalence of all *Salmonella* serotypes with public health significance in broilers. That reduction is key to ensuring that the criteria for *salmonella* in fresh meat of broilers set out in Part E of Annex II to that Regulation and in Chapter 1 of Annex I to Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs [2] can be met.

(3) Regulation (EC) No 2160/2003 provides that the Union target is to include a numerical expression of the maximum percentage of epidemiological units remaining positive and/or the minimum percentage of reduction in the number of epidemiological units remaining positive, the maximum time limit within which the target must be achieved and the definition of the testing schemes necessary to verify achievement of the target. It is also to include a definition, where relevant, of serotypes with public health significance.

(4) 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 [3], and in particular Article 5 thereof, is to be taken into account when setting the Union target.

(5) Article 1 paragraph 1 of 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 1091/2005 [4] sets the target for the reduction of the maximum percentage of flocks of broilers remaining positive for those two *Salmonella* serotypes to 1 % or less by 31 December 2011.

(6) The European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks in 2009 [5] showed that *Salmonella enteritidis* and *Salmonella typhimurium* are the serovars most frequently associated with human illness. Human cases caused by *Salmonella enteritidis* decreased markedly in 2009, while an increase in *Salmonella typhimurium* cases was observed.

(7) In July 2011, the EFSA adopted a Scientific Opinion on a quantitative estimation of the public health impact of setting a new target for the reduction of *Salmonella* in broilers [6]. It concluded that *Salmonella enteritidis* is the most successfully transmitted zoonotic *Salmonella* serotype from parent to offspring in poultry. EFSA also observed that Union control measures in broilers have contributed to a considerable reduction in the number of broiler-associated human salmonellosis cases compared to the situation in 2006. The target should therefore be confirmed.

[1] OJ L 325, 12.12.2003, p. 1.
[2] OJ L 338, 22.12.2005, p. 1.
[3] OJ L 325, 12.12.2003, p. 31.
[4] OJ L 151, 13.6.2007, p. 21.
[5] EFSA Journal 2011; 9(3):2090.
[6] EFSA Journal 2011; 9(7):2106.

(8) Monophasic strains of *Salmonella typhimurium* have developed to be among the most frequently detected *Salmonella* serotypes in several species of animals and in clinical isolates from humans in recent years. EFSA's 2010 Scientific Opinion on monitoring and assessment of the public health risk of "*Salmonella typhimurium*-like strains" adopted on 22 September 2010 [1] also stated that monophasic *Salmonella typhimurium* strains with the antigenic formula 1,4,[5],12:i:-, which includes strains with and without the O5 antigen, have to be considered to be variants of *Salmonella typhimurium* and to pose a public health risk comparable to that of other *Salmonella typhimurium* strains. *Salmonella typhimurium* strains with the antigenic formula 1,4,[5],12:i:- should therefore be included in the target.

(9) To verify whether the Union target has been met, it is necessary to sample flocks of broilers repeatedly. To evaluate and compare the results, it is necessary to describe a common testing scheme to verify whether the Union target has been met.

(10) National control programmes for the achievement of the Union target for 2012 for flocks of broilers 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 [2]. The technical amendments introduced in the Annex to this Regulation are directly applicable. As a result the Commission does not need to re-approve national control programmes implementing this Regulation. A transitional period is therefore not needed.

(11) 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

Union target

1. The Union target, as 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 broilers ('Union target') shall be a reduction of the maximum annual percentage of flocks of broilers remaining positive for *Salmonella enteritidis* and *Salmonella typhimurium equal* to 1% or less.

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 in 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

Repeal of Regulation (EC) No 646/2007

Regulation (EC) No 646/2007 is repealed.

References to the repealed Regulation shall be construed as references to this Regulation.

Article 4

Entry into force

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

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

Done at Brussels, 8 March 2012.

For the Commission
The President
José Manuel BARROSO

[1] EFSA Journal 2010; 8(10):1826.
[2] OJ L 155, 18.6.2009, p. 30.

ANNEX

Testing scheme necessary to verify the achievement of the Union target as referred to in Article 1(2)

1. SAMPLING FRAME

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

2. MONITORING IN BROILERS

2.1. **Frequency of sampling**

(a) Food business operators shall sample all flocks of broilers within three weeks before slaughter.

By way of derogation from the sampling obligation set out in the first subparagraph, the competent authority may provide that food business operators shall sample at least one flock of broilers per round on holdings with more than one flock where:

(i) an all in / all out system is used in all flocks of the holding;

(ii) the same management applies to all flocks;

(iii) feed and water supply is common to all flocks;

(iv) during at least the last six rounds, tests for *Salmonella* spp. according to the sampling scheme set out in the first subparagraph in all flocks on the holding and samples of all flocks of at least one round were carried out by the competent authority;

(v) all results from the testing according to the first subparagraph and point (b) for *Salmonella enteritidis* or *Salmonella typhimurium* were negative.

By way of derogation from the sampling obligations set out in this point the competent authority may authorise sampling in the last six weeks prior to the date of slaughter in case the broilers are either kept more than 81 days or fall under organic broiler production according to Commission Regulation (EC) No 889/2008 ([1]).

(b) The competent authority shall each year sample at least one flock of broilers on 10 % of the holdings with more than 5 000 birds. That sampling may be done on a risk basis and each time the competent authority considers it necessary.

A sampling carried out by the competent authority may replace the sampling by the food business operator as required by point (a).

2.2. **Sampling protocol**

2.2.1. *General instructions for sampling*

The competent authority or the food business operator shall ensure that samples are taken by persons trained for that purpose.

At least two pairs of boot swabs shall be taken for sampling. Boot swabs are put on the boots and the sample is taken by walking around in the poultry house. Swabs from one flock of broilers may be pooled into one sample.

Before putting on the boot swabs, their surface shall be moistened by:

(a) the application of maximum recovery diluents (MRD: 0,8 % sodium chloride, 0,1 % peptone in sterile deionised water);

(b) the application of sterile water;

(c) the application of any other diluents approved by the national reference laboratory referred to in Article 11 (3) of Regulation (EC) No 2160/2003; or

(d) being autoclaved in a container together with diluents.

The way to moisten boot swabs shall be to pour the liquid inside before putting them on or to shake them in a container of diluent.

([1]) OJ L 250, 18.9.2008, p. 1.

It shall be ensured that all sections in a house are represented in the sampling in a proportionate way. Each pair of boot swabs must cover about 50 % of the area of the house.

On completion of sampling, the swabs shall be carefully removed from the boots so as not to dislodge adherent material. Boot swabs may be inverted to retain material. They shall be placed in a bag or pot and labelled.

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, such as biosecurity conditions, the distribution or size of the flock.

If the competent authority approves one pair of boot swabs may be replaced by a dust sample of 100g collected from multiple places throughout the house from surfaces with visible presence of dust. As an alternative, one or several moistened fabric swab(s) of a combined surface of at least 900 cm^2 may be used to gather dust from multiple surfaces throughout the house. Each swab shall be well coated with dust on both sides.

2.2.2. *Specific instructions for certain types of holdings*

(a) For free range flocks of broilers, samples shall only be collected inside the house.

(b) Where access to the houses is not possible due to limited space in flocks with less than 100 broilers, and it is therefore not possible to use boot swabs when walking around, they may be replaced by the same kind of hand fabric swabs that are used for dust, where the swabs are rubbed over surfaces contaminated with fresh faeces, or if this is not feasible, by other sampling techniques for faeces fit for the intended purpose.

2.2.3. *Sampling by the competent authority*

The competent authority shall satisfy itself by conducting further tests and/or documentary checks as appropriate to verify that results are not altered through the presence of antimicrobials or other substances inhibiting the growth of bacteria.

Where the presence of *Salmonella enteritidis* and *Salmonella typhimurium* is not detected but antimicrobials or bacterial growth inhibitory effect are detected, the flock shall be considered to be an infected flock of broilers for the purpose of the Union target referred to in Article 1(2).

2.2.4. *Transport*

Samples shall be sent without undue delay either by via express mail or courier, to the laboratories referred to in Articles 11 and 12 of Regulation (EC) No 2160/2003. During transport they shall be protected from heat over 25°C and exposure to sunlight.

Where it is not possible to send the samples within 24 hours from the time of sampling they shall be stored refrigerated.

3. LABORATORY ANALYSIS

3.1. **Preparation of the samples**

At the laboratory samples shall be kept refrigerated until examination. Examination shall start within 48 hours following the time of receipt of the samples and within four days from the date of sampling.

Dust samples shall be analysed separately. However, the competent authority may decide to pool them with the pair of boot swabs for analysis.

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

The two pairs of boot swabs shall be carefully unpacked to avoid dislodging adherent faecal material, pooled and placed in 225 ml of buffered peptone water (BPW) pre-warmed to room temperature, or 225 ml of diluent is added directly to the two pairs of boot swabs in their container as received in the laboratory.

The boot swabs 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.

If EN/ISO standards on the preparation of faeces for the detection of *Salmonella* are agreed on, they shall replace the provisions on the preparation of samples set out in this point as appropriate.

3.2. **Detection method**

The detection of *Salmonella* spp. shall be carried out according to Amendment 1 of EN/ISO 6579 "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.

3.3. **Serotyping**

At least one isolate from each positive sample taken by the competent authority shall be serotyped, following the current White-Kauffmann-Le Minor scheme.

Food business operators shall ensure that for all isolates, it is at least excluded that they do not belong to the serotypes *Salmonella enteritidis* and *Salmonella typhimurium*.

3.4. **Alternative methods**

With regard to samples taken on the initiative of the food business operator, the methods of analysis provided for in Article 11 of Regulation (EC) No 882/2004 of the European Parliament and of the Council [1], may be used instead of the methods for the preparation of samples, detection methods and serotyping provided for in points 3.1, 3.2 and 3.3 of this Annex, if validated in accordance with EN/ISO 16140.

3.5. **Storage of strains**

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

The competent authority may decide that isolates from sampling by food business operators shall also be stored for future phagetyping or antimicrobial susceptibility testing to provide for isolates to be tested in accordance with Article 2 of Commission Decision 2007/407/EC [2].

4. RESULTS AND REPORTING

4.1. **Calculation of prevalence for the verification of the Union target**

A flock of broilers shall be considered positive for the purpose of verifying the achievement of the Union target, where the presence of *Salmonella enteritidis* and/or *Salmonella typhimurium* (other than vaccine strains) was detected in the flock.

Positive flocks of broilers shall be counted only once per round, irrespective of the number of sampling and testing operations and only be reported in the year of the first positive sampling.

4.2. **Reporting**

Reporting shall include:

(a) the total number of flocks of broilers which were tested at least once during the year of reporting;

(b) the total number flocks positive with any *Salmonella* serotype in the Member State;

(c) the number of broiler flocks positive at least once for *Salmonella enteritidis* and *Salmonella typhimurium* including monophasic strains with the antigenic formula 1,4,[5],12:i:-;

(d) the number of positive broiler flocks for each *Salmonella* serotype or for *Salmonella* unspecified (isolates that are untypable or not serotyped).

The information shall be provided separately for the sampling within the overall national Salmonella control programme as provided for in point 2.1. (a) and (b), the food business operators sampling as provided for in point 2.1. (a) and the competent authorities sampling as provided for in point 2.1. (b).

The results of the tests shall be considered relevant food chain information as provided for in Section III of Annex II to Regulation 853/2004 of the European Parliament and of the Council [3].

[1] OJ L 165, 30.4.2004, p. 1.
[2] OJ L 153, 14.6.2007, p. 26.
[3] OJ L 226, 25.6.2004, p. 22.

At least the following information shall be made available to the competent authority from each flock of broilers tested:

(a) holding reference, remaining unique in time;

(b) house reference, remaining unique in time;

(c) month of sampling.

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 [1].

The food business operator shall notify the competent authority of the confirmed detection of *Salmonella enteritidis* and *Salmonella typhimurium* without undue delay. The food business operator shall instruct the analysing laboratory to act accordingly.

[1] OJ L 325, 12.12.2003, p. 31.