

REGULATIONS

COMMISSION REGULATION (EU) 2019/268

of 15 February 2019

amending Regulations (EU) No 200/2010, (EU) No 517/2011, (EU) No 200/2012 and (EU) No 1190/2012 as regards certain methods for *Salmonella* testing and sampling in poultry

(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 first paragraph of Article 13 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 in particular 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.
- (3) Commission Regulations (EU) No 200/2010⁽²⁾, (EU) No 517/2011⁽³⁾, (EU) No 200/2012⁽⁴⁾ and (EU) No 1190/2012⁽⁵⁾ lay down sampling and testing requirements which are necessary to ensure harmonised monitoring in the achievement of the Union targets for *Salmonella* in poultry populations set out in Regulation (EC) No 2160/2003.
- (4) The European Committee for Standardization and the International Organization for Standardization recently revised a number of reference methods and a protocol to verify compliance with Regulations (EU) No 200/2010, (EU) No 517/2011, (EU) No 200/2012 and (EU) No 1190/2012, therefore these regulations need to be updated accordingly. The update should concern in particular the requirements for the use of alternative methods in light of the revised reference standard protocol EN ISO 16140-2 (validation of alternative methods) and the new reference method for the detection of *Salmonella* (EN ISO 6579-1).

⁽¹⁾ OJ L 325, 12.12.2003, p. 1.

⁽²⁾ 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* (OJ L 61, 11.3.2010, p. 1).

⁽³⁾ 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 (OJ L 138, 26.5.2011, p. 45).

⁽⁴⁾ 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 (OJ L 71, 9.3.2012, p. 31).

⁽⁵⁾ Commission Regulation (EU) No 1190/2012 of 12 December 2012 concerning a Union target for the reduction of *Salmonella* Enteritidis and *Salmonella* Typhimurium in flocks of turkeys, as provided for in Regulation (EC) No 2160/2003 of the European Parliament and of the Council (OJ L 340, 13.12.2012, p. 29).

- (5) Alternative methods appropriately validated against the reference methods are to be considered equivalent to the reference methods. The use of alternative methods is currently limited to food business operators according to point 3.4 of the Annexes to Regulations (EU) No 200/2010, (EU) No 517/2011, (EU) No 200/2012 and (EU) No 1190/2012. However, competent authorities should also have the possibility to use alternative methods, as there is no reason to limit the use of appropriately validated alternative methods to food business operators only.
- (6) Representative sampling for the control of *Salmonella* in flocks of laying hens and breeding hens of *Gallus gallus* is not always practical in enriched cage houses and non-cage multi-tier houses with manure belts between each tier, which are increasingly used for the housing of these birds. It is therefore appropriate to allow an alternative sampling procedure, providing a practical solution for sampling these flocks whilst maintaining at least equivalent sensitivity to current sampling procedures.
- (7) It is appropriate to establish a transitional provision giving food business operators sufficient time to adapt to the revised or new CEN/ISO standards. The transitional provision would also allow food business operators to reduce the burden for the validation of alternative methods in accordance with the new EN ISO 16140-2 on laboratories and on test kit manufacturers, as some certificates based on the previous standard ISO 16140:2003 may still be valid until the end of the year 2021.
- (8) Regulations (EU) No 200/2010, (EU) No 517/2011, (EU) No 200/2012 and (EU) No 1190/2012 should therefore be amended accordingly.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) No 200/2010

The Annex to Regulation (EU) No 200/2010 is amended in accordance with Annex I to this Regulation.

Article 2

Amendments to Regulation (EU) No 517/2011

The Annex to Regulation (EU) No 517/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Amendments to Regulation (EU) No 200/2012

The Annex to Regulation (EU) No 200/2012 is amended in accordance with Annex III to this Regulation.

Article 4

Amendments to Regulation (EU) No 1190/2012

The Annex to Regulation (EU) No 1190/2012 is amended in accordance with Annex IV to this Regulation.

Article 5

Transitional provision

Until 31 December 2021, food business operators may apply the methods referred to in points 3.2 and 3.4 of the Annex to Regulation (EU) No 200/2010, in points 3.2 and 3.4 of the Annex to Regulation (EU) No 517/2011, in points 3.2 and 3.4 of the Annex to Regulation (EU) No 200/2012 and in points 3.2 and 3.4 of the Annex to Regulation (EU) No 1190/2012 applicable before being amended by Articles 1 to 4 of this Regulation.

*Article 6***Entry into force**

This Regulation shall enter into force on the twentieth 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, 15 February 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

The Annex to Regulation (EU) No 200/2010 is amended as follows:

(1) In point 2.2.2.1, the following points (d) and (e) are added:

‘(d) In cage houses where a sufficient amount of faeces does not accumulate on scrapers or belt cleaners at the discharge end of belts, four or more moistened fabric swabs of at least 900 cm² per swab, moistened using appropriate diluents (such as 0,8 % sodium chloride, 0,1 % peptone in sterile deionised water, sterile water or any other diluent approved by the competent authority, shall be used to swab as large a surface area as possible at the discharge end of all accessible belts after they have been run, ensuring each swab is coated on both sides with faecal material from the belts and scrapers or belt cleaners.

(e) In multi-tier barn or free range houses in which most of the faecal material is removed from the house by dropping belts, one pair of boot swabs shall be taken by walking around in littered areas in accordance with point (b) and at least 2 moistened fabric swabs shall be taken as hand-held swabs from all accessible dropping belts, as in point (d).’

(2) In point 3.1, the following point 3.1.5 is added

‘3.1.5. In case of collection of fabric swabs in accordance with point 2.2.2.1(d) or one pair of boot swabs and 2 moistened fabric swabs in accordance with 2.2.2.1(e), pooling shall occur in accordance with point 3.1.3(b).’

(3) In point 3.2, the first paragraph is replaced by the following:

‘The detection of *Salmonella* spp. shall be carried out according to EN ISO 6579-1.’

(4) Point 3.4 is replaced by the following:

‘3.4. Alternative methods

Alternative methods may be used instead of the methods for detection and serotyping provided for in points 3.1, 3.2 and 3.3 of this Annex, if validated in accordance with EN ISO 16140-2 (for alternative detection methods).’

ANNEX II

The Annex to Regulation (EU) No 517/2011 is amended as follows:

(1) Point 2.2.1 is replaced by the following:

‘2.2.1. Sampling by the food business operator

- (a) In cage flocks, 2 × 150 grams of naturally pooled faeces that have accumulated on scrapers or belt cleaners shall be taken from all belts or scrapers in the house after running the manure removal system; however, in the case of 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.

In cage houses where a sufficient amount of faeces does not accumulate on scrapers or belt cleaners at the discharge end of belts, four or more moistened fabric swabs of at least 900 cm² per swab shall be used to swab as large a surface area as possible at the discharge end of all accessible belts after they have been run, ensuring each swab is coated on both sides with faecal material from the belts and scrapers or belt cleaners.

- (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, but not areas outside the house in the case of flocks with outdoor access. 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.

In multi-tier barn or free range houses in which most of the faecal material is removed from the house by dropping belts, one pair of boot swabs shall be taken by walking around in littered areas and at least a second pair of moistened fabric swabs shall be taken from all accessible dropping belts, as in the second paragraph of point (a).

The two samples can be pooled together to form one sample for testing.’

(2) In point 3.1, the following point 3.1.3 is added

‘3.1.3 In case of collection of fabric swabs in accordance with point 2.2.1(a), second paragraph, pooling shall occur in accordance with point 3.1.1.’

(3) In point 3.2, the first paragraph is replaced by the following:

‘The detection of *Salmonella* spp. shall be carried out according to EN ISO 6579-1.’

(4) Point 3.4 is replaced by the following:

‘3.4. **Alternative methods**

Alternative methods may be used instead of the methods for detection and serotyping provided for in points 3.1, 3.2 and 3.3 of this Annex, if validated in accordance with EN ISO 16140-2 (for alternative detection methods).’

ANNEX III

The Annex to Regulation (EU) No 200/2012 is amended as follows:

(1) Point 3.2 is replaced by the following:

‘3.2. Detection method

The detection of *Salmonella* spp. shall be carried out according to EN ISO 6579-1.’

(2) Point 3.4 is replaced by the following:

‘3.4. Alternative methods

Alternative methods may be used instead of the methods for detection and serotyping provided for in points 3.1, 3.2 and 3.3 of this Annex, if validated in accordance with EN ISO 16140-2 (for alternative detection methods).’

ANNEX IV

The Annex to Regulation (EU) No 1190/2012 is amended as follows:

(1) Point 3.2 is replaced by the following:

‘3.2. Detection method

The detection of *Salmonella* spp. shall be carried out according to EN ISO 6579-1.’

(2) Point 3.4 is replaced by the following:

‘3.4. Alternative methods

Alternative methods may be used instead of the methods for detection and serotyping provided for in points 3.1, 3.2 and 3.3 of this Annex, if validated in accordance with EN ISO 16140-2 (for alternative detection methods).’