



Council of the  
European Union

Brussels, 6 November 2018  
(OR. en)

13878/18

AGRILEG 184  
VETER 76  
DENLEG 97

#### COVER NOTE

---

From:	European Commission
date of receipt:	29 October 2018
To:	General Secretariat of the Council

---

No. Cion doc.:	D057409/03
Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Commission Regulations (EU) No 200/2010, (EU) No 517/2011, (EU) No 200/2012 and (EU) No 1190/2012 as regards certain methods for <i>Salmonella</i> testing and sampling in poultry

---

Delegations will find attached document D057409/03.

---

Encl.: D057409/03



Brussels, **XXX**  
SANTE/11696/2017  
(POOL/G4/2017/11696/11696-EN.doc)  
D057409/03  
[...](2018) **XXX** draft

**COMMISSION REGULATION (EU) .../...**

**of **XXX****

**amending Commission 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)

# COMMISSION REGULATION (EU) .../...

of **XXX**

## amending Commission 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<sup>1</sup>, 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<sup>2</sup>, (EU) No 517/2011<sup>3</sup>, (EU) No 200/2012<sup>4</sup> and (EU) No 1190/2012<sup>5</sup> 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) 2160/2003.

---

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

<sup>2</sup> 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).

<sup>3</sup> 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).

<sup>4</sup> 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).

<sup>5</sup> 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).

- (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) Nos 200/2010, 517/2011, 200/2012 and 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).
- (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 colony 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,

*For the Commission*  
*The President*  
*Jean-Claude JUNCKER*