EXPLANATORY MEMORANDUM TO

THE VALIDATING ALTERNATIVE METHODS FOR SALMONELLA TYPING (AMENDMENT) REGULATIONS 2023

2023 No. 793

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department for Environment, Food and Rural Affairs and is laid before Parliament by Command of His Majesty.

2. Purpose of the instrument

2.1 The purpose of this instrument is to amend retained EU legislation to include a reference to a standard adopted by the International Organisation for Standardisation (ISO) for validating alternative methods for salmonella typing in poultry and poultry products.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Extent and Territorial Application

4.1 The extent of this instrument is England and Wales, and Scotland.

4.2 The territorial application of this instrument is England and Wales, and Scotland.

5. European Convention on Human Rights

5.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

6. Legislative Context

6.1 Typing is required to confirm the presence of regulated serotypes of Salmonella in poultry within the regulatory framework of the Salmonella National Control Programme (NCP), which aims to reduce their prevalence and the risk to public health.

6.2 Because of the public health risks posed by Salmonella, many laboratories have transitioned to the Whole Genome Sequencing (WGS) method as it provides much more information than conventional serotyping and facilitates the link between human and animal disease, which is key for aiding in epidemiological outbreak investigations.

6.3 In light of the advantages of WGS, the Animal and Plant Health Agency (APHA) has tested it against conventional serotyping and found the method to have the required level of accuracy. APHA secured accreditation to use WGS for Salmonella testing from the UK Accreditation Service last year.

6.4 Retained EU legislation for the control of Salmonella in poultry and poultry products contains a reference to use of alternative detection methods (ISO – 16140-2) for Salmonella but not alternative typing methods as the ISO chapter had not been finalised (ISO – 16140-6) at the time the legislation was published. The World Organisation for Animal Health Salmonella chapter refers to chapter 6 of the ISO for validation of alternative typing methods for statutory EU control programmes but the NCP legislation itself has not yet been amended to take this into account.

6.5 As the retained EU legislation does not contain the relevant ISO for validating alternative typing methods including WGS, APHA currently uses WGS along with traditional salmonella typing methods for samples from chickens and turkeys. This incurs additional costs and resources. The amendment will permit WGS and other typing methods to be validated in accordance with the ISO standard and will largely remove the need for parallel testing.

6.6 As referenced in section 2, this instrument will allow for the validation of alternative typing methods, such as WGS, for NCP poultry sectors.

7. Policy background

What is being done and why?

7.1 The annexes to the following four regulations will be amended to insert the ISO Code for validating alternative methods for salmonella typing in poultry and poultry products under the NCP:

- 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.
- Commission Regulation (EU) No 517/2011of 25 May 2011implementing 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.
- 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.
- 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.

7.2 Article 4(4)(a) of Regulation (EC) 2160/2003 on the control of salmonella and other specified food-borne zoonotic agents requires the publication of an analysis of the expected costs and benefits of any new target, taking into account the criteria laid down in paragraph 6(c) before making regulations under Article 4(1). This is not applicable as these regulations are not setting a new target.

7.3 Article 4(4)(b) of Regulation (EC) 2160/2003 on the control of salmonella and other specified food-borne zoonotic agents require the data collected in accordance with Article 3(2)(b) to be taken into account before making regulations under Article 4(1).

The data was taken into account and was deemed by the Secretary of State to be not relevant for the purposes of making these Regulations.

Explanations

What did any law do before the changes to be made by this instrument?

7.4 The Regulations for the control of Salmonella in poultry currently do not provide for the relevant ISO code which can validate typing methods.

Why is it being changed?

7.5 To also allow for alternative typing methods when testing for Salmonella in poultry samples under NCPs.

What will it now do?

7.6 Allow alternative typing methods, including WGS, to be validated based on an international standard.

8. European Union Withdrawal and Future Relationship

8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act.

9. Consolidation

9.1 Not applicable to this SI.

10. Consultation outcome

10.1 This is a technical change, it does not need formal consultation, but we have notified stakeholders and received no objection. Devolved administrations have been involved throughout the process as this is a GB-wide SI. Relevant interested departments have also been formally informed.

11. Guidance

11.1 No guidance is required as the alternative typing method is already being used alongside the conventional method for poultry samples. There will be no change in process for businesses.

12. Impact

12.1 There is no, or no significant, impact on business, charities or voluntary bodies.

12.2 The impact on the public sector is positive, as APHA would largely no longer need to run WGS alongside conventional serotyping.

12.3 A full Impact Assessment has not been prepared for this instrument because there would be no additional costs or impact on processing for industry.

13. Regulating small business

13.1 The legislation does not apply to activities that are undertaken by small businesses.

14. Monitoring & review

14.1 The approach to monitoring of this legislation is through the course of normal departmental business.

15. Contact

15.1 Lisa Hoyland at the Department for Environment, Food and Rural Affairs Telephone: 07500 100912 or email: lisa.hoyland@defra.gov.uk can be contacted with any queries regarding the instrument.

15.2 Ronnie Haynes, Deputy Director for Exotic and Endemic Disease Control, at the Department for Environment, Food and Rural Affairs can confirm that this Explanatory Memorandum meets the required standard.

15.3 Lord Benyon at the Department for Environment, Food and Rural Affairs can confirm that this Explanatory Memorandum meets the required standard.