

EXPLANATORY MEMORANDUM TO
THE OFFICIAL CONTROLS (ANIMALS, FEED AND FOOD, PLANT HEALTH
FEES ETC.) REGULATIONS 2019

2019 No. 1488

1. Introduction

- 1.1 This Explanatory Memorandum has been prepared by the Department for Environment, Food and Rural Affairs ('Defra') and is to be laid in the new Parliament by Command of Her Majesty.
- 1.2 This Explanatory Memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

- 2.1 A new EU Regulation applies from 14 December 2019 affecting official controls on compliance with rules on food, feed, animal health, animal welfare, plant health and other aspects of the agri-food chain. This instrument enforces and applies Regulation (EU) 2017/625 ('the new EU Regulation') which replaces Regulation (EC) No 882/2004/ ('the 2004 Regulation'). It replaces the Official Controls (Animals, Food and Feed) (England) Regulations 2006 (S.I. 2006/3472) which partially implemented the 2004 Regulation.
- 2.2 The new EU Regulation aims to create a more comprehensive and consistent risk-based approach to official controls by simplifying and extending the scope current control requirements to the entire agri-food chain. This instrument will contribute to the anticipated benefits of a more efficient and effective control system. By effectively implementing and enforcing the replacement EU official controls regime from 14 December, this instrument will help to improve biosecurity, prevent the spread of animal diseases and uphold the humane treatment of animals. It will also help raise standards of food safety and consumer protection.
- 2.3 Part 6 of this instrument amends secondary legislation relating to plant health fees in England as a result of the application of the new EU Regulation and also Regulation (EU) 2016/2031 of the European Parliament of the Council on protective measures against pests of plants. The latter modernises the plant health regime and replaces current EU legislation for plant health.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

- 3.1 The urgent timescale of this instrument (so that it comes into force on the same date as the new EU Regulation applies on 14 December) and the dissolution of Parliament for the General Election has meant that it has not been possible to lay this instrument in Parliament before it comes into force.
- 3.2 This instrument is being made as an exceptional case during the pre-election period. The new EU Regulation which deals with the verification of official controls will apply from 14 December 2019, and this SI therefore needs to be made as a matter of urgency

- 3.3 This instrument will be laid as soon as the new Parliament in Westminster has been formed after the General Election being held on 12 December 2019.
- 3.4 The consequences of delaying this instrument so that it would not be made until it can be laid in Parliament would result in a failure to meet our legal obligations as an EU Member State, leave enforcement gaps in official controls rules and prevent government agencies from levying fees integral to their financial sustainability.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

- 3.5 As the instrument is subject to the negative resolution procedure there are no matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business at this stage.

4. Extent and Territorial Application

- 4.1 This instrument generally extends to England and Wales only. However, Parts 2 to 4 and regulation 30, and Part 1 so far as it relates to those provisions, extend to the United Kingdom as regards Article 1(2)(i) (organic production and labelling of organic products) and Article 1(2)(j) (use and labelling of protected designations of origin, protected geographical indications and traditional specialities guaranteed) of the Official Controls Regulation.
- 4.2 This instrument generally applies to England and Wales only. However, Parts 2 to 4 and regulation 30, and Part 1 so far as it relates to those provisions, apply to the United Kingdom as regards Article 1(2)(i) (organic production and labelling of organic products) and Article 1(2)(j) (use and labelling of protected designations of origin, protected geographical indications and traditional specialities guaranteed) of the Official Controls Regulation. Regulation 25 of this instrument applies in relation to England and Wales only.
- 4.3 Except for the provisions referred to in sections 4.1 and 4.2 above, this instrument applies to England only.

5. European Convention on Human Rights

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

6. Legislative Context

- 6.1 This instrument is being made to implement the new EU Regulation on official controls and other official activities. The new EU Regulation repeals and replaces the 2004 Regulation on official controls and also replaces a number of other EU Regulations, Directives and Decisions. The new EU Regulation will be directly applicable in the United Kingdom from 14 December 2019. This instrument will ensure enforcement powers are in place to implement the new EU Regulation in England in policy areas covered by Defra. A separate statutory instrument will be made after the General Election being held on 12 December to implement both the new EU Regulation in relation to plant health aspects and the new plant health Regulation (EU) 2016/2031 which applies from the same date. The Food Standards Agency has made related secondary legislation (S.I. 2019/1476) to implement the other food and feed related elements of the new EU Regulation.

- 6.2 The new EU Regulation sets out a framework of requirements for competent authorities in Member States which have responsibilities for organising and performing official controls and other official activities to verify compliance with agri-food chain legislation. The new EU Regulation broadens the scope of the original official food and feed controls set out in the 2004 Regulation to additionally cover plant health and animal by-products legislation (and other agricultural areas such as organic production). This is in order to introduce a more consistent approach to official controls along the entire agri-food chain and to that effect it repeals and amends a number of pieces of EU legislation. In addition, the new EU Regulation provides for a number of empowerments to set out in European Commission tertiary legislation more detailed rules for the performance of official controls and other official activities.
- 6.3 Most of the provisions of the new EU Regulation clarify and simplify existing requirements and aim to introduce a more risk-based approach to controls. Therefore, existing enforcement arrangements in the UK are generally already in line with the new requirements and are therefore replicated as closely as possible with the existing instrument that is being revoked: the Official Controls (Animals, Food and Feed) (England) Regulations 2006.

7. Policy background

What is being done and why?

- 7.1 The objective of the new EU Regulation is to create a more harmonised and consistent risk-based approach to official controls. It does so by simplifying current control rules and by extending those rules to the entire agri-food chain. This instrument will contribute to the anticipated benefits of a more efficient and effective control system. It will improve biosecurity, prevent the spread of animal diseases and uphold the humane treatment of animals. It will also raise food and feed safety standards.
- 7.2 More specifically, effective implementation and enforcement of the replacement EU official controls regime will improve biosecurity, the prevention of spread of animal diseases and the humane treatment of animals together with raising standards of food safety and consumer protection.
- 7.3 This instrument designates the competent authorities responsible for organising and performing official controls and other official activities. It is the Secretary of State and the Food Standards Agency and local authorities who are designated as the competent authorities (primarily the Secretary of State, but with local authorities and the Food Standards Agency also playing a major part in the food and feed sectors). This instrument provides for the sharing of information between designated competent authorities and other Member States for the purpose of applying this instrument and the new EU Regulation.
- 7.4 This instrument designates the Secretary of State on a United Kingdom basis in respect of: organic production and labelling of organic products; and use and labelling of Protected Designation of Origin (PDO), Protected Geographical Indication (PGI) and Traditional Specialities Guaranteed.
- 7.5 This instrument provides for the right of an operator whose animals or goods are subject to sampling and analysis, to a second expert opinion at the operator's own expense. It also provides powers of entry for auditors carrying out audits.

- 7.6 The Secretary of State can require the audit of designated authorities, and to appoint the Food Standards Agency to carry out such audits. There is provision to recover expenses incurred by designated authorities for performing certain official controls on business operators.
- 7.7 Part 5 of this instrument makes necessary consequential amendments to secondary legislation relating to animals, food and trade in England to revise and update references to EU legislation that will be repealed or amended by the new EU Regulation. The Trade in Animals and Related Product Regulations 2011 are substantially amended to take account of changes to the EU legislation covering import procedures.
- 7.8 Part 6 of this instrument introduces amendments to plant health related fee instruments, including the Plant Health etc. (Fees) (England Regulations 2018 and the Plant Health (Fees) (Forestry) (England and Scotland) Regulations 2015. The effect is to revise and update references to EU legislation that will be repealed or amended as a result of the application of the new EU Regulation and Regulation (EU) 2016/2031 of the European Parliament of the Council on protective measures against pests of plants. Existing fees are not being changed by this instrument.

8. European Union (Withdrawal) Act 2018/Withdrawal of the United Kingdom from the European Union

- 8.1 This instrument does not relate to withdrawal from the European Union, and therefore does not trigger the statements required under the European Union (Withdrawal) Act 2018.

9. Consolidation

- 9.1 This instrument, the Official Controls (Animals, Feed and Food, Plant Health Fees etc.) Regulations 2019, revokes and replaces the Official Controls (Animals, Food and Feed) (England) Regulations 2006. Minor consequential amendments are made in Part 5 of this instrument to several Defra related statutory instruments, which are primarily to update references to the replacement EU legislation. There are substantial changes made by Regulation 26 to the Trade in Animals and Related Products Regulations 2011 in order to take account of the main directives dealing with veterinary checks being revoked and replaced by the new EU Regulation and Implementing and Delegated EU Regulations. Defra is planning to consolidate these instruments the next time they require more than minor amendment. Part 6 amends several plant health fee related provisions and consolidation of those instruments will be considered when the fees are next amended.

10. Consultation outcome

- 10.1 No consultation has been undertaken as there are no significant impacts. This instrument makes no significant changes to current official control practices and the plant health fees are in line with principles of full cost recovery of EU inspection and checking requirements.

11. Guidance

- 11.1 Guidance and information material have been published on Defra's website for businesses and further guidance material will be prepared for competent authorities.

12. Impact

- 12.1 The impacts on businesses, charities or voluntary bodies are total costs of £3.1m, which are the one-off transition costs to stakeholders of familiarising themselves with the new EU Regulation. The Government is mitigating these impacts by providing clear advice on gov.uk, running stakeholder workshops and ensuring customer helplines are in place for all new systems. There have been no ongoing costs or benefits identified to businesses, charities or voluntary bodies.
- 12.2 The impact on the public sector is a one-off transition cost of £13,000, which is the costs of familiarisation to enforcement authorities involved in enforcing the new EU Regulation.
- 12.3 A full Impact Assessment has not been prepared for this instrument because the monetised impacts assessed are one-off transition costs of £3.1m, and there are no ongoing impacts on business. The costs to business are one-off transition costs of £3.1m which if we annualise over the 10-year appraisal window is £0.3m per year. A full Impact Assessment is only required if the estimated annual net direct cost to business (the equivalent annual net direct cost to business or 'EANDCB') is plus or minus £5m per year.

13. Regulating small business

- 13.1 This legislation applies to activities that are undertaken by small businesses.
- 13.2 This legislation applies equally to all businesses as in principle compliance with agri-food chain legislation does not depend on the size of businesses.

14. Monitoring & review

- 14.1 A statutory review clause is included in the instrument in line with the requirements of the Small Business, Enterprise and Employment Act 2015.

15. Contact

- 15.1 Donatella Howe at the Department for Environment, Food and Rural Affairs: Donatella.howe@defra.gov.uk can be contacted with any queries regarding the instrument.
- 15.2 Nicola Spence, Deputy Director for plant and bee health, at the Department for Environment, Food and Rural Affairs can confirm that this Explanatory Memorandum meets the required standard.
- 15.3 Lord Gardiner at the Department for Environment, Food and Rural Affairs can confirm that this Explanatory Memorandum meets the required standard.