EXPLANATORY MEMORANDUM

THE VETERINARY MEDICINES (AMENDMENT) REGULATIONS 2012

2012 No. 2711

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

2. Purpose of the Instrument

2.1 This instrument makes amendments in Schedule 5 of the Veterinary Medicines Regulations 2011 (S.I. 2011 No. 2159) in order to:-

2.2 a) correct an error to provide for the implementation of the feed hygiene rules and principles contained in Regulation 183/2005 to establishments manufacturing medicated feedingstuffs.

b) correct the omission of an offence related to the supply of complementary feedingstuffs.

c) delete reference to a repealed Council Directive 76/371 and replace it with Commission Regulation (EC) 152/2009 which lays down the Methods of Sampling and Analysis for the Official Control of Feed.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1. None.

4. Legislative Context

4.1 The VMR provide a single comprehensive set of controls on all aspects of veterinary medicines, medicated feeds and specified feed additives.

4.2 This instrument is being made to:-

a) properly implement the feed hygiene rules and principles of Regulation 183/2005;

b) remedy the omission of an offence relating to the supply of complementary feedingstuff in accordance with approval and registration requirements under EC Regulation 183/2005; and

c) amend a reference to Council Directive 76/371 which has been repealed and replaced by Commission Regulation (EC) 152/2009 laying down the Methods of Sampling and Analysis for the Official Control of Feed.

5. Territorial Extent and Application

5.1 This Instrument applies to the United Kingdom.

6. European Convention on Human Rights

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

7. Policy Background

7.1 **Amendment a)** Article 4 of Directive 90/167 which lays down the conditions governing the preparation, placing on the market and use of medicated feeds in the Community requires medicated feed manufacturers and distributors to operate from premises that have been previously approved by the competent authorities and that the entire manufacturing process must comply with the manufacturing hygiene rules and principles of the Member State in question.

7.2 Regulation (EC) No 183/2005 lays down the approval and feed hygiene requirements for manufacturers and distributors of feed additives. Medicated feeds do not come under the scope of Regulation 183/2005. The VMD considered that the manufacturing hygiene rules and principles contained in this Regulation should be extended to medicated feeds and therefore in accordance with the requirements of Article 4 of Directive 90/167, these rules and principles were laid out in the VMR 2005 and implemented on 1 January 2006.

7.3 During the remaking of the SI an error occurred which resulted in the omission of feed hygiene rules and principles for approval of manufacturing establishments.

7.4 This error could potentially affect the VMD's ability to carry out suitable enforcement action on manufacturing establishments who are not complying with feed hygiene rules. This needs to be remedied as soon as possible.

7.5 **Amendment b)** In the VMR 2011 we implemented Article 8 of EC Regulation 767/2009. This introduced a level of incorporation of specified feed additives (SFA) into feed which would result in a complementary feed.

7.6 Provision for these feeds was made in the VMR. However, we omitted to attribute an offence to the supply conditions set out. The Parliamentary Committee on SIs noticed the omission when VMR 2011 was being considered. As it was plainly intended to have a sanction for non-compliance, we assured Parliament that this would be remedied at the next opportunity.

The Ministry of Justice has confirmed that this does not need to go through the Gateway.

7.7 **Amendment c)** We have taken the opportunity to amend the reference to an EU Directive which has subsequently been repealed and replaced by a directly implemented EU Regulation.

8. Consolidation

8.1 The VMR is currently being reviewed and a consolidated version will come into force on 1 October 2013.

9. Consultation outcome

9.1 As this instrument (i) corrects errors in the 2011 VMR and amendment a) was consulted on in 2005 and amendment b) in 2011; and (ii) amendment c) makes provision for technical amendments in a directly implemented EU Regulation, there has been no formal consultation on this instrument.

10. Guidance

10.1 No additional guidance is required for this amending SI.

11. Impact

11.1 Manufacturers and distributors of medicated feeds have been complying with the feed hygiene rules and principles of Regulation 183/2005 since January 2006. There are no changes and therefore no impact.

11.2 The impact of correcting the absence of an offence in paragraph 17 of Schedule 5 will mean that the enforcement authority will be able to enforce the VMR regarding on-farm manufacturers who mix complementary feeds with other feeds and who do not comply with the conditions of paragraph 17.

12. Regulating small business

12.1 The legislation applies to small businesses.

12.2 The legislation applies to large and small businesses. Small businesses would tend to be farmers mixing medicated feed for their own animals. Their views would have been represented, amongst others, by the National Farmers Union who took part in the original consultation exercises. The activities of the smaller businesses and the fact that they are not selling on the medicated feed for a third party are taken account of in a risk based inspection programme making the costs, inspection and frequency of inspection proportionate to the business concerned.

13. Contact

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