EXPLANATORY MEMORANDUM TO

THE ANIMALS AND ANIMAL PRODUCTS (EXAMINATION FOR RESIDUES AND MAXIMUM RESIDUES LIMITS) (AMENDMENT) REGULATIONS 2013

2013 No. 804

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.

This memorandum contains information for the Joint Committee on Statutory Instruments

2. Purpose of the instrument

2.1 These Regulations amend the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations 1997 (S.I. 1997/1729) (the principal legislation) to provide for the enforcement of EU Regulation 470/2009 (laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin) and EU Regulation 37/2010 (on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin), which repeal and replace EU Regulation 2377/90.

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

3.1 Regulation 470/2009 lays down provisions on establishment and review of Reference Points for Action (RPAs). RPAs were set out in 2005 by Commission Decision 2005/34/EC. They are the concentrations of residues of certain substances, the use of which is unauthorised or prohibited in the EU. Member States are prevented from taking enforcement action where residues of those substances are found below the RPA in food of animal products imported into the EU from third countries. The principle of RPAs was extended informally to animal products produced in the EU by agreement among the Member States. These RPAs have been applied administratively by the UK authorities

3.2 As regards RPAs Article 23 of Regulation 470/2009 provides that food of animal origin containing residues of a pharmacologically active substance shall be considered not to comply with Community legislation “except where a reference point for action has been set for that substance pursuant to this Regulation”.

3.3 These Regulations implement the requirements of Regulation 470/2009 relating to RPAs. However, the RPAs laid down by Commission Decision 2005/34/EC are not established pursuant to Regulation 470/2009. The Commission has clarified that it expects the RPAs set out in 2005 to continue to be applied. It is therefore considered appropriate to continue to apply them by administrative means whilst the Commission regularises the position.

4. Legislative Context

4.1 The surveillance of animals and animal products for residues of veterinary medicinal products and certain other substances is a requirement under EU Law (Council Directive 96/23/EC).

5. Territorial Extent and Application

5.1 This instrument applies to Great Britain.

6. European Convention on Human Rights

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

7. Policy background

- ***What is being done and why***

7.1 These Regulations amend provisions of the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations 1997 (S.I. 1997/1729) to provide for the enforcement of Regulation 470/2009 and Regulation 37/2010 which repeal and replace Council Regulation (EEC) 2377/90, which set out an EU procedure for establishing Maximum Residue Limits for veterinary medicinal products for use in food producing animals.

7.2 In the years following the introduction of Regulation 2377/90 it became apparent that the system established by Regulation 2377/90 was too stringent for pharmaceutical companies to maintain some existing veterinary medicinal products for food producing animals, particularly for minor species, and these were removed from the market. Also, because it was harder to obtain a Marketing Authorisation for a product, fewer applications came forward. In a bid to increase the availability of veterinary medicinal products Regulation 470/2009/EC introduced a number of new measures to try and increase the number of substances with MRLs without reducing consumer safety.

- ***Consolidation***

7.3 The Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations 1997 are being reviewed with a view to being consolidated during 2013/14, with the aim of producing a single, simplified Regulation. It is envisaged that this process will include the introduction of legislative measures in relation to RPAs (referred to in 3 above) in the expectation that the Commission will have produced proposals for a clear legal basis by then.

8. Consultation outcome

8.1 A 12-week public consultation was held for the amendments incorporated in these Regulations. Two substantive responses were received from the 340 organisations

and individuals consulted. However, these did not address the changes made to the Regulations, but rather the effect of the EU legislation and how this may improve the availability of authorised veterinary medicinal products.

9. Guidance

9.1 No guidance on the amendment is necessary.

10. Impact

10.1 There is no foreseen impact on business, charities or voluntary bodies as a result of this amendment.

10.2 The impact on the public sector is that the ability to enforce controls relating to the monitoring of veterinary residues in food-producing animals, and their products, will be maintained.

10.3 An Impact Assessment has not been prepared for this instrument.

11. Regulating small business

11.1 The legislation applies to small businesses.

12. Monitoring and review

12.1 These Regulations will be subject to review before the end of the period of five years beginning with 6 May 2013. However, the principal legislation is being reviewed and will be consolidated during 2013/14, with the aim of producing a single, simplified Regulation. It is expected therefore that this will have been completed before the need to review these Regulations arises.

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