EXPLANATORY MEMORANDUM TO

THE FEEDING STUFFS (APPLICATION TO ZOOTECHNICAL ADDITIVES, ETC.) (SCOTLAND) REGULATIONS 2005

2005 No. 3362

1. This Explanatory Memorandum has been prepared by the Food Standards Agency and is laid before Parliament by Command of Her Majesty.

2. Description

2.1 This instrument provides for the enforcement of Community legal requirements relating to certain feed additives in Scotland which are currently reserved to Westminster by section J4 of Schedule 5 to the Scotland Act 1998.

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

3.1 Currently a section 63 Scotland Act Order relating to non-medicinal animal feed additives is progressing through both Westminster and the Scottish Parliament and is due to be made at Privy Council on 14 February 2006. The Scotland Act (Transfer of Functions to the Scottish Ministers etc.) Order 2006 will *inter alia* transfer functions to Scottish Ministers allowing them to regulate certain zootechnical animal feed additives along with the other non-medicinal animal feed additives that are already devolved. Until the Order is made, the Feeding Stuffs (Application to Zootechnical Additives, etc.) (Scotland) Regulations 2005 will enable zootechnical animal feed additives in the functional groups (a), (b) and (c) ("the three functional groups") in paragraph 4 of Annex I to Regulation (EC) No.1831/2003 on feed additives to be regulated in Scotland when it comes into force on 1 January 2006. This Regulation categorises digestibility enhancers (functional group (a)), gut flora stabilisers (functional group (b)) and substances which favourably affect the environment (functional group (c)) as zootechnical additives for the first time.

3.2 Once the section 63 Order comes into force, the Feeding Stuffs (Application to Zootechnical Additives etc.) (Scotland) Regulations 2005 will be revoked as soon as practically possible thereafter.

4. Legislative Background

4.1 The regulation of the safety and standards of animal feed is generally devolved. Legislation is made for Scotland by the Scottish Ministers on the advice of the Food Standards Agency ("FSA"). An exception to that is the regulation of veterinary medicines and medicinal additives incorporated in animal feed, which is carried out by the Veterinary Medicines Directorate ("VMD"), an executive agency of DEFRA. The domestic law regulating such matters has recently been restructured in the Veterinary Medicines Regulations 2005 ("the 2005 Regulations"). This restructuring is not, however, reflected in the reservation of veterinary medicines under section J4 of Schedule 5 to the Scotland Act 1998, which reserves the subject matter of the Medicines Act

1968 and the Marketing Authorisations of Veterinary Medicinal Products Regulations 1994 as those enactments stood as at 1 July 1999.

4.2 The VMD and the FSA have agreed that additives which do not have a medicinal effect on the animals that consume them should be regulated within the framework of animal feed law. They consider that the feed additives in the three functional groups have no medicinal effect on the animals which consume them. They are not controlled by the 2005 Regulations.

4.3 It is therefore necessary to ensure that any animal feed additives not regulated by the under the 2005 Regulations can be regulated by the Scottish Ministers for Scotland alongside their existing devolved functions in this area. The draft section 63 Scotland Act Order will address the restructuring of regulatory functions in the 2005 Regulations by transferring to the Scottish Ministers powers to regulate non-medicinal feed additives in so far as those are not already devolved.

4.4 The additives in the three functional groups are not regulated under the 2005 Regulations but may fall within the broad definition of a medicine for the purposes of the 1968 Act. They enable the animal to digest its food more efficiently, and lower the environmental impact of farm animals (for example, by reducing the production of methane by cows). There is no impact upon the health of the animal itself. It is necessary to ensure that any feeding stuffs or feed additives not regulated by the VMD can be regulated by Scottish Ministers alongside their existing devolved functions in this area. Feeding stuffs and feed additives which do have a medicinal effect on animals and veterinary medicinal products will continue to be regulated on a UK basis by the VMD.

4.5 It is anticipated that the Scotland Act Order transferring the necessary powers to the Scottish Ministers will be made at Privy Council in February 2006.

4.6 The Feeding Stuffs (Application to Zootechnical Additives, etc.) (Scotland) Regulations 2005 enable animal feed additives to be regulated in Scotland from 1 January 2006, until the section 63 Scotland Act Order is made. Specifically, they allow for the enforcement of the following Regulations in so far as they apply to non-medicinal feed additives:

- EC Regulation 1829/2003 of the European Parliament and of the Council on genetically modified food and feed;
- EC Regulation 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition;
- EC Regulation 183/2005 of the European Parliament and of the Council laying down requirements for feed hygiene; and
- EC Regulation 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with food and feed law, animal health and welfare rules.

5. Extent

5.1 This instrument extends to Scotland only.

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 It is agreed between VMD and FSA that additives which do not have a medicinal effect on the animals that consume them should be regulated within the framework of animal feed law rather than veterinary medicines legislation. The policy objective of this instrument is to ensure that in light of the reservation of medicines under the 1998 Act, and following the new EC classification of feed additives in EC Regulation 1831/2003, the law in relation to all non-medicinal animal feed additives in Scotland is fully enforced. The Regulations are designed to be a temporary measure and it is intended that they will be revoked as soon as possible after the Scotland Act Order comes into force.

8. Impact

8.1 A Regulatory Impact Assessment has not been prepared for this instrument as it has no impact on business, charities, voluntary bodies or the public sector.

9. Contact

9.1 Any queries in respect of the instrument can be answered by Joseph Nicholas at the Food Standards Agency, telephone 020-7276-8462 or e-mail: joseph.nicholas@foodstandards.gsi.gov.uk.