EXPLANATORY MEMORANDUM TO

THE ANIMALS AND ANIMAL PRODUCTS (EXAMINATION FOR RESIDUES AND MAXIMUM RESIDUE LIMITS) (AMENDMENT) REGULATIONS 2006

2006 No. 755

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

This memorandum contains information for the Joint Committee on Statutory Instruments

2. Description

2.1 This instrument extends the ban on the use of hormonal growth promoters to prohibit the use of oestradiol 17ß and its ester-like derivatives for oestrus induction in cattle, sheep, pigs and goats from October 2006. There remain a small number of other lawful therapeutic uses in cattle for these products.

3. Matters of Special Interest to the Joint Committee on Statutory Instruments

3.1 This SI, amongst other things, implements changes to the Animals and Animal Products (Examination For Residues and Maximum Residue Limits) Regulations 1997 SI 1729 - the "Residues Regulations" recommended by the JCSI in its 11th report of the 1997/98 session. It also makes two minor changes to harmonise with the Veterinary Medicines Regulations 2005 SI 2745 (which came into force in October 2005).

3.2 The changes recommended by the JCSI are to:-

- make rebuttable a presumption that animals commonly used for human consumption to which beta-agonists were administered, or products derived there-from are intended for human consumption (regulation 2(3)(d)):

- clarify upon whom an authorised officer may serve a notice specifying the test result of a sample analysed for residues (regulation 2(9)):

- clarify in which circumstances and upon whom an authorised officer may serve a notice requiring the detention of animals for inspection purposes (regulation 2(11)):

- apply the statutory maximum penalty for offences tried summarily (rather than level 5 on the standard scale) (regulation 2(12)(iii)):

- clarify that section 32 of the Food Safety Act 1990 (1990 c16) is applied for the purposes of the Regulations (regulation 2(20)(b)):

3.3 Harmonising involves the revocation

- of the prohibition on administering substances not mentioned in Annexes I, II or III of Council Regulation (EEC) No 2377/90, as an equivalent prohibition is found in regulation 8(1) of the "Residues Regulations", read with the paragraph 2(1) of schedule 1 to the Veterinary Medicines Regulations 2005;
- of the regulation 32(1) record keeping requirements, which requirements are imposed in regulation 19 of the Veterinary Medicines Regulations 2005; and

- of the regulation 33 power to suspend a manufacturing authorisation in specified circumstances, which power is contained in paragraph 5(1) of schedule 2 to the Veterinary Medicines Regulations 2005.

4. Legislative Background

4.1 Council Directive 96/22/EC, which is implemented in the UK by the "Residues Regulations" contains a prohibition on the sale, possession or administration of any beta-agonist or hormonal substance unless it is a specifically authorised veterinary medicinal product. One of the authorised substances is oestradiol 17ß – a hormonal substance which helps the reproductive cycle of cows.

4.2 Council Directive 96/22 has been amended by Directive 2003/74. Article 4 of this Directive requires the use of all products containing oestradiol 17ß, or its derivatives, to be phased out for oestrus induction in cattle, horses, sheep and goats by October 2006. There will remain three specific lawful therapeutic uses in cattle for these products viz for the treatment of pyometra, foetus maceration and mummification. Thus products containing oestradiol 17ß cannot be used in horses, sheep or goats after October 2006.

4.3 This instrument therefore amends the "Residues Regulations" to implement the changes required by Directive 2003/74/EC. Implementation was required by October 2004 so transposition into GB legislation is late.

4.4 These amendments Regulations also take the opportunity to remove duplication following the adoption of the Veterinary Medicines Regulations 2005 SI 2745 which implemented Council Directive 2001/82/EC.

5. **Extent**

5.1 This instrument applies to Great Britain. Northern Ireland is introducing parallel legislation to the same timescale.

6. European Convention on Human Rights

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

7. **Policy Background**

7.1 The EU has banned the use of hormonal growth promoters in all food-producing animals since 1988. This means that non-EU countries wishing to export to the EU must offer equivalent guarantees in respect of their produce. The UK has consistently voted against the ban on the grounds that it could not be justified scientifically, but nevertheless has always implemented it.

7.2 The Government is continuing to fulfil its EU obligations by bringing forward legislation to enforce the proposals agreed by the Council and European Parliament.

7.3 Although this amendment is a relatively small extension of the hormones ban, the ban is nevertheless a highly political issue which attracts media interest. There is a long-running trade dispute over the use of growth promoting hormones in food-producing animals in some non-EU countries. The issue was first brought before the WTO by the US and Canada in 1998. The WTO disputes settlement body decreed at the time that the European Community did not have the scientific evidence to justify the ban. However, the Commission believes that it now has the evidence to underpin the ban and has returned to the WTO. A WTO Hormones Panel was set up in June 2005 to hear the case. It is expected that the panel will report in October 2006.

7.4 A twelve-week consultation period on the draft Statutory Instrument has taken place. Over two hundred organisations in Great Britain were consulted. Two responses were received.

- The British Equestrian Veterinary Association would be concerned if oestradiol 17β was not legally available in the UK for use in horses, and considered it was commonly used in horse reproductive medicine.

- Stock First, a company involved in artificial insemination who use synchronisation programs, were concerned at the loss of oestradiol benzoate which they regularly use to synchronise oestrus in cattle and which they feel has significant benefits.

7.5 There was no response to the consultation from other interested organisations who might have been expected to respond. Whilst there are some UK Government concerns about the potential impact on animal welfare of these changes the level of response to the consultation exercise suggests that those concerns are not shared by the majority of the industry.

8. Impact

8.1 A Regulatory Impact Assessment is attached to this Memorandum.

9. Contact

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can answer any queries regarding this instrument.

TRANSPOSITION NOTE

The Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations 1997 SI 1729 implement:

- Directive 96/22/EC (OJ L125 23.5.96) concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and on beta-agonists. This repeals Directives 81/602/EEC, 88/146/EC and 88/299/EC.

- Directive 96/23/EC (OJ L125 23.5.95) on measures to monitor certain substances and residues thereof in live animals and animal products. This repeals Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EC.

- Council Regulation EEC/2377/90 (OJ L224 18.8.90) - enforcement and execution of the prohibition in Articles 5 and 14 of this Regulation.

The Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (Amendment) Regulations 2006

- Amend provisions of Articles 1-8 of The Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations 1997 SI 1729, which give effect to Council Directive 96/23/EC, to take account of amendments made to that Directive by Directive 2003/74/EC (OJ L262 14.10.03) (regulations 2(3) (c) (4), (5), (13)-(17)).

- Regulations making reference to amended and/or new Community legislation have, been updated or inserted (regulations 2(a) (b)(i) and (ii), 9(e), (f), (g) and (q)).

- Provisions that duplicate those of the Veterinary Medicines Regulations 2005 SI 2745 (which implement Directive 2001/82/EC of the European Parliament and the Council) have been revoked (regulations 2(6)(a), (18)(a) and (19)).

REGULATORY IMPACT ASSESSMENT

The Animals and Animal Products (Examination for Residues and Maximum Residues Limit) (Amendment) Regulations 2006

Purpose and intended effect of the proposal

Issue:

Directive 2003/74

Council Directive 2003/74/EC introduces a small extension to the EU Hormones ban, which has been in place since 1988. The hormones ban is enforced in Great Britain by the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations 1997 SI 1729 (the "Residues Regulations"). Despite the EU hormones ban, some zootechnical (oestrus induction) and therapeutic treatments with hormonal substances, such as oestradiol 17ß, have been allowed under Community law. However, Directive 2003/74 requires the use of all products containing oestradiol 17β for oestrus induction in cattle, horses, sheep or goats or its derivatives to be phased out by October 2006 and also limits its other permissible therapeutic uses to three specific treatment types – viz for treatment of pyometra, foetus maceration and mummification in cattle only. Thus products containing oestradiol 17β cannot be used at all in horses, sheep or goats after October 2006.

Other amendments are included in this Statutory Instrument (SI). These result from the scrutiny by the Joint Committee on Statutory Instruments (JCSI) on the Residues Regulations and the recent introduction of the new Veterinary Medicines Regulations 2005 SI 2745. These changes aim to clarify the meaning of the legislation and do not affect the operation of the law or add costs to industry.

Objectives:
To meet our obligations under Directive 2003/74/EC of the European Parliament and Council. To make minor amendments to comply with the recommendations of the JCSI and clarify the Residues Regulations.

*Risk assessment**:***
If the amendment relating to Directive 2003/74/EC is not introduced, the UK will not be fulfilling its obligations under Community law. This would risk infraction proceedings against the UK by the Commission**.**

Options:

1. **To not make the amendments** – the UK would not be fulfilling its obligations under Community law.
2. **To make the amendments in relation to the Directive 2003/74, but not the two sets of minor amendments** – the UK would meet its EU obligations, but by not clarifying the legislation the JCSI will remain unhappy and express concern over the SI.

3. **To make the amendments in relation to Directive 2003/74, JCSI recommendations and the Veterinary Medicines Regulations 2005 –** The UK would meet its EU obligations and clarify the existing law.

Issues of equity and fairness:

All EU Member States are required to implement the ban on the use of oestradiol 17ß - based substances for oestrus induction in farm animals and the further restrictions in the use of this and related substances.

Benefits:

By implementing Directive 2003/74/EC, we will be fulfilling our obligations under Community law. We will, therefore, avoid infraction proceedings by the Commission.

The other amendments relating to the JCSI recommendations and the Veterinary Medicines Regulations will simplify and clarify the existing law for the benefit of our stakeholders.

Compliance Costs:

Business sectors affected:
Currently there is one authorised product containing an oestradiol-related substance for oestrus induction in food-producing animals. This is PRID, which is used in beef and dairy cattle to stimulate ovarian activity in anovulary and suboestrus animals. The company has reformulated the product to remove the oestradiol-related substance. A marketing authorisation (MA) was granted for the reformulated product in January 2006.

Compliance Costs for a "typical" business:

It is very difficult to estimate the costs of typical business. Despite asking consultees for information on the possible costs of the removal of oestradiol-based substances for business, none identified any costs. We therefore believe that any extra costs to the livestock industry will be small. The company marketing PRID will have had to invest in repackaging and generating new data to support its application for an MA. Also, there are alternative medicinal products for oestrus induction in cattle; for example, Prostavet and Prosolvin, based on prostaglandin analogues.

However, in the consultation, two organisations expressed concern over the removal of oestradiol-based substances for oestrus control. This may be because prostaglandins have to be administered at the precise moment to be effective, whilst oestradiol-related substances give more leeway. It is, therefore, possible that there could be a longer period between calvings for such animals.

Impact on small business:
As above, for the small proportion of anoestrus cows there may be a longer period between calvings in anovulary and suboestrus animals. With the prostaglandin-based alternative medicinal products available to veterinarians and farmers, we do not believe any extra costs to be large.

Other Costs:
We can identify no other costs associated with the amendments.

Results of Consultations:
Two responses to the Consultation Exercise were received.

- The British Equestrian Veterinary Association would be concerned if oestradiol were not legally available in the UK for use in horses as it considered its use commonplace in horse reproductive medicine.
- Stock 1st, a company involved in artificial insemination that uses synchronisation programs, was concerned at the loss of oestradiol benzoate which it regularly uses to synchronise oestrus in cattle and they feel has significant benefits.

No comments were received over the possible costs of the proposal.

Summary and recommendations:

The UK is required by EU law to implement Directive 2003/74. We estimate that the costs to the livestock industry will be small. There would also have been costs to the company in reformulating PRID and gaining its revised marketing authorisation which was granted in January 2006. The two sets of technical amendments are deregulatory. Therefore, it is recommended that the amending SI is approved and made law.

Enforcement, sanctions, monitoring and review:

Some of these changes will have a very minor impact on enforcement and sanctions, but not on monitoring and review arrangements.

Contact Point:
Enquiries and comments on this compliance cost assessment should be addressed to:

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Declaration:

I have read the Regulatory Impact Assessment and I am satisfied that the balance between cost and benefit is the right one in the circumstances.

Signed by the responsible Minister: .....

Date : .....