EXPLANATORY MEMORANDUM TO

THE FEEDINGSTUFFS (ZOOTECHNICAL PRODUCTS) AND MEDICATED FEEDINGSTUFFS (AMENDMENT) (ENGLAND, SCOTLAND AND WALES) REGULATIONS 2005

2005 No.1033

1. This explanatory memorandum has been prepared by the Veterinary Medicines Directorate and is laid before Parliament by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Description

2.1 This Regulation implements the fees for the annual registration of manufacturers and distributors of medicated feedingstuffs and zootechnical feed additives for 2005/6.

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

3.1 This instrument increases fees by 3.1% rounded to the nearest pound which was the rate of inflation as of September 2004.

4. Legislative Background

4.1 Council Directive 95/69/EC, which lays down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector, introduced a registration system for establishments and intermediaries (premises) that manufacture, or distribute certain feed additives. The provisions of this Directive were implemented in the UK in The Feedingstuffs (Zootechnical Products) Regulations 1999.

4.2 Council Directive 90/167/EC, which lays down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community, introduced a registration system for establishments and distributors that manufacture or distribute medicated feedingstuffs. The provisions of this Directive were implemented in the UK in The Medicated Feedingstuffs Regulations 1998.

4.3 Fees for registration are set annually. They are set out in the UK legislation referred to in paragraphs 4.1 and 4.2, as last amended by the Feedingstuffs (Zootechnical Products) and Medicated Feedingstuffs (Amendment) (Scotland, England and Wales) Regulations 2004, S.I. 2004/1036, which set fees for 2004/5.

4.4 The above legislation is enforced by the Royal Pharmaceutical Society of Great Britain's (RPSGB) Animal Medicines Inspectorate (AMI). The

Feedingstuffs (Zootechnical Products) Regulations 1999 and The Medicated Feedingstuffs Regulations 1998 require amendment in order to set the levels of fees that the RPSGB may charge for the approval of premises for 2005/6. This is being given effect in The Feedingstuffs (Zootechnical Products) and Medicated Feedingstuffs (Amendment) (England, Scotland and Wales) Regulations 2005.

5. Extent

5.1 This Instrument applies to England, Scotland and Wales only. The Department for Agriculture and Rural Development has its own inspectorate and is responsible for setting equivalent fees for the registration and inspection of similar establishments in Northern Ireland.

6. European Convention on Human Rights

6.1 Not applicable.

7. Policy background

7.1 EC legislation requires manufacturers and distributors of medicated feedingstuffs or zootechnical feed additives (antibiotic growth promoters, coccidiostats and histomonostats) to register and be inspected to ensure compliance with certain requirements.

7.2 Regular inspection minimises the risks to animals, consumers and the environment from incomplete/inaccurate mixing or poor hygiene.

7.3 The RPSGB seeks to recover the full operating costs of its AMI through charging fees to those it inspects. The levels of the fees it charges to feed manufacturers are set down in legislation.

8. Impact

8.1 A full Regulatory Impact Assessment is attached to this Explanatory Memorandum. The fee rises for 2005/6 range from £3 to £26 a year which represents a 3.1% increase for all categories of establishments, rounded to the nearest pound. The lower figure would relate to a farmer manufacturing for his own use and the higher figure would relate to large feed mills. Impact is expected to be very low.

9. Contact

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can answer any queries regarding the instrument.

FULL REGULATORY IMPACT ASSESSMENT

1. Title:

The Feedingstuffs (Zootechnical Products) and Medicated Feedingstuffs (Amendment) (Scotland, England and Wales) Regulations 2005

2. Purpose and intended effect

(i) Objective

To fund the cost of registration and inspection of manufacturers, intermediaries and distributors of medicated feeds and feed additives by the Animal Medicines Inspectorate (AMI) of the Royal Pharmaceutical Society of Great Britain (RPSGB). The charges under this legislation apply to England, Wales and Scotland. In Northern Ireland, the Department for Agriculture and Rural Development is responsible for setting equivalent fees for the registration and inspection of similar establishments in Northern Ireland.

(ii) Background

Legislation

The Feedingstuffs (Zootechnical Products) Regulations 1999 and the Medicated Feedingstuffs Regulations 1998 (which were both last amended by the Feedingstuffs (Zootechnical Products) and Medicated Feedingstuffs (Amendment) (England, Scotland, and Wales) Regulations 2004) permits the RPSGB to charge fees for the registration and inspection of manufacturers, intermediaries and distributors of medicated feeds and feed additives. It is proposed to amend these fees so that the RPSGB can continue to recover the full costs of the AMI carrying out this work in 2005/06.

Review of AMI

Over the last few years, it has become increasingly apparent that the current funding arrangements for the AMI are unlikely to be sustainable over the long term due to significant reductions in the number of registered premises. This in turn could compromise the UK's ability to fully meet its EC obligations in this area.

The VMD is therefore carrying out a review of current enforcement arrangements for manufacturers, distributors, merchants and saddlers dealing with medicated feedingstuffs and zootechnical feed additives. It is intended to go out to full public consultation on our proposals in this area in 2005. However the proposed changes are unlikely to take full effect immediately and the AMI will need to be financially viable in order to continue to carry out its duties in 2005.

(iii) Risk assessment

All authorised veterinary medicinal products are subject to strict controls regarding sale, supply and usage. Medicated premixes are used in animal feedingstuffs for the prevention and treatment of disease. Zootechnical products are used in animal feedingstuffs as growth promoters, coccidiostats and histomonostats. All of these types of products contain potent substances that must be correctly mixed in animal feed. If not incorporated in accordance with instructions there are risks to the treated animals, the manufacturer and through residues to the consumer.

The approval and inspection by the AMI of establishments handling and supplying these substances forms a key part of these controls. Failure to provide an appropriate mechanism by which the RPSGB can fully recover the costs of running its AMI could result in a reduction in the quality of the service that it is able to supply in this area, thus increasing these risks to animal, human health and consumer safety.

3. Options

Option 1. To recover the full costs of the AMI through an increase in fees payable by industry

Option 2. Keep fees payable by the industry at the 2004/05 levels and reduce the frequency of inspections carried out by the AMI.

Option 3. To increase fees by the rate of inflation (3.1% as at September 2004) and to provide Government funds to supplement the fees to support the AMI while new arrangements are being implemented.

Option 1 would allow the current enforcement arrangements to continue, but may impose an unacceptably high increase in fees payable by industry, aggravating the risk of more establishments failing to register. It could also jeopardise the current consensus amongst stakeholders in support of the current proposals for the long-term future of these arrangements.

Option 2 would not provide the AMI with sufficient funds to enforce these regulations effectively and consequently could result in a drop in the levels of assurance that they provide for animal health and consumer safety. It would also mean that the UK was unable fully to meet its EC legislative requirements.

Option 3, like Option 1, would also allow the current enforcement arrangements to continue. However, this Option will provide a basis for the smooth transfer of inspection arrangements as proposed under our current review, and will retain the goodwill and co-operation of all those concerned with proposed new arrangements, including the industry and those businesses that may otherwise cease trading in these products.

4. Preferred Option

Option 3.

To increase fees by the rate of inflation (3.1% as at September 2004). This is being achieved, with the HM Treasury's agreement, by providing central Government funds to supplement the RPSGB's income from fees while new arrangements are being implemented.

5. Benefits

Option 3 allows the current enforcement arrangements to continue and will not jeopardise the implementation of the outcomes of the current review. It retains the goodwill and co-operation of all those concerned with the proposed new arrangements, including the industry and those businesses that may otherwise cease trading in these products. This transfer of arrangements will in turn allow the enforcement authorities to carry out their duties fully in accordance with EU legislation and to minimise the increasing funding problems that have been apparent over the past few years.

6. Proposed fees under Option 3

A	B	C	D
Establishment category	**Current fee** (2004/05) **£**	**Proposed fee** (2005/06) **£**	**Amount of Increase** (C minus B)
Distributor/intermediary	124	128	4
I.3P	112	115	3
AB	131	135	4
I.3M	182	188	6
AA	354	365	11
1.3M (special)	530	546	16
AA (special)	530	546	16
I.2 (Premixture)	840	866	26
I.1 (Additive)	840	866	26

7. Issues of equity and fairness

The AMI is required by law to recover its actual costs. The proposed 3.1% increase would apply equally to all registered premises.

8. Costs

(i) Compliance costs

The RPSGB has calculated that for 2005/6 it requires £237.213 to fund the registration and inspection of these premises to achieve full cost recovery. Figures for compliance are listed in the above table.

(ii) Other Costs

No other costs.

9. Consultation with small business: Small Business Impact Test

A small business impact test would not have been proportionate to the fee rises concerned, between £3 and £26 a year. We therefore did not carry out this exercise.

10. Competition assessment

We have assessed this against the competition filter and consider that the proposed increases will not affect competition.

The competition filter		
Q4:	Would the change in the fees affect some firms more substantially than others	No
Q5:	Is the change in fees likely to affect the market structure, changing the number or size of firms	No
Q6:	Would the change in fees lead to higher set-up costs for new or potential firms that existing firms do not have to meet	No
Q7:	Would the change in fees lead to higher ongoing costs for new or potential firms that existing firms do not have to meet	No
Q8:	Is the market characterised by rapid technological change	No
Q9:	Would the change in fees restrict the ability of firms to choose the price, quality, range or location of their products	No

11. Enforcement and sanctions:

Collection of these fees and any legal action resulting from non-payment of them or from non-compliance with legislation is the responsibility of the AMI.

12. Monitoring and review

These proposals do not change existing arrangements for monitoring and review.

13. Consultation

Our consultation letter was sent to 140 organisations. We have received one response from the Agricultural Industries Confederation (AIC). The AIC is very concerned at the continued upward trend in the level of fees. They note that the fees are being increased in line with inflation for one year only. With declining businesses and with further decreases due to the prohibition of antibiotic growth promoters in January 2006, they are questioning the justification of any fee increase at all. Accepting that this is unlikely to be acceptable they have proposed a flat rate fee increase across all the categories of establishments covered by the legislation. They also make the point that all establishments falling within the scope of the legislation should be approved, and they request the introduction of a risk assessment of the establishments subject to schemes such as the Universal Feed Assurance Scheme

(UFAS) being taken into consideration. The AIC also note that we are reviewing the inspection arrangements under this legislation, and they have expressed the view that the AMI Inspectorate is experienced and have the appropriate knowledge for feed mill inspections and would hope to see AMI inspectorate expertise introduced into the future arrangements.

14. Summary and recommendations

The increase in fees is necessary to ensure the continued financial viability of the AMI to allow it to continue to undertake its legal responsibilities under National and European legislation during 2005/06. However, because of the current situation regarding the future of the AMI, it is recommended that Option 3 – increasing fees by the rate of inflation together with some central funding towards the costs of the increases - be adopted.

15. Declaration

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed …Ben Bradshaw

Date 24th March 2005

Ben Bradshaw
Parliamentary Under Secretary - Commons

Contact Point

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