

# Statutory Instrument 1998 No. 1048

## The Medicated Feedingstuffs and Feedingstuffs (Zootechnical Products) (Consequential Provisions) Regulations 1998

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### STATUTORY INSTRUMENTS

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**1998 No. 1048**

### MEDICINES

#### The Medicated Feedingstuffs and Feedingstuffs (Zootechnical Products) (Consequential Provisions) Regulations 1998

<i>Made</i>	<i>9th April 1998</i>
<i>Laid before Parliament</i>	<i>15th April 1998</i>
<i>Coming into force</i>	<i>6th May 1998</i>

The Secretary of State and the Minister of Agriculture, Fisheries and Food, being Ministers designated[1] for the purposes of section 2(2) of the European Communities Act 1972[2] in relation to medicinal products and the common agricultural policy of the European Community, acting jointly, in exercise of the powers conferred on them by the said section 2(2), hereby make the following Regulations:

#### Title and commencement

**1. These Regulations may be cited as the Medicated Feedingstuffs and Feedingstuffs (Zootechnical Products) (Consequential Provisions) Regulations 1998 and shall come into force on 6th May 1998.**

#### Revocations and savings

2. - (1) Subject to paragraph (2), the instruments listed in Schedule 1 are revoked.

(2) The revocation of the instruments at items 1 and 3 of Schedule 1 shall not have effect to prevent the provisions of:

(a) regulation 43(2) of the Medicated Feedingstuffs Regulations 1998[3], or

(b) regulation 74(2) of the Feedingstuffs (Zootechnical Products) Regulations 1998[4] from applying to matters to which they would have applied had paragraph (1) not come into force.

**Amendments**

3. The instruments listed in Schedule 2 are hereby amended in accordance with that Schedule.

*Sewel*

Parliamentary Under Secretary of State, Scottish Office

1st April 1998

*Jeff Rooker*

Minister of State, Ministry of Agriculture, Fisheries and Food

9th April 1998

**SCHEDULE 1**

**Regulation 2**

**REVOCATIONS**

<i>Title of instrument</i>		<i>Reference</i>
1.	The Medicines (Feeding Stuffs Additives) Order 1975	S.I. 1975/1349
2.	The Medicines (Exemption from Licences) (Intermediate Medicated Feedingstuffs) Order 1989	S.I. 1989/2325
3.	The Medicines (Intermediate Medicated Feedingstuffs) Order 1989	S.I. 1989/2442
4.	The Medicines (Exemption from Licences) (Intermediate Medicated Feedingstuffs) (Amendment) Order 1990	S.I. 1990/567
5.	The Medicines (Medicated Animal Feedingstuffs) (No. 2) Regulations 1992	S.I. 1992/1520
6.	The Medicines (Medicated Animal Feedingstuffs) (Amendment) Regulations 1994	S.I. 1994/1531
7.	The Medicines (Medicated Animal Feedingstuffs) (Amendment) Regulations 1995	S.I. 1995/799

8.	The Medicines (Medicated Animal Feedingstuffs) (Amendment) Regulations 1996	S.I. 1996/769
9.	The Medicines (Medicated Animal Feedingstuffs) (Amendment) Regulations 1997	S.I. 1997/638

**SCHEDULE 2**

**Regulation 3**

**AMENDMENTS**

**Amendment of 1988 Regulations**

**1. The Medicines (Labelling of Medicinal Products for Incorporation in Animal Feeding Stuffs and of Medicated Animal Feeding Stuffs) Regulations 1988[5] shall be amended as follows -**

**(a) in regulation 2(1) -**

**(i) in the definition of "active ingredient", the words ", veterinary written direction" shall be omitted;**

**(ii) the following definitions shall be omitted -**

**"appropriate non-proprietary name";**

**"approved name";**

**"approved synonym";**

**(iii) in the definition of "container", after the words "medicated feeding stuff" there shall be inserted the words ", intermediate product or zootechnical product";**

**(iv) in the definition of "dosage unit" the words "or excepted medicated feeding stuff shall" be omitted at both places where they occur;**

**(v) the following definitions shall also be omitted -**

**"data sheet";**

**"excepted medicated feeding stuff";**

**"expiry date";**

**"final medicated feeding stuff";**

**"foreign or international compendium of standards";**

**"intermediate medicated feeding stuff";**

**"international non-proprietary name";**

**(vi) immediately before the definition of "marketing authorisation" there shall be inserted the following definition -**

**" "intermediate product" has the same meaning as in Part I of Schedule 2 to the Medicated Feedingstuffs Regulations 1998";**

**(vii) for the definition of "medicated feeding stuff" there shall be substituted the following definition -**

**" "medicated feeding stuff" has the same meaning as that given to "medicated feedingstuff" in Part I of Schedule 2 to the Medicated Feedingstuffs Regulations 1998";**

**(viii) in the definition of "package" there shall be inserted after the words "medicated feeding stuffs" the words "intermediate products or zootechnical products";**

**(ix) the following definitions shall also be omitted -**

**"person responsible for the composition of the medicinal product or excepted medicated feeding stuff";**

**"prescription only medicine";**

**"proprietary designation";**

**(x) in the definition of "quantity", there shall be omitted the words ", excepted medicated feeding stuff"; and**

**(xi) after the definition of "quantity", there shall be substituted for all the remaining definitions the following definition -**

**" "zootechnical product" has the same meaning as in regulation 2( 1) of the Feedingstuffs (Zootechnical Products) Regulations 1998.";**

**(b) in regulation 3, after the words "medicated feeding stuffs" there shall be inserted the words ", intermediate products and zootechnical products";**

**(c) regulations 4, 5 and 7 shall be omitted;**

**(d) for regulation 6 there shall be substituted the following regulation -**

**" Medicinal tests on animals**

**6. - (1) Subject to paragraph (2) below, where a medicated feeding stuff, an intermediate product or a zootechnical product is for administration in a medicinal test on animals, every container and package of such feeding stuff or product shall be labelled with the words "For Animal Test Use Only" and to show the particulars set out in Schedule 4.**

**(2) Where any container or any package enclosing the container of -**

**(a) a medicated feeding stuff,**

**(b) an intermediate product, or**

**(c) a zootechnical product,**

**for administration in a medicinal test on animals is of such a size as to make it impracticable for such container or package to be labelled to show all particulars required by paragraph (1) above, such container or package shall be labelled with the words "For Animal Test Use Only", and to show the particulars set out in paragraphs 1, 2, 7, and 8 of Schedule 4, and a leaflet containing all the particulars required by paragraph (1) above (other than those set out in paragraph 9 of that Schedule) shall be supplied with such container or package and be delivered to the purchaser or consignee thereof.";**

**(e) for regulation 8 there shall be substituted the following regulation -**

**" Sale or supply of medicated feeding stuffs, intermediate products or zootechnical products not enclosed in a container**

**8. A person who, in the course of a business carried on by him, sells or supplies a medicated feeding stuff, an intermediate product or a zootechnical product for administration in a medicinal test on animals without its being enclosed in a container shall not be taken to contravene regulation 6 if a leaflet which complies with the requirements of regulation 6 is supplied with such feeding stuff or product and such leaflet is delivered to the purchaser or consignee with such feeding stuff or product.";**

**(f) in regulation 9 -**

- (i) after the words "medicated feeding stuffs", at each place where they occur, there shall be inserted the words ", intermediate products or zootechnical products";**
- (ii) after the words "medicated feeding stuff", at each place where they occur, there shall be inserted the words ", intermediate product or zootechnical product"; and**
- (iii) paragraphs (3), (7) and (8) shall be omitted;**

**(g) in regulation 10 -**

- (i) after the words "medicated feeding stuff" in the first place where they occur there shall be inserted the words ", intermediate product or zootechnical product"; and**
- (ii) the words "(not being an excepted medicated feeding stuff)" shall be omitted;**

**(h) in regulation 11 -**

- (i) after the words "medicated feeding stuff", in each place where they occur, there shall be inserted the words ", intermediate product or zootechnical product"; and**
- (ii) in paragraph (b), after the words "medicated feeding stuffs" there shall be inserted the words ", intermediate products or zootechnical products";**

**(i) regulation 12 shall be omitted;**

**(j) in regulation 13, the words from "or who contravenes" to "excepted medicated feeding stuffs" shall be omitted;**

**(k) Schedules 1, 2 and 3 shall be omitted; and**

**(l) in Schedule 4 -**

**(i) for the heading there shall be substituted the following heading:**

#### **" SCHEDULE 4**

#### **Regulations 6 and 8**

#### **PARTICULARS REQUIRED IN THE LABELLING OF CONTAINERS AND PACKAGES OF MEDICATED FEEDING STUFFS, INTERMEDIATE PRODUCTS OR ZOOTECHNICAL PRODUCTS FOR MEDICINAL TESTS ON ANIMALS";**

**(ii) in paragraph 2, sub-paragraph (a) shall be omitted, and in sub-paragraph (b), the words "or excepted medicated feeding stuff" shall be omitted in both places where they occur and the words ", intermediate product or zootechnical product" shall be inserted immediately after the words "medicated feeding stuff" in both places where they survive;**

**(iii) in paragraphs 3, 4, 6, 8 and 9, after the words "medicated feeding stuff", in each place where they occur, there shall be inserted the words ", intermediate product or zootechnical product";**

**(iv) paragraph 5 shall be omitted;**

**(v) in paragraph 7, sub-paragraph (a) shall be omitted and in sub-paragraph (b) the words "(not being an excepted medicated feeding stuff)" shall be omitted and the words ", intermediate product or zootechnical product" shall be inserted immediately after the words "feeding stuff" in each place where they survive; and**

**(vi) in paragraph 9, for the words "regulation 6(3)" there shall be substituted the words "regulation 6(2)".**

#### **Amendment of 1994 Regulations**

**2. After paragraph (iii) of regulation 6(2)(b) of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994[6] shall be inserted the following paragraphs:**

**" (iiiA) in the case of an authorised medicated pre-mix, as defined in regulation 2(1) of the Medicated Feedingstuffs Regulations 1998, other than one which falls within the next paragraph of this sub-paragraph, the capital letters "MFS";**

**(iiiB) in the case of an authorised medicated pre-mix, as so defined, which falls within regulation 18(3), 21(3) or 28(4) of those Regulations, the capital letters "MFSX";".**

### **Amendment of 1997 Regulations**

**3. Paragraph 3 of Schedule 3 to the Medicines (Products for Animal Use - Fees) Regulations 1997[Z] shall be omitted.**

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## **EXPLANATORY NOTE**

*(This note is not part of the Regulations)*

**These Regulations make provision consequent on the making of the Medicated Feedingstuffs Regulations 1998 and the Feedingstuffs (Zootechnical Products) Regulations 1998.**

**Regulation 2 and Schedule 1 revoke the Medicines (Feeding Stuffs Additives) Order 1975, S.I. 1975/1349, the Medicines (Exemption from Licences) (Intermediate Medicated Feedingstuffs) Order 1989, S.I. 1989/2325, the Medicines (Intermediate Medicated Feedingstuffs) Order 1989, S.I. 1989/2442, the Medicines (Exemption from Licences) (Intermediate Medicated Feedingstuffs) (Amendment) Order 1990, S.I. 1990/567, the Medicines (Medicated Animal Feedingstuffs) (No. 2) Regulations 1992, S.I. 1992/1520, the Medicines (Medicated Animal Feedingstuffs) (Amendment) Regulations 1994, S.I. 1994/1531, the Medicines (Medicated Animal Feedingstuffs) (Amendment) Regulations 1995, S.I. 1995/799, the Medicines (Medicated Animal Feedingstuffs) (Amendment) Regulations 1996, S.I. 1996/769 and the Medicines (Medicated Animal Feedingstuffs) (Amendment) Regulations 1997, S.I. 1997/638, subject to a saving in relation to S.I. 1975/1349 and S.I. 1989/2442.**

**Regulation 3 and Schedule 2 amend the Medicines (Labelling of Medicinal Products for Incorporation in Animal Feeding Stuffs and of Medicated Animal Feeding Stuffs) Regulations 1988, S.I. 1988/1009, so that (with the exception of regulation 9) they apply only to the labelling of containers and packages of feed materials for administration in medicinal tests on animals. They also amend the product categorisation labelling requirement of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, S.I. 1994/3142 and delete one provision from the Medicines (Products for Animal Use - Fees) Regulations 1997.**

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### **Notes:**

**[1] S.I. 1972/811.[back](#)**

**[2] 1972 c. 68.[back](#)**

**[3] S.I. 1998/1046.[back](#)**

**[4] S.I. 1998/1047.[back](#)**

**[5] S.I. 1988/1009, relevant amending instruments are S.I. 1994/3142 and S.I. 1996/2194.[back](#)**

**[6] S.I. 1994/3142 to which there are amendments not relevant to these Regulations.[back](#)**

**[7] S.I. 1997/1469.back**



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