

S.I. No. 176/1994 — European Communities (Animal Remedies and Medicated Feedingstuffs) Regulations, 1994.

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FEEDINGSTUFFS) REGULATIONS, 1994.

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I, JOE WALSH, Minister for Agriculture, Food and Forestry, in exercise of the powers conferred on me by section 3 of the European Communities Act, 1972 (No. 27 of 1972), for the purpose of giving effect to Council Directive 90/167/EEC of 26 March 1990¹ hereby make the following Regulations:

¹O.J. No. L92 of 7/4/90, p. 42.

1. (1) These Regulations may be cited as the European Communities (Animal Remedies and Medicated feedingstuffs) Regulations, 1994.

(2) These Regulations shall come into operation on the 1st day of July, 1994.

2. In these Regulations—

"the Act" means the Animal Remedies Act 1993 (No. 23 of 1993);

"animal remedy" has the meaning assigned to it by the Animal Remedies Act, 1993 ;

"authorised officer" means—

(a) a person who is an authorised officer within the meaning of the Animals Remedies Act, 1993 or

(*b*) a person who for the time being stands appointed under Regulation 17 of these Regulations;

"authorised pre-mix" means any pre-mix for the manufacture of a medicated feedingstuff in respect of which there is for the time being in force a product authorisation;

"competent authority" has the meaning assigned to it by the European Communities (Veterinary Medicinal Products) Regulations, 1986 (S.I. No. 22 of 1986);

"the Council Directive" means Council Directive 90/167/EEC;

"document" includes computer and other recording media, and any other means by which or on which information can be recorded or stored;

"hormone legislation" has the same meaning as in the European Communities (Control of Oestrogenic, Androgenic, Gestagenic and Thyrostatic Substances) Regulations, 1988 (S.I. No. 218 of 1988);

"human consumption" includes intended for incorporation in, or manufacture into, a food intended for human consumption and kindred words shall be construed accordingly;

"intermediate product" means a combination of an authorised pre-mix and one or more feedingstuffs which are intended for the subsequent manufacture of a ready to use medicated feedingstuff;

"manufacture" includes processing, compounding, formulating, filling, dividing up, packaging and labelling;

"manufacturer" means, as the case may be, a person licensed in accordance with the provisions of these Regulations to manufacture a medicated feedingstuff or intermediate product;

"medicated feedingstuff" means any mixture of an animal remedy or remedies and feed or feeds which is ready prepared for marketing and intended to be fed to animals without further processing because of its curative or preventative or other properties as an animal remedy;

"Minister" means the Minister for Agriculture, Food and Forestry;

"person" includes legal persons;

"pharmacist" means a registered dispensing chemist and druggist, a registered druggist and a registered pharmaceutical chemist as defined in Section 4 (10) of the Animal Remedies Act, 1993 ;

"pre-mix for a medicated feedingstuff" means any animal remedy prepared in advance with a view to the subsequent manufacture of medicated feedingstuffs;

"product authorisation" has the same meaning as in the European Communities (Veterinary Medicinal Products) Regulations, 1986 (S.I. No. 22 of 1986);

"registered veterinary surgeon" means a person currently registered in the register established under the Veterinary Surgeons Act, 1931 (No. 6 of 1931);

"sell" includes supply, offer for sale or expose for sale, distribute (whether for reward or not), send in the post or otherwise place on the market and cognate words shall be construed accordingly;

"substance" has the meaning assigned to it by the Animal Remedies Act, 1993 and includes any preparation, additive, pre-mixture, feedingstuff or other thing consisting of or containing any such substance as aforesaid;

"tissues" includes bodily fluids;

"vehicle" includes a ship, hovercraft, aircraft and offshore installation;

"veterinary medicines legislation" has the same meaning as in the European Communities (Control of Veterinary Medicinal Products and their Residues) Regulations, 1990 (S.I. No. 171 of 1990);

"veterinary medicinal product" has the same meaning in these Regulations as it has for the purposes of the European Communities (Veterinary Medicinal Products) Regulations, 1986 (S.I. No. 22 of 1986);

(2) Subject to paragraph (1), a word or expression that is used in these Regulations and is also used in the Council Directive has, unless the contrary intention appears, the meaning in these Regulations that it has in the Council Directive.

(3) In these Regulations any reference to a Regulation or Schedule shall be construed as a reference to a Regulation contained in these Regulations, or, as the case may be, to a schedule thereto, unless it is indicated that a reference to some other provision is intended, and any reference in a Regulation to a paragraph or sub-paragraph shall be construed as a reference to a paragraph or a sub-paragraph of the Regulation, unless it is indicated that a reference to some other provision is intended.

3. (1) Subject to Regulation 11 (4), the incorporation of an animal remedy in an animal feedingstuff or the possession of a feedingstuff in which an animal remedy has been incorporated, and the placing on the market of a medicated feedingstuff is hereby prohibited save under licence of the Minister.

(2) Subject to paragraph (8), notwithstanding that the Minister has granted a licence for the incorporation of an animal remedy in a feedingstuff, the licensee may only incorporate an animal remedy which is an authorised pre-mix and in respect of which there is for the time being in force a product authorisation or an intermediate product, as provided for by paragraph (3), prepared from such an authorised pre-mix.

(3) The Minister may, subject to any specific conditions laid down in the relevant product authorization, authorise, by licence, the manufacture of intermediate products for the manufacture of a medicated feedingstuff, where the manufacture of such an intermediate product is necessary or desirable to ensure the proper incorporation of the authorised pre-mix in the feedingstuff.

(4) A medicated feedingstuff shall, subject to paragraph (6) consist of a single authorised pre-mix and a feed or combination of feeds.

(5) An intermediate product shall, unless otherwise provided for by licence of the Minister where the conditions of a product authorization specifically provide for the mixing of two or more specified authorised pre-mixes in an intermediate product, only contain a single authorised pre-mix.

(6) (a) Where there is no authorised pre-mix containing the necessary combination of therapeutic agents in pre-mix form for the disease or condition to be treated, a registered veterinary surgeon may issue a written veterinary direction for the combination of two or more authorised pre-mixes in the medicated feedingstuff.

(b) Where it is necessary to combine two or more authorised pre-mixes in an intermediate product in order to ensure proper incorporation in the feedingstuff, such intermediate product, subject to paragraph (5), must be used immediately and may not be stored or placed on the market in the form of an intermediate product.

(7) Subject to paragraph (8), an authorised pre-mix may only be used for the treatment of the conditions and species specified in the product authorization.

(8) (a) Where there is no authorised pre-mix for the treatment of a

particular disease or condition or for the treatment of a particular species, a registered veterinary surgeon may issue a written veterinary direction for

(i) the use of an authorised pre-mix containing the appropriate therapeutic agent for the treatment of a different disease or condition or species, or

(ii) where there is no such authorised pre-mix, the use of an extemporaneously prepared pre-mix manufactured in accordance with the prescription of a registered veterinary surgeon by a person lawfully entitled pursuant to the law of the State to manufacture a pre-mix for a medicated feedingstuff.

(b) The use of an authorised pre-mix or an extemporaneously prepared pre-mix in accordance with sub-paragraph (a) shall comply with the law of the State and the provisions of Article 4 of Council Directive 81/851/EEC¹ as amended by Article 1 (4) of Council Directive 90/676/EEC².

¹O.J. L317 of 6/11/81, p. 1.

²O.J. L373 of 31/12/90, p. 15.

4. (1) Subject to the subsequent provisions of this Regulation, on application to the Minister in that behalf by or on behalf of any person and on payment to the Minister of such fee as is for the time being prescribed by the Minister, the Minister may grant a licence authorising the manufacture, distribution, possession, storage or sale of a medicated feedingstuff or an intermediate product.

(2) (a) A person who the Minister has authorised by licence to engage in the business of storage, distribution, supply and sale of ready-made medicated feedingstuffs, not manufactured by that person, shall hereinafter be referred to as an authorised distributor.

(b) An authorised distributor may sell or supply only medicated feedingstuffs which are pre-packaged in small quantities and ready to use.

(c) An authorised distributor shall comply with the same conditions as a licensed manufacturer regarding the packaging, labelling, storage, keeping of records, transport and sale or supply of medicated feedingstuffs.

(3) The Minister may, if he thinks it appropriate to do so for the purpose of ensuring compliance with these Regulations and the law of the State and having regard to the provisions of this Regulation, attach conditions to a licence at the time of grant of the licence or subsequently amend or revoke a condition attached to a licence.

(4) Unless the licence granted by the Minister specifies otherwise, a manufacturer may not incorporate an authorised pre-mix or intermediate product at a rate below 2 kg per tonne of feedingstuff.

(5) The Minister shall not grant a licence authorising the manufacture of medicated feedingstuffs or intermediate products unless the Minister is satisfied that:—

(*a*) the manufacturer has premises which have been authorised for the manufacture of animal feedingstuffs pursuant to the provisions of the Fertilisers, Feedingstuffs and Mineral Mixtures Regulations, 1957 (No. 264 of 1957);

(*b*) the manufacturer has suitable and adequate premises and equipment for the manufacture and storage of medicated feedingstuffs and adequate inspection facilities;

(*c*) the medicated feedingstuffs plant is manned by staff whose knowledge of, and qualifications or training, in mixing technology are adequate.

(6) The Minister shall refuse to grant a licence to a person, or shall revoke a licence held by a person, if:—

(*a*) the person has been convicted of, or committed, an offence under these Regulations, or the Act, or the hormones legislation or the veterinary medicines legislation or, is, for other reasons (including conviction of any other offences) not, in the opinion of the Minister, a fit and proper person to hold a licence;

(*b*) in the opinion of the Minister, the medicated feedingstuff or intermediate product so manufactured or distributed would be sold in contravention of these Regulations or of the Act;

(*c*) in the opinion of the Minister, the premises are not, or the equipment, machinery or plant used or to be used, is not, having due regard to the law of the State and the Council Directive, not suitable for the purpose of such manufacture;

(*d*) in the opinion of the Minister the premises, equipment, machinery or plant are not or will not be manned by persons whose knowledge and qualifications or training in mixing technology are adequate.

5. (1) An application for a licence under these Regulations shall be made on such form as the Minister may specify.

(2) A person applying for a licence under these Regulations shall furnish the Minister with such information as he may reasonably require for his functions under these Regulations.

(3) The Minister may refuse to grant a licence under these Regulations if, in relation to the application therefor, information required by the Minister has not been furnished or information which, in the opinion of the Minister is false or misleading in a material particular, has been furnished to him.

(4) (*a*) Where the Minister proposes to refuse the grant of a licence under these Regulations or to attach a condition to (other than a standard condition), or amend or revoke a condition attached to, such a licence, the Minister shall notify in writing the person who made the application for or, as the case may be, holds the licence, of his proposal and the reasons for it.

(*b*) A person who has been notified of a proposal under subparagraph (*a*) may, within 21 days of the date of issue of the notification, make representations in writing to the Minister and the Minister shall—

(i) before deciding the matter, take into consideration any representations duly made to him under this paragraph in relation to the proposal, and

(ii) notify the person in writing of the decision taken following consideration of the representations and the reasons therefor.

(*c*) A notification under subparagraph (*a*) shall include a statement that the person concerned may make representations to the Minister within 21 days of the receipt by such person of the notification.

6. (1) A manufacturer of a medicated feedingstuff shall ensure that:

(*a*) only feedingstuffs or combinations thereof which comply with the law of the State and provisions of the legislation of the European Community on feedingstuffs are used in the manufacture of medicated feedingstuffs;

(*b*) the feedingstuff used produces a homogeneous and stable mix with the authorised pre-mix;

(*c*) the authorised pre-mix is used during the manufacturing process in accordance with the conditions laid down in the product authorization and in particular that:

(i) there is no possibility of any undesirable interaction between animal remedies, additives and feedingstuffs;

(ii) the medicated feedingstuff will remain in good condition for the stipulated period;

(iii) the feeding stuff to be used for producing the medicated feedingstuff does not contain the same antibiotic or the same coccidiostat as those used as an active ingredient in the authorised pre-mix.

(*d*) the daily dose of the medicinal product is contained in a quantity of feedingstuff corresponding to at least half the daily feed ration of the animals treated or, in the case of ruminants, corresponding to at least half the daily requirements of non-mineral supplementary feedingstuffs.

(*e*) premises, staff and equipment used and participating in the entire

manufacturing process must comply with the principles of good hygiene and the manufacturing process must conform to good manufacturing practice.

(*f*) the manufacturer shall carry out regular checks, (the frequency of which may be specified in writing or as a condition of a licence by the Minister) on medicated feedingstuffs manufactured, including appropriate laboratory tests for homogeneity to ensure that the medicated feedingstuff complies with the requirements of these Regulations and of the Council Directive, especially in respect to its homogeneity, stability and storability. The manufacturer shall keep a record of such checks for a period of three years and shall make them available on request for inspection by an authorised officer.

(*g*) the manufacturer shall keep daily records of the types and quantities of authorised pre-mixes, intermediate products and feedingstuffs used and the medicated feedingstuffs manufactured, held or dispatched, together with the names and addresses of the owner or person in charge of the animals and in the case provided for by Regulation 4 (2), the name and address of the authorised distributor, and where appropriate the name and address of the prescribing veterinary surgeon. These records must be retained for at least three years and the Minister may by a condition of a licence or by a notice in writing specify the form in which such records shall be retained.

(*h*) Authorised pre-mixes and medicated feedingstuffs shall be stored in suitable separate and secured rooms or areas or hermetic containers which are specially designed for the storage of such products.

(2) The provisions of this Regulation in so far as they relate to storage and the retention of records shall apply to authorised distributors.

7. (1) Medicated feedingstuffs may only be imported, distributed, supplied or sold in packages or containers sealed in such a way that if the package or container is opened, the closure or seal is damaged and cannot be reused.

(2) Where road tankers or similar containers are used to place medicated feedingstuffs on the market, these must be adequately cleaned before any re-use in order to prevent any subsequent undesirable interaction or contamination.

8. (1) Medicated feedingstuffs may not be placed on the market unless the labelling complies with the law of the State in relation to the labelling of feedingstuffs. Furthermore, the label on the package or container shall be clearly marked 'Medicated Feedingstuff' and shall bear a notice stating or indicating:

(*a*) the appropriate commercial or common name of the active medicinal ingredient in the medicated feed or if it contains more than one active medicinal ingredient, of each ingredient and the proportion thereof in the medicated feedingstuff;

(*b*) if the active medical ingredient has not an appropriate commercial or

common name, the appropriate scientific name of such ingredient;

(*c*) the feeding rate and withdrawal period to be observed;

(*d*) a description of the species and, if appropriate, the class of animals to which the medicated feedingstuff may be administered;

(*e*) the name of the manufacturer and, if appropriate, the authorised distributor of the medicated feedingstuff.

(2) Prior to the supply of a medicated feedingstuff to an owner or person in charge of animals a notice stating:

(*a*) the name and address of the person to whom the medicated feedingstuff has been supplied, and

(*b*) the date of supply

shall be affixed to the label or outer wrapping of the container of the medicated feed.

(3) Where road tankers or similar containers are used to place medicated feedingstuff on the market it shall be sufficient for the information referred to in paragraphs (1) and (2) to be contained in the accompanying documents.

9. (1) An authorised pre-mix may only be sold or supplied to:

(*a*) a person licensed pursuant to the provisions of these Regulations, to manufacture medicated feedingstuffs or intermediate products;

(*b*) a veterinary surgeon;

(*c*) a pharmacist;

(*d*) a person engaged in the bona fide sale by wholesale of animal remedies in accordance with the law of the State.

(2) An intermediate product may only be sold or supplied to a person licensed, pursuant to the provisions of these Regulations, to manufacture medicated feedingstuffs.

(3) A medicated feedingstuff may only be supplied to:

(*a*) an owner or person in charge of animals named in the veterinary written direction, as in the form specified in the first Schedule to these Regulations, of a registered veterinary surgeon;

(*b*) a person licensed by the Minister to be an authorised distributor of medicated feedingstuffs;

(c) any other person or class of person specified by a licence granted for such purpose by the Minister.

(4) A licensed manufacturer or authorised distributor shall not supply medicated feedingstuffs:

(a) in excess of the quantity prescribed by the registered veterinary surgeon in accordance with the veterinary written direction;

(b) in quantities greater than 31 days requirement as established in accordance with the veterinary written direction.

(5) (i) A veterinary written direction shall be valid for the period stated by the prescribing registered veterinary surgeon which may not exceed 31 days.

(ii) A veterinary written direction shall be valid for a single treatment only and may not be repeated.

(6) (i) A manufacturer or authorised distributor, as the case may be, shall cancel each veterinary written direction when the medicated feedingstuff has been supplied by completing the veterinary written direction by the insertion of the details specified in Section III of the direction.

(ii) A manufacturer or authorised distributor shall retain the veterinary written direction for a period of three years and shall make such records available on request for inspection by an authorised officer.

(7) (i) A manufacturer or authorised distributor may hold stocks of commonly used medicated feedingstuffs in anticipation of receipt of veterinary written directions for their supply.

(ii) A manufacturer or authorised distributor may not release a medicated feedingstuff to an owner or person in charge of animals without prior receipt of a veterinary written direction.

(iii) Notwithstanding subparagraph (ii), a manufacturer or authorised distributor may, in a case of emergency, in order to prevent any unnecessary suffering to animals, supply a medicated feedingstuff on foot of a facsimile copy of the veterinary written direction. The original veterinary written direction must be sent within 72 hours thereafter.

10. (1) A registered veterinary surgeon shall not issue a veterinary written direction for the manufacture and subsequent use of a medicated feedingstuff unless:

(a) the animals to which it relates are under the care of and, concerning which, the issuing registered veterinary surgeon has been consulted in a professional capacity, and

(b) he is satisfied that the veterinary written direction will be used (by the person to whom it is granted) for such animals.

(2) (a) For the purposes of paragraph (1), the registered veterinary

surgeon shall have been given responsibility for the health of the herd or flock in question by the owner or agent of the owner or person in charge of the animals, and

(b) (i) either recently have seen the animal or herd or flock in question for the purpose of diagnoses, or

(ii) have carried out tests, or have had recourse to the results of tests or analyses carried out on samples taken from the animal or animals in the herd or flock in question, and

(iii) have visited the farm or other premises on which the animal or herd is kept sufficiently often and recently enough to have acquired from personal knowledge and inspection, an accurate picture of the current health of animals on that farm to enable him to make a diagnosis or prescribe for the animal or herd or flock in question.

(3) A veterinary surgeon must, prior to issuing a veterinary written direction, be satisfied that:

(a) the use of the medication to be directed is justified for the species concerned on veterinary grounds;

(b) administration of the animal remedy to be incorporated in the medicated feedingstuff is not incompatible with a previous treatment or use and that there is no contra indication or interaction where several pre-mixes are used;

(c) that the medicated feedingstuff and the feedingstuff currently used to feed treated animals do not contain the same antibiotic or coccidiostat.

(4) A veterinary surgeon may only issue a veterinary written direction for a medicated feedingstuff:—

(a) for such quantity as is necessary for the purposes of the treatment subject to a maximum quantity of 31 days supply;

(b) in which the daily dose of the animal remedy is contained in a quantity of feedingstuff corresponding to at least half the daily feed ration of the animals treated and in the case of ruminants corresponding to at least half the daily requirements of non mineral supplementary feedingstuff.

(5) (a) A veterinary written direction shall be issued in triplicate. The original shall be forwarded to the manufacturer or authorised distributor; a copy of the original shall be given to the owner or person in charge of the animals to be treated and a copy of the original shall be retained by the registered veterinary surgeon.

(b) Copies of veterinary written directions are to be retained for 3 years and to be made available for inspection on request by an authorised officer.

(6) A veterinary written direction shall be in the form prescribed in the First Schedule to these Regulations.

(7) When a veterinary surgeon directs the manufacture of a medicated feedingstuff using an extemporaneously prepared pre-mix or where a combination of authorised pre-mixes are used or where an authorised pre-mix is to be used other than in accordance with the product authorisation Section IV of the veterinary written direction shall be completed by the veterinary surgeon and a copy of the veterinary written direction shall be forwarded to the competent authority.

(8) A veterinary written direction shall be written in ink so as to be indelible and signed in ink by, and bear the practice stamp of, the issuing registered veterinary surgeon.

11. (1) A person shall not administer a medicated feedingstuff to any animal except a medicated feedingstuff which complies with the provisions of these Regulations and the Council Directive.

(2) A person shall not administer to any animal, or use in any other way in connection with any animal, a medicated feedingstuff except in accordance with the terms of a veterinary written direction given by a registered veterinary surgeon and under the guidance of such persons or class of persons as the registered veterinary surgeon states in the veterinary written direction as appropriate to that administration.

(3) Where medicated feedingstuffs are administered to animals whose meat, offal or products, including milk and eggs, are intended for human consumption, the owner or person in charge of the animals concerned shall ensure that treated animals are not slaughtered in order to be offered for human consumption before the end of the withdrawal period and that products obtained from a treated animal before the end of such a withdrawal period are not disposed of with a view to their being offered for human consumption.

(4) Regulation 3 (1) shall not apply to the possession of a medicated feedingstuff on premises or other land where animals are kept for farming purposes in respect of which a veterinary written direction has issued to the person in possession or control of the medicated feedingstuffs for the administration to animals on the relevant premises.

(5) An owner or person in charge of an animal who administers a medicated feedingstuff to an animal shall record such administration in the veterinary medicines record prescribed by Regulation 19 (2) of the Poisons (Control of Residues in Foods of Animal Origin) Regulations, 1985, (S.I. No. 257 of 1985) in the form prescribed in Part 1 of the Third Schedule to the said Regulations.

(6) An owner or person in charge of animals to which medicated feedingstuffs have been administered shall keep for a period of 3 years copies of all veterinary written directions for the manufacture and use of medicated feedingstuffs administered to

animals under his control on the relevant premises and make such copies and the records prescribed in paragraph (5) available for inspection on request by an authorised officer.

12. (1) No person shall import an animal feedingstuff in which an animal remedy has been incorporated from a Member State of the European Communities unless the feedingstuff:

(*a*) has been manufactured in accordance with the provisions of the Council Directive; and

(*b*) has been manufactured using either an authorised pre-mix or an animal remedy authorised in accordance with the provisions of Council Directive 81/851/EEC by the exporting Member State, which has the same active ingredient(s) of equivalent dose rates to those authorised within the State; and

(*c*) is packaged, labelled and transported in accordance with the provisions of the Council Directive; and

(*d*) is accompanied by a certificate in the form set out in the Second Schedule to these Regulations.

(2) (*a*) A person who imports a medicated feedingstuff shall keep a record of:

(i) the date of importation; and

(ii) the details specified in the accompanying certificate, and

(iii) in the case of importation by an authorised distributor, the same records regarding distribution, sale or supply as apply to a medicated feedingstuff manufactured within the State.

(*b*) Such records shall be kept for a period of three years and shall be furnished on request for inspection by an authorised officer.

(3) The provisions of Regulation 9 apply to the distribution, sale or supply of an imported medicated feedingstuff by an authorised distributor.

(4) No person, other than an authorised distributor, may import a medicated feedingstuff unless a veterinary written direction has issued in respect of the medicated feedingstuff so imported.

13. (1) The importation of an animal feedingstuff in which an animal remedy has been incorporated from a place other than a Member State of the European Communities is hereby prohibited save under licence of the Minister.

(2) The Minister may not grant a licence for the importation of a feedingstuff in which

an animal remedy has been incorporated unless:—

(*a*) the Minister is satisfied that such a feedingstuff has been manufactured under equivalent conditions and to an equivalent standard as required by these Regulations and the feeding stuff complies with the law of the State in relation to feedingstuffs, and

(*b*) the medicated feedingstuff is manufactured using an authorised pre-mix as the active medicinal agent.

(3) The general provisions relating to the granting of a licence under Regulation 4 apply to the granting of a licence under this Regulation.

14. (1) Notwithstanding Regulations 3, 12 and 13, a person may manufacture, import into the State or sell a pre-mix or medicated feedingstuff which consists of or contains a prohibited substance under and in accordance with a licence under this Regulation.

(2) Subject to the subsequent provisions of this Regulation, on application to the Minister by or on behalf of any person and on payment to the Minister of such fee as the said Minister may specify, the Minister may grant a licence authorising the manufacture, importation or sale by the person of such quantity as may be specified in the licence of the pre-mix which is a prohibited substance or the medicated feedingstuff containing the prohibited substance so specified.

(3) The Minister may, if he thinks it appropriate to do so for the purpose of ensuring compliance with these Regulations and the law of the State and having regard to the provisions of this Regulation, attach conditions to a licence at the time of the grant of the licence or subsequently and may amend or revoke a condition attached to a licence.

(4) The Minister shall not grant a licence authorising the manufacture of a pre-mix which is a prohibited substance or of a medicated feedingstuff containing such a pre-mix unless the Minister is satisfied that—

(*a*) all the pre-mix or medicated feedingstuff is intended to, and will be administered to animals in the course of a test or trial authorised by a licence under Regulation 5 of the European Communities (Control of Veterinary Medicinal Products and Their Residues) Regulations, 1990 (S.I. No. 171 of 1990);

(*b*) all of the pre-mix or medicated feedingstuff is intended to, and will be exported from the State; or

(*c*) all of the pre-mix is intended to, and will be supplied to the competent authority for the purpose of an application for a product authorisation.

(5) The Minister shall not grant a licence authorising the importation of a pre-mix which is a prohibited substance or medicated feedingstuff containing such a pre-mix unless he is satisfied that all of the substance is intended to, and will, be administered to

animals in the course of a test or trial referred to in paragraph (4) or will be supplied to the competent authority for the purpose of an application for a product authorisation.

(6) The Minister shall refuse to grant a licence to a person or shall revoke a licence held by a person if—

(*a*) the person has been convicted of, or committed, an offence under the hormone legislation or the veterinary medicines legislation or is for other reasons (including conviction of any other offence) not, in the opinion of the Minister, a fit and proper person to hold a licence,

(*b*) the manufacture, importation or sale (as may be appropriate having regard to the particular class of licence applied for or held) of the prohibited substance or medicated feedingstuff concerned—

(i) is contrary to the law of the State, or

(ii) in the opinion of the Minister, prejudices or would prejudice public or animal health or the trade in the exportation of animals or animal products from the State,

(*c*) in the opinion of the Minister, the substance concerned is being or would be sold or used in the State otherwise than for a purpose specified in paragraph (4) or (5) of this Regulation;

(*d*) in the case of a licence authorising the manufacture of a premix or a medicated feedingstuff, the manufacturer is not authorised in accordance with the provisions of these Regulations or the law of the State to manufacture such premix or medicated feeding stuff;

(*e*) in the case of a medicated feeding stuff to be exported to a Member State of the European Communities, the medicated pre-mix used is not authorised in the Member State of destination.

(6) Any person who intends to export to a Member State of the European Communities a medicated feedingstuff shall (if so required by the Member State of destination) make application in writing to the Minister, not less than 72 hours before the date of exportation and upon payment of the approved fee, for a certificate corresponding in form to that set out in the Second Schedule of these Regulations.

15. The provisions of these Regulations other than Regulation 14 do not apply to tests and trials of pre-mixes for the purposes of Article 5 (1) of Council Directive 81/851/EEC in respect of which the Minister has granted a licence in accordance with the provisions of Regulation 5 of the European Communities (Control of Veterinary Medicinal Products and Their Residues) Regulations, 1990 (S.I. No. 171 of 1990).

16. (1) The Minister shall establish and maintain a register of licences to manufacture medicated feedingstuffs or intermediate products and to carry on the business of an authorised distributor, (hereinafter referred to as "the register") of every such licence granted under these Regulations.

(2) There shall be entered in the register:—

- (a) the full name, address and description of the holder of the licence;
- (b) an exact description of the location and the limits and extent of the premises and activities to which the licence relates;
- (c) the date on which the licence was issued and the expiry date thereof;
- (d) such other particulars of, or in respect of, the licence or of the activity to which it relates, as the Minister may, from time to time, direct.

(3) Whenever a licence to which this Regulation applies is altered or revoked, there shall be entered in the register such particulars of the alteration or revocation, as the case may be, as the Minister may, from time to time, direct.

(4) A certificate purporting to be under the hand of an officer, authorised by the Minister in that behalf, of the Minister that the name of the manufacturer of medicated feedingstuffs or intermediate products or the authorised distributor specified in the certificate is not entered in the register shall, until the contrary is proved, be evidence of the matters so certified and it shall not be necessary to prove the signature of such officer, or that he was such an officer, or that he was in fact so authorised.

17. (1) The Minister may appoint in writing such and so many of his officers or other persons as he thinks fit to be authorised officers for the purposes of these Regulations.

(2) A person appointed under this Regulation shall be furnished with a warrant of his appointment as an authorised officer and when exercising any power conferred on an authorised officer by these Regulations shall, if requested by a person affected, produce the warrant to that person.

(3) An appointment under this Regulation shall remain in force until it is withdrawn by the Minister by an instrument in writing.

18. (1) An authorised officer, on production of the officer's warrant if so required by any person affected, may, for the purposes of these Regulations and the Council Directives, do all or any of the following things, namely:—

- (a) at all times enter—
 - (i) any premises or place where he reasonably believes that tests or trials referred to in Regulation 15 are being carried on, or
 - (ii) any premises or place or vehicle where it is proposed to manufacture, sell or use medicated feedingstuffs, intermediate products or premixes or where he reasonably believes that such

manufacture, sale or use is being carried on, or

(iii) any premises or place or vehicle where he reasonably believes that a medicated feedingstuff, intermediate product, premix or substance is kept, or

(iv) any premises or place or vehicle where he reasonably believes that an animal to which a medicated feedingstuff has been, or is to be administered, is to be found,

and there carry out, or procure the carrying out of such inspections, examinations, tests and checks of the premises or place and any equipment, machinery or plant or animals in or at the premises or place as he reasonably considers to be necessary or expedient;

(*b*) require any person on the premises or at the place or in charge of the vehicle, to give to him such information and to produce to him such records and other documents within the power or procurement of the person as he reasonably considers to be necessary or expedient;

(*c*) examine and take copies of, or copies of extracts from, any such records or documents aforesaid;

(*d*) take, without payment, such samples of any substance found on the premises or at the place or in the vehicle as he may reasonably require and carry out or procure the carrying out on the samples such examinations, tests, checks and analyses as he reasonably considers necessary or expedient;

(*e*) take such specimens (including blood, urine, faeces, or tissue) from any animals, meat or meat products found on the premises or at the place or in the vehicle and may, for that purpose, perform any procedure (including surgery) as he reasonably considers necessary or expedient on such animals, meat or meat products; and

(*f*) seize and detain anything he believes to be a substance and in respect of which he has reasonable grounds to believe an offence under these Regulations is being or has been committed.

(2) A person who obstructs or impedes an authorised officer in the exercise of a power or, without reasonable excuse, does not comply with a requirement, under this Regulation or who, in purported compliance with such a requirement, gives information to an authorised officer that he knows to be false or misleading in a material respect shall be guilty of an offence.

19. (1) Where in proceedings for an offence under these Regulations, there is produced a certificate which—

(*a*) purports to be signed by the State Chemist or the Assistant State Chemist or by a person appointed by the Minister for the purposes of these Regulations, (in this Regulation referred to as an "appointed person"), and

(*b*) states that the certificate is given for the purpose of these Regulations,

and

(c) certifies—

(i) that an examination, test or analysis of a particular sample submitted by an authorised officer, a member of the Garda Síochána or an officer of Customs and Excise was carried out, and

(ii) the result of such examination, test or analysis,

then such certificate shall, without proof of the signature of the person purporting to sign it, or, in the case that the certificate purports to be signed by an appointed person, proof that at the time at which the certificate purports to have been given, such person stood appointed as an appointed person, be evidence for all purposes that such test, examination or analysis was carried out and of such result, unless the defendant requires the person who made the analysis to be called as a witness.

(2) (a) The Minister may by an instrument in writing appoint a person to issue certificates for the purpose of these Regulations.

(b) An appointment under this Regulation shall remain in force until it is withdrawn by the Minister by an instrument in writing.

20. Where in proceedings for an offence under these Regulations there is produced a certificate which—

(a) (i) purports to be signed by the Secretary of the National Drugs Advisory Board or by a person appointed by that Board for that purpose, and

(ii) states that the certificate is given for the purposes of these Regulations, and

(iii) certifies that in the case of a particular substance, a manufacturer's licence to manufacture a veterinary medicinal product or a product authorisation, as the case may be, has not been granted by the National Drugs Advisory Board,

then such certificate shall, without proof of the signature of the person purporting to sign it, or, in the case that the certificate purports to be signed by a person appointed by the competent authority or authorised by the said Minister, proof that at the time at which the certificate purports to have been given, such person stood so appointed or authorised, be evidence for all purposes that such licence or authorisation was not granted, unless the defendant requires the person who issued the certificate to be called as a witness.

21. (1) A person shall not forge or utter a document knowing it to be a forged document purporting to be a veterinary written direction granted under and in accordance with the provisions of these Regulations by a registered veterinary surgeon;

(2) A person shall not alter with intent to deceive a veterinary written direction granted under these Regulations by a registered veterinary surgeon;

(3) A person shall not have in his possession a forged veterinary written direction;

(4) Paragraph (3) of this Regulation shall not apply in relation to any of the following persons—

(*a*) a member of the Garda Síochána when acting in the course of his duty as such;

(*b*) an authorised person for the purposes of executing and enforcing these Regulations;

(*c*) a person who has taken into his possession such document for the purpose of—

(i) preventing another from committing or continuing to commit an offence under these Regulations, or

(ii) delivering it into the custody of a person specified in paragraph (*a*) or (*b*) of this sub-paragraph.

22. (1) A person who contravenes a provision of these Regulations or a condition of a licence under these Regulations shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding £1,000 or to imprisonment for a term not exceeding one year or to both.

(2) Proceedings for an offence under these Regulations may be brought and prosecuted by the Minister.

(3) Where an offence under the Regulations has been committed by a body corporate and is proved to have been committed with the consent or connivance of or to be attributable to any neglect on the part of a person, being a director, manager, secretary or other officer of that body corporate, or a person who was purporting to act in any such capacity, that person, as well as the body corporate, shall be guilty of an offence and shall be liable to be proceeded against and punished as if guilty of the first-mentioned offence.

(4) Notwithstanding section 10 (4) of the Petty Sessions (Ireland) Act, 1851, proceedings for an offence under these Regulations may be instituted at any time within two years of the date of the commission of the offence.

23. (1) Fees paid to the Minister under these Regulations shall be paid into, or disposed of for the benefit of, the Central Fund in accordance with the directions of the Minister for Finance.

(2) The Public Offices Fees Act, 1879 (1879 c58) shall not apply in respect of any fees paid under these Regulations.

24. In a prosecution for an offence under these Regulations in relation to an animal remedy, pre-mix, intermediate product or medicated feedingstuff that is also an additive, pre-mixture or feedingstuff within the meaning, in each case, of the European Communities (Additives in Feedingstuffs) Regulations, 1989 to 1994, it shall be a defence for the person charged with the offence to show—

(*a*) in the case that the animal remedy is an additive, that it is an additive specified in the First or Second Schedule to those Regulations or that it is a medicinal additive manufactured or imported in pursuance of an additive licence under those Regulations, and

(*b*) in the case that the animal remedy is a pre-mixture, intermediate product or feedingstuff that it contains an additive that complies with sub-paragraph (*a*),

and that the said European Communities (Additives in Feedingstuffs) Regulations, 1989 to 1994 were complied with in relation to the additive.

25. The provisions of these Regulations in relation to the possession of an animal remedy, authorised pre-mix, intermediate product or medicated feedingstuff shall not apply to any such preparation—

(*a*) in the possession of or under the control of a registered veterinary surgeon or pharmacist and required by such a person solely for the purposes of their professional practice, or

(*b*) in the possession or control of an authorised officer, member of the Garda Síochána, Officer of Customs and Excise or an approved person for the purpose of executing and enforcing these Regulations, or

(*c*) in the possession of an officer of the competent authority for the purpose of an application for a product authorisation, or

(*d*) in possession of a person for the purpose and intention of supplying to the competent authority for the purposes specified in subparagraph (*c*), or

(*e*) in possession of a person authorised in accordance with the law of the State to manufacture or sell by wholesale such preparations,

26. (1) These Regulations are in addition to and not in substitution for,

(*a*) the Animal Remedies (Registration of Manufacturers, Importers and Wholesalers) Regulations, 1980 (S.I. No. 115 of 1980);

(*b*) The European Communities (Veterinary Medicinal Products) Regulations, 1986 (S.I. No. 22 of 1986);

(c) The European Communities (Control of Veterinary Medicinal Products and their Residues) Regulations, 1988 to 1990;

(d) The Animal Remedies (Prohibition on Certain Sales) Regulations, 1991 (S.I. No. 244 of 1991).

(e) Subject to the subsequent provisions of this Regulation

(i) The Poisons (Control of Residues in Foods of Animal Origin) Regulations, 1985 and 1986,

(ii) The Animal Remedies (Control of Sale) Regulations, 1985 and 1986

shall not apply.

(2) Regulation 14 of the Poisons (Control of Residues in Foods of Animal Origin) Regulations, 1985 (S.I. No. 257 of 1985) shall not apply to the manufacture of a medicated feedingstuff to which these Regulations apply, provided the provisions of these Regulations have been complied with in relation to such manufacture.

(3) Regulation 5 of the Animal Remedies (Control of Sale) Regulations 1985 (S.I. No. 285 of 1985) shall not apply to the sale of a medicated feedingstuff to which these Regulations apply, provided the provisions of these Regulations have been complied with in relation to such sale.

(4) Nothing in these Regulations shall be construed as affecting any provision of the European Communities (Additives in Feedingstuffs) Regulations, 1989 to 1994.

27. The Animal and Poultry Compound Feeding Stuffs (Control of Antibiotics) Regulations, 1972 (S.I. No. 335 of 1972) are hereby revoked.

GIVEN under my Official Seal, this 15th day of June, 1994.

JOE WALSH,

Minister for Agriculture, Food and Forestry.

FIRST SCHEDULE.

DIRECTION FOR THE INCORPORATION OF AN ANIMAL REMEDY IN AN ANIMAL FEEDINGSTUFF OR FOR THE SALE OR IMPORTATION OF A MEDICATED FEEDINGSTUFF (VETERINARY WRITTEN DIRECTION).

SECTION I.

To be completed by the veterinary surgeon or owner or person in charge of the animals to which this direction relates.

1. Name and business name and address of the manufacturer or supplier of the medicated feedingstuff:

.....

.....

.....

SECTION II.

To be completed in it's entirety by the veterinary surgeon.

Name and address of owner or person in charge of the animals:

.....

.....

.....

Identification (species etc.) and number of the animals:

.....

.....

.....

Designation of the authorised pre-mix(es) (proprietary name(s) and veterinary product
authorisation (VPA) number(s) and/or generic name(s):

.....

.....

.....

Quantity of medicated feedingstuff:

Please manufacture/sell/import.....tonnes/kg* of
meal/pellets/crumb containing.....g/tonne (mg/kg) of.....(pre-mix as
designated above) to give in total.....g/tonne (mg/kg)
of.....

.....

(precise description of active substance(s)) in the final medicated feedingstuff.

SPECIAL INSTRUCTIONS FOR THE OWNER OR PERSON IN CHARGE OF THE
ANIMALS TO WHICH THIS DIRECTION APPLIES

- (1) Disease to be treated:.....
.....
- (2) Quantity of medicated feedingstuff to be given daily:
.....
- (3) Duration of treatment:.....
.....
- (4) Withdrawal periods:
- Animals must not be slaughtered for human consumption
for.....hours/days* after last treatment.
- (5) Special precautions (if any):

.....
.....

.....

*Delete as appropriate.

SIGNATURE OF VETERINARY SURGEON

.....

NAME IN BLOCK CAPITALS

.....

PRACTICE ADDRESS

.....

PRACTICE TELEPHONE NUMBER.....
.....

PRACTICE STAMP

SECTION III.

To be completed by the manufacturer/seller.

Date(s) of delivery.....

To be used before.....

Signature of manufacturer or seller.....

SECTION IV.

To be completed by veterinary surgeon if applicable.

Reason for directing the incorporation by a manufacturer of an unauthorised medicated pre-mix.

.....

.....

.....

SECOND SCHEDULE

ACCOMPANYING CERTIFICATE IN RESPECT OF MEDICATED
FEEDINGSTUFFS FOR ANIMALS INTENDED FOR TRADE.

Name and address of the manufacturer or approved distributor:

.....
.....

.....
.....

.....
.....

Name of the medicated feedingstuff:

.....
.....

Type of animal for which the medicated feedingstuff is intended:

.....
.....

Name and composition of the authorised pre-mix:

.....
.....

Dosage of the authorised pre-mix in the medicated feedingstuff:

.....
.....

Quantity of medicated feedingstuff:
.....

Name and address of the recipient:.....
.....

.....

.....

.....
.....

It is hereby certified that the medicated feedingstuff as described above has been
manufactured by an authorised person in accordance with Directive 90/167/EEC.

.....

Place and Date.

Stamp of the veterinary authority or
other competent authority.

.....

(signature).

Name and position.

EXPLANATORY NOTE.

These regulations implement Council Directive 90/167/EEC of 26 March 1990 laying down conditions governing the preparation, placing on the Market and use of medicated feedingstuffs in the community.

The regulations provide for the control of the manufacture, availability and use of medicated feedingstuffs. The activities of manufacture, distribution and sale of medicated feedingstuffs and intermediate products for the manufacture thereof is subject to licensing by the Minister. The use of medicated feedingstuffs is prohibited save under and in accordance with the terms of a veterinary written direction.

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