HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Definition of an Animal Remedy and the Classification Process

ADV-G0002-8
12 NOVEMBER 2019
This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

CONTENTS

ABBREVIATIONS

ECJ	European Court of Justice
HPRA	Health Products Regulatory Authority

RELEVANT LEGISLATION

This document is intended as a guideline only and should not be assumed to be a definition of the law in this area. It may be subject to change in the light of new developments over time or as appropriate.

The guide should be read in conjunction with the various relevant Directives, Acts and Regulations, in particular the following:

Directives

2004/28/EC	(Veterinary Medicines)
2001/82/EC	(Veterinary Medicines)
70/524/EEC	(Feed Additives)
90/167/EC	(Medicated Feedingstuffs)
2008/38/EC	(Feedingstuffs for Particular Nutritional Purposes)

Act

Act No. 29 of 1995	(Irish Medicines Board Act, as amended)
Act No. 23 of 1993	(Animal Remedies Act)

Regulations

No. 528 of 2012	(Biocidal Products Regulation)
No. 767of 2009	(Animal Feed)

Statutory instruments

S.I. No. 786 of 2007	(European Communities (Animal Remedies) (No. 2) Regulations 2007)
S.I. No. 176 of 1994	(European Communities (Animal Remedies and Medicated Feedingstuffs) Regulations 1994)
S.I. No. 507 of 1998	(Control of Animal Remedies and their Residues Regulations)
S.I. No. 488 of 2010	(Food and Feed Hygiene)
S.I. No. 432 of 2009	(Food and Feed Hygiene)

1 INTRODUCTION

The Health Products Regulatory Authority (HPRA) is the statutory authority in Ireland for determining applications for marketing authorisations (provided for in Article 5 of Directive 2001/82/EC, as amended) in respect of veterinary medicinal products, pursuant to the provisions of the Irish Medicines Board Act 1995, as amended, and for animal remedies, pursuant to the Animal Remedies Act, 1993.

Note: The Department of Agriculture, Food and the Marine is the statutory authority for issue of certain licences to address exceptional circumstances – this guide does not deal with such exceptional licences and any enquiries in this regard should be addressed to the Department of Agriculture, Food and the Marine, Backweston Campus, Young's Cross, Celbridge, Co. Kildare.

The European Communities (Animal Remedies) (No. 2) Regulations 2007 require that an *Animal Remedy* shall not be sold or supplied without a Veterinary Product Authorisation (VPA). Under these regulations, it is also illegal to advertise or promote an animal remedy in advance of it being granted a marketing authorisation. The granting of such authorisation ensures that the product complies with the required standards of quality, safety and efficacy. It is the responsibility of those marketing veterinary medicinal products to comply with the relevant legislation, and to ensure that such products are marketed only in accordance with this legislation.

An *Animal Remedy* is defined in the Animal Remedies Act, 1993, as being 'any substance or combination of substances which-

(a) is intended for administration to animals,
(b) may be administered to animals, or
(c) is, whether expressly or by implication, presented for administration to animals,

for the purpose of-

(i) treating, preventing or modifying diseases in animals,
(ii) making a medical or surgical diagnosis in animals,
(iii) restoring, correcting or modifying physiological functions in animals, or
(iv) except for a substance or combination of substances being a feedingstuff commonly known and solely used as such, otherwise improving the health or condition of animals.'

According to the same Act, 'administration' includes internal or external application, by oral, parenteral, and topical means and by inhalation, incorporation in food or water, and by automatic means.

'Disease' includes any injury, ailment or defect.

In most cases, the classification of a product as an *Animal Remedy* is clear in that the nature of the substance, its effects on the body, the indications for use/contraindications, and the manner

of marketing are consistent with the definition of a veterinary medicinal product in the European Directives.

Article 1 (2) of Directive 2001/82/EC, as amended by Directive 2004/28/EC, defines a veterinary medicinal product as:

'*Any substance or combination of substances presented as having properties for treating or preventing disease in animals: or*

Any substance or combination of substances which may be used in or administered to animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.'

Therefore, an *Animal Remedy* is a veterinary medicinal product.

However, there are products which could be said to occupy a 'borderline' position between, for example:
- Animal remedies and nutritional products
- Animal remedies and shampoos or other surface agents
- Animal remedies and herbal, or other feedingstuffs
- Animal remedies and biocidal products

This document is intended to describe HPRA policy in recommending whether products should be classified as *Animal Remedies* for veterinary use, or whether they can be considered as out of the scope of the legislation.

When a product is determined by the HPRA as 'out-of-scope' (i.e. not an animal remedy), it must carry the following statement on the product labelling: *This is not a veterinary medicine which is subject to authorisation by the Health Products Regulatory Authority*'. Its product literature is also reviewed by the HPRA to ensure that it does not include any statements that constitute medicinal claims. Such products must also not be promoted as being medicinal.

2 THE HEALTH PRODUCTS REGULATORY AUTHORITY

The general powers and functions of the HPRA are set out in the Irish Medicines Board Act 1995, as amended, referred to above. The HPRA is the competent authority for the licensing and supervision of veterinary medicines in Ireland. The aim of the HPRA is to protect and enhance public and animal health through the regulation of veterinary medicinal products which are available in Ireland, or manufactured in Ireland for Irish or export markets. The regulation of these products is founded on science and law to ensure their purity, potency, safety, efficacy and stability as appropriate during storage, transport and distribution.
The HPRA also participates in systems designed to ensure quality, safety and efficacy of medicines throughout the European Union. Under the terms of the Irish Medicines Board Act

1995, as amended, and the Animal Remedies Act 1993, anyone who contravenes a regulation made by the Minister under the Act, is liable to a fine or to a prison term, or both as appropriate.

3 THE REQUIREMENTS OF AN ANIMAL REMEDY

Before an *Animal Remedy* can be authorised for use by the HPRA, an application must be made for a veterinary product authorisation to that body (or, in the case of centrally authorised products, to the European Medicines Agency). Such applications must contain the data necessary to demonstrate the quality, safety and efficacy of the product. The application is reviewed and a decision on the application reached, based upon the likely balance of the benefits versus risks associated with the product. The HPRA requires that the interests of users of animal remedies and consumers of treated animals should be protected, particularly in the following areas:

1. An *Animal Remedy* should be of such quality that its contents and its pharmaceutical performance conform to acceptable standards.
2. The risk to animals and users of administering an *Animal Remedy* should be acceptable and reasonable, taking into account that the use of any medicine carries a risk which should be considered in the light of the intended benefit.
3. There should be a demonstrable therapeutic benefit. If a medicinal claim is made, the purchaser is entitled, within reason, to expect a benefit and the application process should protect the consumer, in so far as possible, from products which do not offer a potential for such benefit.
4. Whenever appropriate, the holder of a product authorisation must ensure that their product does not present any threat to consumers of food-producing animals.

In addition, there is a requirement that the holder of a product authorisation should keep the HPRA informed of the discovery of any adverse effects or any events with potential safety consequences for their products.

4 WHAT IS AN ANIMAL REMEDY?

The clear definition of a veterinary medicinal product is given in Article 1(2) of Directive 2001/82/EC, as amended. Under national legislation, the definition of an Animal Remedy is set out in the Animal Remedies Act, 1993 (see Introduction).

These definitions cover both the presentation of the product and the purpose for which it is administered.

4.1 Presentation

The Directive refers to the presentation of the product as follows:

'Any substance or combination of substances presented for treating or preventing disease in animals'.

The Animal Remedies Act uses the wording:
a) intended for administration to animals
b) may be administered to animals
c) is, whether expressly or by implication, presented for administration to animals.

In reviewing a product application in this context, the HPRA examines the 'totality' of the product, for example:

4.1.1 Products which (explicitly or implicitly) claim to cure, alleviate or prevent disease will be considered by the HPRA as *Animal Remedies*. Any particular words or phrases which imply such a claim will be taken into account.

While not intended to be exhaustive, the following list contains examples of such words or phrases:

'Prevents, cures, heals, treats, restores, remedies, clears, relieves, repairs, stops, protects, helps with, alleviates, controls, combats, counters, traditionally used for, strengthens the immune system, calms, aids in the healing of, helps maintain normal water balance, helps in the prevention of.'

4.1.2 Products which are presented so that the labelling, the packaging, the pharmaceutical form or the promotional material implies a medicinal usage are considered as *Animal Remedies*.

4.1.3 Once a given product has been classified by the HPRA as an *Animal Remedy* it is possible that closely related products may be similarly classified.

4.2 The purpose for which a product is administered

The second paragraph of Article 1(2) of the Directive states:

'Any substance or combination of substances which may be administered to animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in animals is likewise considered a veterinary medicinal product'.
The Animal Remedies Act (1993) states the following:
- treating, preventing or modifying disease,

- improving the health or condition of animals (except for a feedingstuff commonly known and solely used as such).

Any product containing a substance with a pharmacological effect on physiological function at the dosage used will usually be classified as an *Animal Remedy* by the HPRA irrespective of the presence or absence of claims in the product packaging or literature. In order not to be considered as an *Animal Remedy*, the onus rests with the applicant to suitably demonstrate the absence of a pharmacological effect on physiological function at the dosage used.

It should be further noted that any product containing a substance which is confined to supply on veterinary prescription by virtue of the European Communities (Animal Remedies) (No. 2) Regulations 2007, is automatically deemed to be an Animal Remedy requiring an authorisation.

4.3 HPRA policy and practice

ECJ judgements, the evolution of scientific and regulatory opinion, changes in legislation or in marketing practices, and other changing circumstances have required corresponding changes to the way the HPRA assesses applications.

In particular, it takes full account of the ECJ view that competent authorities of Member States should consider all the characteristics of the individual products, and are obliged to consider what impression of the product an averagely well informed person would be likely to gain.

Thus in practice, the HPRA considers each individual product on its merits and any information which may have a bearing on the product's status, such as:

a) The claims made for the product (including any claims made on linked 'help-lines', websites or publications, or in the product's actual name).

b) The pharmacological properties of the ingredient(s) and any significant effect(s) they have on animals.

c) The labelling, and the packaging literature, including any pictorial descriptions.

d) The promotional literature (including testimonials and any literature issued by a third party on behalf of the manufacturer or producer) and advertisements.

e) The product form (e.g. tablet, capsule, ointment, etc.) and the way in which it is intended to be used or administered.

f) To whom the product or information about the product is directed.

g) Whether there are similar authorised Animal Remedies on the market fulfilling similar functions.

h) The potential presence or not of residues of the product in food-producing animals.

i) Whether the product is controlled under alternative legislation, e.g. feedingstuffs intended for particular nutritional purposes or biocidal products (see Appendix 2).

j) Whether the product has its effects by physical or biochemically mediated means.

k) Whether the product is ingested by the animal as a food.

l) Whether the product is applied to the animal directly or to the local environment in which the animal is kept.

5 BORDERLINE PRODUCTS

This guideline has been drawn up to explain the HPRA's policy and practice on borderline products, and the principles on which they are based.

In general, the presence of substances such as antibiotics, antifungal agents, hormones and anaesthetics in products can only be justified on the basis that the products are medicinal and as such will require product authorisations.

Preparations intended to be ingested, inhaled, injected or implanted in the animal body cannot be considered to be cosmetic products. Similarly, preparations for use in the eye (e.g. artificial tears), on horn buds for de-budding animals, for intramammary or intra-uterine use are considered as medicinal products, by virtue of their route of administration and their potential risks.

Other specific examples are given below.

5.1 Foods and feedingstuffs

In general, most foods are not medicinal products. However, some manufactured preparations contain substances such as vitamins, minerals, amino acids, zinc oxide and herbal ingredients, presented in certain forms which are usually associated with medicines (e.g. capsules, tablets, drenches, premixes). Such preparations may be classed as medicinal products even in circumstances where they may be described by the manufacturers concerned as 'foods' or 'food supplements'. In these cases, the use by the purchasers and users of the products (the primary objective) will be taken into account by HPRA in classifying the products.

The following is an outline of those products which are presented in a form usually associated with *Animal Remedies*.

5.1.1 Products containing nutrients, vitamins and/or mineral ingredients

Some proprietary preparations are products which are foods, feed additives (Council Regulation (EC) 1831/2003) or feedingstuffs coming within the scope of Regulation (EC) No. 767 of 2009. These do not come within the scope of the Animal Remedies legislation when labelled and used in accordance with the legislation concerned.

However, proprietary preparations are considered to be *Animal Remedies* when:

a) their labelling or accompanying or associated literature makes any preventative, curative or remedial claim (e.g. prevention of nutrition deficiency); or

b) the use of a product intended for administration to food producing animals may require a withdrawal period in order to avoid violative residues; or

c) the product is intended for parenteral administration (any injectable product is an Animal Remedy, as stated previously); or

d) the intake of any constituent at the recommended dosage could be toxic to normal animals.

5.1.2 Herbals (products containing medicinal herbal ingredients)

Herbal remedies are considered by the HPRA to be *Animal Remedies* when they are present in a product for the purpose of preventing or treating a disease in the animal.

However, it should be noted that preparations consisting of dried or crushed herb(s) which form a minor component of a product intended for oral administration to healthy animals, as part of the animal's diet, are not regarded as *Animal Remedies* provided that:

- no indication for use of the product as an *Animal Remedy* is made,
- none of the herbal substance(s) has pharmacological action on physiological function at the dose administered to the target animal, or the quantity of herb(s) is representative of that which might reasonably be expected to be ingested by an animal grazing on native pasture.

5.1.3 Feedingstuffs intended for particular nutritional purposes

Regulation (EC) No. 767 of 2009 establishes the definition and the conditions of use, manufacturing and marketing of certain feedingstuffs, which are not considered as *Animal Remedies*. These feedingstuffs exclude any medicated substance or additive as described in the Directive 90/167/EEC of March 1990, which require a product authorisation.

When feedingstuffs are elaborated for specific nutritional purposes, the manufacturer should ensure that the labelling complies with all the directions as laid out in Regulation (EC) No. 767 of 2009 and Annex I to Directive 2008/38/EC (Feedingstuffs intended for particular nutritional purposes).

This legislation is administered by the Department of Agriculture, Food and the Marine, which should be consulted.

5.1.4 Zinc Oxide

Where zinc oxide is being prescribed for inclusion in diets for pigs, for the prevention of diarrhoea, it will be regarded by the HPRA as an *Animal Remedy*.

5.1.5 Colostrum products

Pure colostrum and colostrum substitutes are regarded as nutritional supplements and not *Animal Remedies* provided:
- no preventative or treatment claim is made
- no reference to immunological content, antibodies or immunity is made.

While the word 'colostrum' is not considered medicinal, where medicinal claims are made for a product, the product will be regarded by the HPRA as an *Animal Remedy*.

6 HOMEOPATHIC MEDICINES

Homeopathic medicines represent special types of *Animal Remedies* for which particular rules apply, in accordance with the requirements of Directive 2001/82/EC, as amended.

Under Article 16, all homeopathic veterinary medicinal products must be registered or authorised. Thus, all homeopathic veterinary medicinal products are considered to be *Animal Remedies*.

Under Article 17, a special, simplified registration procedure may apply for non-immunological homeopathic veterinary medicinal products, as long as there are no specific therapeutic indications. There are also restrictions on the degree of dilution. With this procedure all the usual requirements for authorisation of a veterinary medicine apply, except for proof of efficacy. The HPRA is empowered by virtue of Regulation 7(2) of the European Communities (Animal Remedies) (No. 2) Regulations 2007 to determine whether the simplified procedure should apply in any given case.

7 DISINFECTANTS/TEAT DIPS

If no medicinal claims are made, disinfectants/antiseptics intended for application to the skin for general hygiene use may be classified as biocides, and so subject to registration under the Biocidal Products Regulation (Regulation (EU) No. 528 of 2012), rather than as a veterinary medicine. This also applies to insect repellents for use on animals, as long as they have no lethal effect on insects. Applicants are advised to make the usual classification enquiry to the HPRA in the first instance.

A disinfectant/antiseptic preparation which is intended to treat wounds or other skin lesions is considered to be an *Animal Remedy* requiring a product authorisation.

Any disinfectant intended for administration into the uterine tract or a body cavity (e.g. uterine wash) is considered by the HPRA to be an *Animal Remedy*.

Further to clarification from the EU Commission in September 2008, teat dips are classified as biocidal products and are to be authorised in accordance with the requirements of Regulation (EU) No. 528 of 2012 **as long as no medicinal claim is made** [emphasis added].

8 PRODUCTS NOT REGARDED AS ANIMAL REMEDIES

There are certain products which are not *Animal Remedies*.

If:

1 no medicinal claims are made on the product literature,
2 the product does not contain pharmacologically active substances,
3 the product does not fulfil the criteria described in (4) above,
4 the product is used as intended,

the following products would not be regarded as *Animal Remedies* by the HPRA:

- Products used solely for the treatment of the environment of the animal
- Nutritional preparations intended for oral administration to healthy animals for several days or weeks to achieve nutritional benefit
- Non-nutrient substances added to a food (or to a diet) of animals to improve preservation, colour, palatability, texture or nutritive value of food, including (for example) preservatives, antioxidants, emulsifiers, stabilisers, acids, non-stick agents, firming agents, anti-foaming agents, colourants and flavourings
- Topical physical barriers, e.g. topical paraffin based (non-medicated) ointment and creams
- Non-medicated shampoos and baths
- Hoof oil
- Footbaths used for hardening hooves
- Marking sticks or paints used for animal identification or 'heat' detection

- Medical devices, such as sutures, controlled by Council Directive 93/42/EEC (medical devices for human use)
- Semen extenders used in artificial insemination
- Fly repellent sprays
- Salt or mineral licks

9 CLASSIFICATION PROCEDURE WITHIN THE HPRA

It is clear that classification of veterinary products occupying the borderline area between veterinary medicines and, for example, nutritional or cosmetic substances, is important since the producers and users of such products need to be aware of the more stringent legislation which exists for marketing of veterinary medicinal products.

Any company or individual who attempts to market a borderline product may discover that the product might in fact be subject to veterinary medicines legislation and prior authorisation/registration is required. It is for this reason that the HPRA has set up a classification procedure whereby applicants can request an opinion on the classification of a given product prior to placing it on the market. In this way applicants can obtain an opinion and avoid the risk of breaking the law by placing a veterinary medicinal product on the market without the necessary authorisation.

9.1 Applying for classification of a veterinary product by the HPRA

To apply for classification of a borderline veterinary product by the HPRA, download the form 'Request for Classification of a Borderline Product for Animal Use' from the 'Publications and Forms' section of www.hpra.ie. Complete the appropriate sections of the form, entering N/A if any one section is not applicable. In order to arrive at a decision regarding classification of the product, the HPRA must be in receipt of sufficient accurate information about the product and its intended use. This includes any labelling and promotional material relating to the product.

The form must be signed by the applicant. All applications (including the supporting data) must be in English.

Submit the signed form with attachments and the appropriate fee to the Receipts and Validation section of the HPRA at the address on the form.

Requests to amend the labelling and/or product literature, subsequent to a decision regarding classification of the product, will be treated as a new determination and thus will be subject to the appropriate fee. To apply for an amendment, an application should be submitted as detailed above.

9.2 The classification process

The application details and associated product information are assessed by the Veterinary Sciences department to determine whether the product:

- is outside the European Communities (Animal Remedies) (No. 2) Regulations 2007 and Directive 2001/82/EC, as amended and is therefore 'out-of-scope',
- falls within the legislation and requires a veterinary medicinal product authorisation from the HPRA, or
- is regulated by the Biocidal Products Regulation (EU) No 528/2012 or the animal feedingstuffs for particular nutritional purposes Directive (2008/38/EC), in which case the applicant is referred to the Department of Agriculture, Food and the Marine.

The classification query may be referred to HPRA experts for an opinion if necessary.

9.3 Duration of the classification process

Usually, provided the applicant has provided clear and comprehensive information as detailed in the application form, the HPRA can give an opinion within 40 days of validation of the application. In the case of applications which are novel or complex, necessitating consultation with HPRA experts, the procedure to complete the evaluation may take up to six months.

9.4 Right to appeal the classification decision

Should an applicant disagree with a negative determination, they may appeal within 14 days of receiving the HPRA's notification. The request for the appeal should be directed to the Classification Administrator together with all supporting information for consideration of the appeal and the appropriate fee. The decision of the HPRA following appeal shall be final.

10 SUMMARY

10.1 The definition of an *Animal Remedy* used in Ireland and throughout the European Community is based on that contained in Article 1 of European Council Directive 2001/82/EC, as amended by Directive 2004/28/EC and the Animal Remedies Act, 1993.

This definition (as outlined in Appendix 1) is in two parts, covering the presentation of the product and the purpose for which it is administered.

10.2 A summary of the HPRA's policy is as follows:

10.2.1 Products which claim to cure, alleviate or prevent disease are considered *Animal Remedies*. The HPRA takes into account in its decision the words used, the presentation and relationship to similar products.

10.2.2 Products which contain substances of a type and in amounts such as to exert a pharmacological effect will also be considered as *Animal Remedies*.

10.2.3 Products presented as nutritional or cosmetic substances will be considered as *Animal Remedies* if medicinal claims are made or if they contain ingredients which have significant pharmacological effects.

10.3 It is the express responsibility of the person or organisation marketing such a product to ensure compliance with the relevant legislation. Failure to comply with the legislation may result in prosecution, with liability for fines or prison terms as specified in the Irish Medicines Board Act 1995, as amended and the Animal Remedies Act 1993.

APPENDIX 1 DEFINITIONS

An **Animal Remedy** means any substance or combination of substances which:

a) is intended for administration to animals,
b) may be administered to animals, or
c) is, whether expressly or by implication, presented for administration to animals for the purpose of:
   (i) treating, preventing or modifying disease in animals,
   (ii) making a medical or surgical diagnosis in animals,
   (iii) restoring, correcting or modifying physiological functions in animals, or
   (iv) except for a substance or combination of substances being a feedingstuff commonly known and solely used as such, otherwise improving the health or condition of animals.

[Animal Remedies Act, 1993, S.I. No. 23 of 1993]

A **veterinary medicinal product** is

- any substance or combination of substances presented for treating or preventing disease in animals
- any substance or combination of substances which may be administered to animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in animals is likewise considered a medicinal product
  [Council Directive 2001/82/EC as amended by Directive 2004/28/EC]

An **immunological veterinary medicinal product** is a veterinary medicinal product administered to animals in order to produce active or passive immunity or to diagnose the state of immunity.
[Directive 2001/82/EC as amended by Directive 2004/28/EC]

A **homeopathic veterinary medicinal product** is any veterinary medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described in the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the Member States.
[Council Directive 2001/82/EC as amended by Directive 2004/28/EC]

Feedingstuff shall mean products of vegetable or animal origin in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, used singly or in mixtures, whether or not containing additives, for oral animal feeding.
[Council Directive 93/74/EEC]

Feed materials means products of vegetable or animal origin, whose principal purpose is to meet animals' nutritional needs, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not

containing feed additives, which are intended for use in oral animal-feeding either directly as such, or after processing, or in the preparation of compound feed, or as carrier of premixtures.
[Regulation (EC) No. 767 of 2009]

Compound feed means a mixture of at least two feed materials, whether or not containing feed additives, for oral animal-feeding in the form of complete or complementary feed.
[Regulation (EC) No. 767 of 2009]

Feed intended for particular nutritional purposes means feed which can satisfy a particular nutritional purpose by virtue of its particular composition or method of manufacture, which clearly distinguishes it from ordinary feed. Feed intended for particular nutritional purposes does not include medicated feedingstuffs within the meaning of Directive 90/167/EEC.
[Regulation (EC) No 767 of 2009]

Particular nutritional purpose means the purpose of meeting the specific nutritional needs of animals whose process of assimilation, absorption or metabolism is, or could be, temporarily or irreversibly impaired and who can therefore benefit from the ingestion of feed appropriate to their condition.
[Regulation (EC) No. 767 of 2009]

Animal means mammals (other than humans), birds, fish, reptiles, molluscs, crustaceans, honey bees and any other animal kept for human consumption or any of whose produce is intended for human consumption and a domestic animal, a wild animal, in captivity and any other wild animal.
[Animal Remedies Act, 1993, S.I. No. 23 of 1993
Animal Remedies Act (Section 2) Order 2005, S.I. No. 733 of 2005]

Food Producing Animal means an animal of the bovine, caprine, ovine or porcine species, poultry, rabbits, deer, fish or honeybees if such rabbits, deer or fish are intended for use as food for human consumption or equidae intended for use as food for human consumption in accordance with the European Communities (Equine Stud-Book Competition) Regulations 2004 (S.I. No. 399 of 2004)).
[European Communities (Animal Remedies) (No. 2) Regulations 2007, S.I. No. 786 of 2007]

Companion Animal includes domestic dog, cat, rabbit (other than a rabbit kept for human consumption), a small rodent, cage bird, homing pigeon, terrarium animal and an aquarium fish or an equid declared as not intended for use as food for human consumption in accordance with the European Communities (Equine Stud-Book Competition) Regulations 2004 (S.I. No. 339 of 2004).
[European Communities (Animal Remedies) (No. 2) Regulations 2007, S.I. No. 786 of 2007]

APPENDIX 2 REFERENCES

Animal Remedies Act, 1993 (S.I. No. 23 of 1993)

European Communities (Animal Remedies) (No. 2) Regulations, 2007 (S.I. No. 786 of 2007)

Irish Medicines Board Act 1995, as amended (S.I. No. 29 of 1995)

Council Directive 93/74/EEC of 13 September 1993 on feedingstuffs intended for particular nutritional purposes

European Communities (Feedingstuffs Intended for Particular Nutritional Purposes) Regulations, 1996, as amended

Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community

Council Directive 81/602/EEC of 31 July 1981 concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action

Council Directive 2001/82/EC of 6 November 2001 on the Community code relating to veterinary medicinal products, as amended by Directive 2004/28/EC

Council Directive 90/677/EEC of 13 December 1990 extending the scope of Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products and laying down additional provisions for immunological veterinary medicinal products

Council Directive 70/524/EEC of 29 November 1984 concerning additives in feedingstuffs

Council Directive 98/8/EC of 16 February 1998 concerning the placing of biocidal products on the market

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

Regulation (EU) No. 528 of 2012 of 22 May 2012 concerning the making available on the market and use of biocidal products

Commission Directive 2008/38/EC of 5 March 2008 establishing a list of intended uses of animal feedingstuffs for particular nutritional purpose

European Communities (Food and Feed Hygiene) Regulations 2009 (S.I. No. 432 of 2009)

European Communities (Food and Feed Hygiene) (Amendment) (No. 2) Regulations 2010 (S.I. No. 488 of 2010)

Regulation (EU) No 767/2009 of 13 July 2009 on the placing on the market and used of feed, amending European Parliament and Council Regulation (EC) No. 1831 of 2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC