VETERINARY RESIDUES MANAGEMENT GUIDANCE

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1. Introduction

Veterinary medicines are used to treat sick animals, to prevent diseases in herds and flocks and for stock management, e.g. reproduction and stress control. These medicines must be safe and effective, and reliably administered. Inappropriate action could endanger the animals treated with them, those administering the product, or consumers of meat and animal products and could damage the environment.

In recent years there have been a number of well-publicised incidents involving banned substances or unauthorised veterinary medicines in imported products. For example:-

Animal feed	chloramphenicol, medroxy progesterone
Honey	chloramphenicol, streptomycin
Poultry	nitrofurans, chloramphenicol
Seafood	nitrofurans, chloramphenicol

This Guidance aims to assist chilled prepared food manufacturers in managing veterinary residues by

- Providing an overview of the issues and legislation
- Providing clarity on how veterinary medicine residues arise including as a result of the routes through which veterinary medicines are administered.
- Indicating the various responsibilities throughout the chain
- Outlining best practice in control measures
- Providing information to assist in auditing feed mills, farms and slaughterhouses
- Providing sources of update information

It should be noted that the European Commission is reviewing the range of legislation related to the evaluation of residues of pharmacologically active substances and for their control. Legislative proposals are to be developed to bring the relevant legislation in line with the principles of Regulation 178/2002/EC ('General Principles of Food Law') and is expected to include modification of the relevant legislative instruments, i.e. Regulation 2377/90/EEC, and Directive 96/23/EC.

We gratefully acknowledge the assistance of the Veterinary Medicines Directorate in the development of this document.

The Association welcomes comment on the Guidance, both in terms of the general approach taken and on detailed requirements.

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2. Scope

- Farmed animal-derived products including meat and meat fats, poultry, fish and seafood, eggs, dairy products and honey
- Whilst the emphasis is on residues from veterinary medicines, the scope of this Guidance includes reference to other chemical substances, which might be present in products derived from animal sources and therefore includes:-
  - Any pharmacologically active substances, permitted or not, applied to the source animal.
  - Other substances and environmental contaminants that could leave residues in animal products. The route of entry into animals of these substances is generally orally, arising from the environment (e.g. from agricultural land, water or contaminated feed).

These substances are listed in Table 1, which is based on Council Directive 96/23/EC (Measures to monitor certain substances and residues thereof in live animals and animal products).

Table 1: Substances within Scope of this Guidance (categorised according to Annex I of 96/23/EC)

Substance	Permitted?
GROUP A: SUBSTANCES HAVING ANABOLIC EFFECT AND UNAUTHORISED SUBSTANCES	
Stilbenes, stilbene derivatives, and their salts and esters	No
Antithyroid agents	No
Steroids	No
Resorcylic acid lactones including zeranol	No
Beta-agonists	No
Compounds included in Annex IV (as amended) to Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin	No
GROUP B: VETERINARY DRUGS[§] AND CONTAMINANTS	
1. Antibacterial substances, including sulphonomides, quinolones	Yes
2. Other veterinary drugs a) Anthelmintics b) Anticoccidials, including nitroimidazoles c) Carbamates and pyrethroids d) Sedatives e) Non-steroidal anti-inflammatory drugs (NSAIDs) f) Other pharmacologically active substances	Yes
3. Other substances and environmental contaminants (adventitious contaminants) a) Organochlorine compounds including PCBs b) Organophosphorus compounds c) Chemical elements d) Mycotoxins e) Dyes f) Others, e.g. dioxins	No

[§] Including unlicensed substances which could be used for veterinary purposes.

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3. Types of Veterinary Residues

Table 1 sets out substances within scope of this Guidance. Table 2 below refers specifically to the various types of veterinary medicines and their uses.

Table 2: Classification, usage and examples of veterinary medicines

Class of Medicine	Example	Therapeutic	Prophylactic	Growth Promoter
Antimicrobials & antibiotics	Sulphonamides, ß-lactams, tetracyclines, aminoglycosides, macrolides, quinolones & fluoroquinolones	Y	Y	*Y
Anabolic agents**	Oestradiol, testosterone, progesterone, trenbolone, zeranol, hexoestrol, diethylstilboestrol, dienestrol	N	N	***N
Anthelmintic agents	Ivermectin, benzimidazoles (levamisole, thiabenzadole, cambenzadole, fenbenzadole, oxfendazole, mebendazole, albendazole)	Y	Y	N
Coccidiostats	Carbanilides, pyrimidines, pyridinols, 4 hydroxy quinolones, sulphonomides, nitrofurans, ionophores	Y	Y	N
Tranquilisers & ß-agonists	Azaperone, azaperol, ****clenbuterol	N	N	N
Non-hormonal growth promoters*****	Quinoxaline, carbadox, olaquindox	N	N	Y

* Four (monensin, salinomycin, avilomycin and flavophospholipol) are still permitted for use as growth promoters in animal feed fed to animals marketed in the EU. It is intended that all will be banned from this use from 01/01/06.

** The use of hormonal growth promoters has been banned in the European Community since 1988. In addition, any third country which permits the use of growth promoting hormones is required to guarantee that no animal and no meat coming from animals to which they have been administered will be exported to the Community.

*** Still permitted for this use in the USA – impact on trade

**** Illegal usage in feed as a growth promoter in the past

***** The use of the quinoxaline N dioxides carbadox and olaquindox has been banned in the EC since 1999

In September 2003, the EC adopted Directive 2003/74 amending Council Directive 96/22/EC. This is expected to result in a definitive ban on all uses of 17 β-oestradiol and its derivatives in food producing animals by 2008. Five other banned growth-promoting hormones would continue to be prohibited for use for growth-promoting purposes, but would still be available for certain therapeutic and zootechnical purposes, under strict control. The position would be provisional, pending the availability of more complete scientific evidence.

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4. Legislation

Since 1984, UK legislation on veterinary medicines and control of their residues in food is governed by Regulations and Directives agreed at European level. They apply to the EU as a whole.

Key legislation regarding veterinary residues includes:-

- The Veterinary Checks Directive (91/496/EEC) which lays down the principles governing the organisation of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC. Amended by Council Directive 96/43/EC.
- Regulation of the European Parliament and of the Council on additives for use in animal nutrition (1831/2003/EC, replacing 70/524/EEC - to come into force September 2004), which consolidates existing rules on additives in feedingstuffs and clarifies certain procedural aspects related to dossier evaluation and the types of authorisation granted to feed additives
- Regulation on Official Food and Feed Controls (under development). The proposed Regulation will streamline and reinforce the existing control system with stricter enforcement mechanisms. It aims to improve the efficiency of control services performed by both Member States and the EC. It will define stronger enforcement measures, including criminal sanctions. It will also create a framework to support developing countries in meeting EU import requirements and provides for a financial framework to organise activities that enhance food and feed safety.

It should be noted that the European Commission is reviewing the range of legislation related to the evaluation of residues of pharmacologically active substances and for their control. Legislative proposals are to be developed to bring the relevant legislation in line with the principles of Regulation 178/2002/EC ('General Principles of Food Law') and are expected to include modification of the relevant legislative instruments, i.e. Regulation 2377/90/EEC, and Directive 96/23/EC.

In the UK, Marketing Authorisations for Veterinary Medicinal Products 1994 SI No 3142 provides the basis for regulating the manufacture, sale and supply of veterinary medicinal products. Medicinal feed additives are also regulated by several different regulations according to their legal categories (see 4.1). All products must be authorised before they are marketed, and used only in accordance with the authorisation. Under these regulations, the licensing authority for veterinary medicines is VMD, which is an agency of Defra.

The VMD, formed in 1989, is responsible in the UK for:-

- Advising ministers on the approval of veterinary medicines
- The control of the manufacture and marketing of animal medicines
- The surveillance for residues of animal medicines in meat and other animal products

VMD is advised by an independent body of experts, the Veterinary Products Committee (VPC), which includes veterinarians, medical clinicians, toxicologists, agricultural specialists and environmental toxicologists. VPC also seeks advice from other expert bodies in Defra, the Department of Health and the VRC.

The Feeding Stuffs Regulations 2000 SI 2481, as amended, is the principal secondary legislation made under Part IV of the Agriculture Act 1970. It replaces the Feeding Stuffs Regulations 1995, which had been amended several times. The Regulations apply mainly to England. There are separate but parallel regulations for Scotland, Wales and Northern Ireland. The Regulations cover the composition, labelling and marketing of animal feeding stuffs (including petfood), and contain provisions relating to the additives they may contain, the maximum levels of certain contaminants, labelling information for farmers/producers, and the dietetic claims which may be made for certain products.

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4.1 Legal Categories of Veterinary Medicines/Feed Additives

All animal medicines in the UK are assigned under the Medicines Act 1968 to one of several legal categories as set out in Table 3.

Table 3: Legal Categories of Veterinary Medicines/Feed Additives

Category	Conditions of sale	Specific Legislation
General Sale List (GSL)	May be sold in any retail outlet. Mainly anthelmintics. Excludes MFS. Records held by retailer and farmer.	The Medicines (Veterinary Drugs) (General Sale List) Order 2001 SI No 1645 The Medicines (Pharmacy and General Sale - Exemption) Order 1980 SI No 1924 (as amended) Retailers' Records for Veterinary Medicinal Products Regulations 2000 SI No 7 The Sheep Scab Order 1997 SI No 968
Medicated Feedstuffs (MFS)	Authorised medicated premixes can be incorporated into animal feed under the terms of a medicated feeding stuffs (MFS) prescription signed by a veterinary surgeon for animals under his/her care. MFS and premixes going into them and intermediate products are strictly controlled. Manufacturers or anyone wishing to buy feedingstuffs to mix or feedingstuffs premises must be registered with the RPSGB in GB or DARD NI. It is an offence to mix MFS with another feed without authorisation and prescription, even on a farm. The same rules apply to imported feedingstuffs. Control of carry over is via the application of Codes of Practice, for example those produced by AIC.	Medicated Feedingstuffs Regulations 1998 SI No 1046 Council Directive 90/167/EEC laying down conditions governing the preparation, placing on the market and use of medicated feedingstuffs.
MFSX	Anthelmintics in feedingstuffs that are exempt from the need for a prescription. Can be supplied to keepers of animals by agricultural merchants were premises are registered and where the sale is authorised by a suitably qualified person.	Medicated Feedingstuffs Regulations 1998 SI No 1046 The Feeding Stuffs (Establishments & Intermediaries) Regulations 1999 SI No 1872
Zootechnical Products	'Zootechnical additive' means an additive belonging to one or more of the groups of additives specified in Part I of Annex C to Directive 70/524/EEC (to be replaced by 1831/2003/EEC in 2004), as amended by Directive 96/51/EC. They may be added to any feedstuffs.	The Feeding Stuffs (Zootechnical Products) Regulations 1999 SI No 1871 The Feeding Stuffs (Establishments & Intermediaries) Regulations 1999 SI No 1872

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Category	Conditions of sale	Specific Legislation
Pharmacy List (P)	Can only be supplied by veterinary surgeons in respect of animals under their care, or from a pharmacy under the supervision of a pharmacist. Records on both sides are kept for 3 years.	The Medicines (Veterinary Drugs) Prescription Only Regulations 2001 SI No 1646 The Medicines (Pharmacy and General Sale -Exemption) Order 1980 SI No 1924 (as amended)
Pharmacy & Merchants List (PML)	Animal medicines that appear on the PML can also be supplied to keepers of animals by agricultural merchants where premises are registered and where the sale is authorised by a suitably qualified person. Records on both sides are kept for 3 years.	Medicines (Exemptions for Merchants of Veterinary Drugs) Order 1998 SI No 1044 as amended
Prescription Only Medicines (POM)	Can only be supplied by veterinary surgeons for animals under their care, or dispensed from a pharmacy in accordance with a written prescription from a veterinary surgeon. Records on both sides are kept for 3 years.	The Medicines (Veterinary Drugs) (Prescription Only) Order 2001 SI No 1646

Unauthorised treatments can only be provided by veterinary surgeons for animals under their care if an authorised medicine is available but not applicable to that species and it is necessary to prevent suffering. Withdrawal Periods must be specified by the vet. Records on both sides are kept for 3 years. Legislation applicable in this case is The Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Amendment Regulations 1994.

4.2 MRLs and Approval Status

Veterinary MRLs are based on the type and amount of residues considered to be associated with minimal toxicological, pharmacological and microbiological risk for human health, as expressed by the Acceptable Daily Intake (ADI).

The regulatory process for veterinary medicines comprises:-

1. **Setting the ADI for the active substance**. International bodies assess data from a wide range of short and long-term studies. From these, they identify a concentration that had no effect in any of the studies - the 'No Observed Effect Level' (NOEL). This concentration is then divided by a safety factor, typically 100-1,000, to allow for possible differences between species and individuals.

2. **Identifying all residues of human health concern**. Different species of animals may be treated with a particular medicine. Also, each might convert the active substance in the medicine into other compounds (metabolites). The regulatory process takes account of this.

3. **Setting maximum residue limits** (MRLs) for each tissue such that the ADI is not exceeded. The ADI is divided among all the edible tissues, taking account of:-

   - How much of a particular food may be eaten each day
   - How much of the substance occurs in each food
   - How much of the substance is changed in the animal's body; and
   - Other possible sources of residues, as some substances are used as pesticides or human medicines

   MRLs are set so that even if all of the foods contain residues at the respective MRLs, the ADI will not be breached.

   In the EU, statutory MRLs are developed by the Committee for Veterinary Medicinal Products (CVMP) and its Safety Working Party. MRLs in target tissues are set in European legislation (Annexes I and III to Council Regulation 2377/90/EEC).

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The Annexes are:-

Annex I	Legally applied licensed pharmacologically active substances for which MRLs have been set
Annex II	Legally applied licensed medical substances not subject to an MRL
Annex III	Pharmacologically active substances used in veterinary medicine for which a provisional MRL has been set for the active principle
Annex IV	Substances for which no MRL can be fixed

Regulation 2377/90/EEC additionally prohibits the administration of pharmacologically active substances other than those approved in the EU.

ADIs and MRLs for veterinary medicines are also set at an international level by bodies such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA). JECFA MRLs may then go on to be considered as food standards by FAO/WHO Codex Alimentarius (in the Codex Committee on Residues of Veterinary Drugs in Foods - CCRVDF).

CODEX texts are particularly relevant where cases are brought in front of the World Trade Organisation's (WTO) disputes panel. EU legislation respects its obligations under WTO and, where relevant, is in line with Codex Alimentarius.

Adventitious contaminants such as dioxins, zinc, lead and cadmium are mainly land contaminants and mercury is mainly a water contaminant. Maximum levels are set in the Feeding Stuffs Regulations 2000 SI No. 2481, as amended, and the Contaminants in Food Regulations 2002 SI No. 890. Aflatoxin M1 is mainly a feed contaminant, as are several other harmful substances (e.g. ricin). Aflatoxin M1 and certain other substances are subject to maximum limits relevant to the materials used as 'undesirable substances' under the Feeding Stuffs Regulations 2000 SI No 2481, as amended.

4. **Setting Withdrawal Periods.** To make sure that any residues are below the relevant MRLs in each tissue where an MRL has been set for a particular tissue and species Withdrawal Periods are set. In practical terms, the Withdrawal Period is the length of time that must pass after the end of treatment with a medicine before an animal or animal product can be used for human consumption. In putting forward applications for Marketing Authorisations for veterinary medical products, pharmaceutical companies must provide residue depletion data from tissue studies showing the time taken for residues of all pharmacologically active ingredients of the product to fall below their respective MRLs. Withdrawal Periods are ultimately set by the CVMP or the Veterinary Products Committee in the UK. Where no safe concentrations can be defined (e.g. in the case of some carcinogens), the limit of determination (LOD) of the most sensitive analytical method is usually used.

5. **Analyse samples of foods via residues surveillance schemes**. The UK's surveillance schemes check that any residues are below the MRLs that the EU regulatory authorities have set (section 5), and for non-authorised or illegal use.

   Adherence to MRLs set in Council Regulation 2377/90/EEC is implemented in Great Britain by the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations 1997 SI No 1729. This enables post-authorisation surveillance to be carried out to determine whether animals and animal products for human consumption contain veterinary residues in excess of the prescribed limits. Similar but separate requirements apply in NI.

4.3 Third Country Approval Process

Import requirements and attendant certification are dependant on confidence in that countries systems and associated problems. Imports from all countries must be accompanied by the correct certificate signed by a vet.

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4.4 Legal Responsibilities

Under UK law it is an offence to sell or supply for slaughter (for human consumption) an animal or animal product containing residues of an authorised veterinary medicine in excess of the prescribed MRL or residues of a non-authorised or illegal substance. Primary producers/primary processors must ensure that where an authorised veterinary medicinal product has been used that the withdrawal period has been observed.

The primary processor has a responsibility to ensure this and not to process such meat. UK legislation Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations 1997 SI No 1729 requires animal products to be free from all residues above MRLs and from unauthorised or illegal residues. The requirements are also applied to imported meat and meat products via import Regulations (Imported Foods Regulations 1984, Directive 92/118/EEC).

Organic production normally permits only homeopathic medicines. Allopathic medicines and antibiotics are permitted only for a limited number of 'necessary' administrations per year, which are reported to the notified body (Organic Products Regulations 2001, EC Regulation 2092/91/EEC). Veterinary medicinal products for use in food-producing animals are covered by the Marketing Authorisations Veterinary Medicinal Products Regulations 1994 SI No. 3142.

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5. Surveillance

VMD's Residues Surveillance Team co-ordinates two complementary programmes for surveillance of veterinary medicines and certain other substances in animals and animal products. Responsibility for the planning of surveillance and the Annual Report on Surveillance for Veterinary Residues lies with the VRC. Quarterly surveillance results are published in MAVIS.

5.1 Statutory Surveillance Programme (SSP)

Directive 96/23/EEC sets out the sampling regime and the drugs that must be monitored by each EU Member State in its SSP.

The SSP focuses on the protection of food safety by ascertaining the correct and responsible usage of veterinary medicines and ensuring that no banned materials are used. The SSP focuses on red meat, poultry, salmon and trout, eggs, wild and farmed game, honey and milk.

In the UK, responsibility for advising the Government on veterinary medicines issues rests with the VMD, who receive advice from the VRC and the VPC.

VMD base their sampling requirements on national throughput in accordance with EU legislation. The majority of samples are taken from the red meat and poultry meat sectors and are largely taken from abattoirs based on the throughput of the business. The sampling officer will choose the animal to be sampled, so at this point only he or she knows the farm of origin of the sample. This is recorded on the RIM form that accompanies the sample from there to the end of analysis.

VMD's focus is on testing materials for residues. If exceptional results are found an SVS checks on-farm practices, providing advice on controls to the farmer.

Annexes I and II of 96/23/EEC set out the groups of veterinary residues that all Member States are obliged to test for. From this, VMD consults the VRC, CEFAS (Centre for Environment Fisheries and Aquaculture Science), FRS (Fisheries Research Services), FSA, DH, Defra and DARD NI in drawing up a national plan for this testing, which is presented to the European Commission working group comprising all Member States. The EU's Standing Committee on Food Chain and Animal Health (SCoFCAH) (previously called the Standing Veterinary Committee) reviews all MS plans and adopts them.

Annex III sets out the sampling strategy to be followed for Group A (substances having anabolic effect and unauthorised substances) and Group B (veterinary drugs and contaminants)

Annex IV sets out the number of samples all Member States are obliged to test as a fixed proportion of the animals and animal products, which the Member States forecasts will be slaughtered during the year. A specific percentage of the total UK samples are allocated to Northern Ireland each year in the SSP. In addition Commission Decision 97/747/EC sets out the targeting criteria to be adopted.

The Charges for Inspections and Controls Regulations 1997 implement in the UK the provisions of Council Directive 96/43/EEC in relation to the SSP required by 96/23/EC (the statutory testing programme). This covers the cost of collection and analysis of samples, inspections and advice given, and all of VMD's operating costs, which are borne by industry.

5.1.1 Collection of samples

1. Red meat and poultry
   - The Meat Hygiene Service collects from carcasses at slaughterhouses
   - SVS collect from live animals and feed on farms

2. Salmon and trout
   - CEFAS collect samples collect samples from fish farms in England and Wales
   - FRS (Fisheries Research Services) collects samples from fish farms in Scotland.

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3. Eggs
   - Defra's Egg Marketing Inspectors (EMIs) collect eggs from egg packing stations in England and Wales
   - the Scottish Office's Egg Marketing Officers (EMOs) collect in Scotland.

4. Milk
   - SVS collect samples from bulk tanks on farms.

5. Honey
   - Sample collection from honey producers in England and Wales is by officers of the National Bee Unit (NBU) on behalf of Defra and the National Assembly of Wales. There is currently no surveillance programme applying to Scotland and Northern Ireland.

In Northern Ireland, inspectors employed by DARD's veterinary service collect samples from meat plants and farms. Officers from the department's QA division collect egg, milk and fish samples in a similar way to the rest of Great Britain.

Samples are analysed by contracted laboratories working for VMD, the tender for which takes place every 5 years. The Laboratory of the Government Chemist (LGC) in Great Britain and the Department of Agriculture's Veterinary Sciences Division and Food Sciences Division laboratories in Northern Ireland will be undertaking the analyses for the statutory programme work until 2008.

5.1.2 Follow up Action

All results that are above the relevant MRL or Action Level are also provided to the FSA who can give an opinion on the significance for human health and can issue RASFF (European Rapid Alert System for Food & Feed) alerts to the Commission to disseminate other Member States, as appropriate. FSA can also raise issues with Local Authorities who then visit implicated suppliers to investigate. The FSA will normally through the Local Authorities locate and have removed from the food chain products which are unfit for human consumption (for example containing illegal/unauthorised veterinary residues). It is rare that a RASFF is issued for the SSP.

Follow up action instigated by the VMD is taken by SVS on positive red meat, poultry meat, game, egg and milk samples and by CEFAS and FRS on fish samples. A thorough on-farm investigation is undertaken by a Veterinary Officer from SVS who advises the farmer and may take further samples. If a serious breach of the legislation is suspected the SVS may be accompanied by an Investigation Officer of Defra's legal department and a prosecution will be considered.

For honey, follow up investigations are undertaken by officers from the NBU on behalf of the VMD for all positive residues detected. The VMD may take further action where there is evidence that substances have been used illegally.

There are powers under the Food Safety Act 1990 to remove from the food chain food products containing residues at concentrations that present a danger to human health. The FSA may therefore be asked to take on this responsibility.

Where appropriate, VMD may also contact consumer organisations, Local Authorities, relevant trade associations (TAs) and producers, to make them aware of results. VMD also discuss the results with TAs who may have developed their own guidance on the avoidance of residues in food.

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5.1.3 Reporting of Results

Results of surveillance are reported in VMD's MAVIS (Medicines Act Veterinary Information Service) newsletter, on the VMD and VRC websites and at VRC meetings.

Results from the surveillance of red meat and poultry are reported to the operators of slaughterhouses within 10 working days of the end of each month. Results are also sent to fish farms and egg packing stations when they are reported to the VMD.

5.2 Non-Statutory Scheme (NSS)

This supplements and complements the statutory scheme by including foods not covered in the scheme, e.g. imported prawns, and imported raw meats.

Most samples are subjected to a range of analyses to obtain the maximum possible information on residues.

5.2.1 Collection of Samples

Samples are collected under the non-statutory scheme by:-

- Border Inspection Posts - staff at BIPs collect samples of imported foods including raw meat for analysis
- Mintel under contract to the VMD purchase from retail outlets

Samples are analysed by the Central Science Laboratory (CSL) York.

5.2.2 Follow Up Action

Follow up action is as for the SSP.

5.2.3 Reporting of Results

Retailers are informed by VMD of any 'positives' from products purchased from their stores. Defra's Animal Health International Trade Division is also informed of 'positives' arising from imported products purchased at stores or collected at the BIPs. For imported products the VMD arranges for Defra's Chief Veterinary Officer to write to his counterpart in the country of origin of the product. The CVO is requested to look into the cause of the residue and advise Defra of their findings. The FSA is informed and may seek through local authorities to get any affected product still in the food chain removed from the UK food supply. RASSF are also raised.

All of the results of the both the Statutory and Non-Statutory Scheme are reported in VMD's MAVIS newsletter and on the VMD and VRC websites.

Summary results from statutory and non-statutory surveillance schemes are published quarterly in MAVIS and in the VRC's annual report on Surveillance for Veterinary Residues. Detailed results from the statutory and non-statutory surveillance are reported to the EU annually.

5.3 Non-Defra Surveillance Sources

Food manufacturers' emphasis is on assurance of the integrity of supply chain controls and systems rather than on end-product testing.

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5.3.1 UK

A number of organisations involved in food production and sale undertake surveillance exercises for residues of veterinary medicinal products. Their sampling programme complements the work of the VMD and provides additional guarantees for retailers and consumers.

These data are not generally published, but in the past the VMD has been given access to the results of a number of these exercises. The data are generated in a range of laboratories. In some instances, different methodologies and sensitivities are employed for the same analyte/matrix combination, which does not allow for direct comparison of results.

The VMD also takes an active interest in food safety incidents notified to FSA under the Food and Environmental Protection Act 1995.

5.3.2 Non-UK

Any country that is not in membership of the EU and wishes to export meat/animal products into the EU must be able to demonstrate that they can effectively monitor for residues in the products they wish to export to the EU in compliance with EU legislation.

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6. Sources of Residues/Routes of Administration

Veterinary medicines in the UK are most commonly administered to food-producing animals by these routes:.

- Oral (e.g. water, feed)
- Injection
- Dipping
- Intramammary
- Pour on
- Vaccine

Table 4: Key Administration Routes for Each Class of Veterinary Medicine

Class	Injection	Oral	Dipping	Pour on	Intramammary	Vaccine
Therapeutic	Y	Y	Y	Y	Y	
Prophylactic		Y (most effective)	Y	Y	Y	Y

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7. Supply Chain Responsibilities

7.1 Due Diligence Defence

This defence applies provided that the person accused can provide a due diligence defence, namely that he took all reasonable precautions and exercised all due diligence to avoid commissioning of the offence. All relevant legislation is subject to the due diligence defence.

7.2 Controls At Various Stages of the Food Supply Chain

Control is primarily via the enforcement of legislation, the registration of medicines and premises and participation in trade association schemes, e.g. UFAS (AIC), OVOCOM, GMP$^+$ for animal feed. Many of these schemes take a HACCP-based approach to controls in their sector.

For food manufacturers, the emphasis is on active supply chain management including using assurance schemes relevant to the raw materials supply chain. Awareness of surveillance systems and related Government control activities is also required.

All suppliers should be encouraged to belong to applicable farm and/or feed assurance schemes with standards equivalent to those managed by AIC, focusing on aspects relating to food, drink and veterinary treatments.

AIC's UFAS (Universal Feed Assurance Scheme) deals with the production and delivery of compounds feeds and the supply of feed materials to the farm. Its FEMAS (Feed Materials Assurance Scheme) covers the sourcing and production of feed materials back to the country and/or processor where they are produced. Both the UFAS and FEMAS schemes are HACCP-based and are audited by independent examiners. Major UK multiples require scheme participation for UK-produced livestock products.

Control systems applicable at various points of the supply chain are summarised in table 5.

Table 5: Supply Chain Controls and Schemes

All sectors of the supply chain must be aware of their legal obligations and must be in compliance with them.

Supply Chain Element	Key Action Points in addition to legal compliance	Relevant Control Approach/Scheme
Medicines authorisation, control of manufacture and availability	• Compliance with codes of practice	Medicines & Healthcare Products Regulatory Agency: www.mhra.gov.uk
Feed manufacturer (inc. medicine manufacture, premixes and on-farm)	• Demonstrate ○ Risk Assessments ○ Evidence of best practice ○ Full traceability via assurance scheme membership	AMI: www.rpsgb.org.uk/ FEMAS & UFAS: www.agindustries.org.uk

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Supply Chain Element	Key Action Points in addition to legal compliance	Relevant Control Approach/Scheme
Pharmacies		RPSGB: www.rpsgb.org.uk
Merchants		AMI: www.rpsgb.org.uk
Veterinarians	• Compliance with codes of practice	SVS: www.defra.gov.uk
Farmer	• Buy feed from registered or certified suppliers or be registered for on-farm mixing • Participate in appropriate assurance scheme	ACCS: http://www.everysite.co.uk/casi/default.asp?s=accs ACP: www.assuredchicken.org.uk AMI: www.rpsgb.org.uk Assured Food Standards: www.littleredtractor.org.uk FABBL: www.fabbl.co.uk FAWL: www.welshlambandbeef.co.uk Genesis: www.genesisqa.com UFAS: www.agindustries.org.uk
Abattoir	• Be aware of requirements placed on producers (above) • Take animals from farm assured farms • Demonstrate full traceability	SVS: www.defra.gov.uk VMD: www.vmd.gov.uk
Cutting plant	• Be aware of requirements placed on producers (above) • Take animals from farm assured farms and audited abattoirs • Demonstrate full traceability	SVS: www.defra.gov.uk
Dairy producer	• Participate in relevant assurance scheme • Monitor surveillance data	NDFAS: www.ndfas.org.uk
Egg producer	• Participate in relevant assurance scheme • Monitor surveillance data	BEIC: www.britegg.co.uk
Honey producer	• Monitor surveillance data	National Bee Unit: www.csl.gov.uk
UK Agent	• Be aware of requirements placed on producers and feed manufacturers (above) • Buy only from assured sources • Have and be able to rapidly provide evidence of compliance with legal and customer requirements • Have demonstrable traceability in place	Port Health Authorities: www.apha.org.uk
Importer from EC	• Be aware of requirements placed on producers and feed manufacturers (above) • Buy only from assured sources which have been audited (may be documentary evidence of self-audit) • Encourage supplier participation in assurance schemes • Have and be able to rapidly provide evidence of compliance with legal and customer requirements • Be aware of systems, problems and limitations in country of production • Have demonstrable traceability in place • Monitor surveillance data and RASFF reports	Relevant Member State Enforcement http://www.eurep.org (animal and feed sector work ongoing)

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Supply Chain Element	Key Action Points in addition to legal compliance	Relevant Control Approach/Scheme
Importer from Third countries	• Be aware of requirements placed on producers and feed manufacturers (above) • Be aware of problems and limitations in country of production via EC Approval process • Buy only from assured sources which have been audited (may be documentary evidence of self-audit) • Encourage supplier participation in assurance schemes • Have and be able to rapidly provide evidence of compliance with legal and customer requirements • Monitor results of Port Authority testing • Inform manufacturing customers and take corrective action on any Port rejections • Have demonstrable traceability in place • Monitor surveillance data and RASFF reports	Port Health Authorities: www.apha.org.uk
Food manufacturer using products of animal origin in the final product	• Be aware of requirements placed on producers and feed manufacturers (above) • Risk assess suppliers and products • Buy only from assured, audited sources • Have systems in place to demonstrate full traceability • Be aware of RASFF, MAVIS and FSA reports • Monitor surveillance data	

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8. Incident Management

Exceedances of MRLs can be found through *ad hoc*, statutory and non-statutory surveillance and reported by a number of means such as RASFF, FHW and MAVIS.

In the case of a residues alert at either international, EU, national or company level the procedure outlined below should be followed:

1. Food manufacturer liaison with suppliers, customers and relevant experts (refer to section 10) to ascertain the level and nature of the residue and its source.

2. Food manufacturer to carry out a risk assessment on the amount of residue present in final foodstuffs, backed up by expert advice if required to ensure that a sound risk assessment is carried out.

3. If it is assessed that there is a significant risk of there being a health hazard in the final product, the food manufacturer to liaise with customers and relevant authorities on recall of final product

   If any form of public recall is involved, the extent of the problem must be made clear. For example,

   - Restricted to a particular batch/size/distribution area;
   - Reassure that all other batches/sizes/products are safe;
   - Number of packages involved;
   - Speed and efficiency of recall; and
   - Cause of fault being investigated

   Full traceability is therefore paramount.

4. Outputs should be determined in terms of corrective actions on the farm/supply chain.

   Corrective actions should involve the consideration of:-

   i) Review of traceability and control systems
   ii) What to do to re-establish control - action required of producers, agents, marketing organisations, assurance schemes, primary preparers to re-gain control and prevent reoccurrence
   iii) What to do with product and raw material held in stock in the supply chain that might be out of specification
   iv) When the action taken should be completed, i.e. the timescale for the action
   v) Who has responsibility for the action

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9. Definitions

Action Level - The concentration of a residue in an animal product that will spark a follow-up investigation by VMD and/or authorities. Where a Maximum Residue Limit has been set, this is the concentration used. Where no MRL has been set, the Limit of Quantification (LOQ) is used. But if a substance as been entered into Annex IV of Council Regulation (EEC) No. 2377/90 (i.e. human consumption at any level is unsafe and the substance is unauthorised for use in food production animals - see section 4.2), any confirmed residue will be reported as in excess of the Action Level.

ADI – Acceptable Daily Intake. An estimate of the amount of a substance, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk.

Aflatoxins - Toxic substances produced by strains of *Aspergillus*, a fungus, growing on many vegetable foods, notably peanuts and grain.

AGVR - Advisory Group on Veterinary Residues, A VMD-chaired group of stakeholders, which provided advice to VMD on surveillance and consumer safety. Replaced in 2001 by the Veterinary Residues Committee (VRC).

AIC – Agricultural Industries Confederation, formerly UKASTA (United Kingdom Agricultural Supply Trades Association).

Allopathic – A system of medical therapy in which a disease or abnormal condition is treated by creating an environment that is antagonistic to the disease or condition (i.e. antibiotic for infection).

AMI – Animal Medicines Inspectorate. Part of the Royal Pharmaceutical Society of Great Britain (RPSGB) which acts as the enforcement agency on behalf of the VMD regarding premises where certain animal medicines and feedingstuffs are manufactured, stored or sold.

Aminoglycosides – A closely related group of bactericidal antibiotics derived from bacteria of the order Actinomycetales.

Anabolic Agents –Hormonal drugs which can be used to control reproduction and which have the potential for carry over into milk prior to calving. Withdrawal Periods are the control measure.

Analyte – A compound in a test sample, the presence of which has to be detected and/or quantified.

Anthelmintics - Anthelmintics control and kill internal parasites such as liver fluke, tapeworms and roundworms and are used to treat diseases caused by parasitic worm infestations.

Antibiotics - A substance produced by or derived from a microorganism that selectively destroys or inhibits the growth of other microorganisms, usually associated with an infection.

Antibiotic resistance – The ability of a microorganism to withstand an antimicrobial.

Antimicrobials - Compounds that at low concentrations exhibit selective toxicity towards microorganisms. The term includes any substance of natural, synthetic or semi synthetic origin that is used to kill or inhibit the growth of microorganisms (bacteria, fungi, protozoa or viruses). Antimicrobials include antibiotics, disinfectants, preservatives and other substances.

Bacteriostatic - An agent, such as a chemical or biological material, that inhibits bacterial growth

Beta agonists - A group of veterinary medicines that, as muscle relaxants, can be used in animals to aid calving. Beta agonists, such as clenbuterol and salbutamol, have been found to have been used abroad illegally at much higher concentrations as growth promoters, where they result in a higher proportion of lean meat. These illegal higher concentrations can in some people result in increase pulse rate, palpitations or flu-like symptoms.

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Beta lactams – Semi synthetic antibiotics derived from cephalosporin C, a natural antibiotic produced by the mould *Cephalosporium acremonium.* Bactericidal products that act by inhibiting synthesis of the bacterial cell wall.

BIPs – Border Inspection Posts. EC approved entry points for products of animal origin, originating in countries outside the European Union. Such products must undergo certain veterinary checks in accordance with European Directive 97/78/EC. Staff at BIPs collect samples of imported foods for analysis under the Non-Statutory Scheme.

CEFAS – Centre for Environment, Fisheries and Aquaculture Science. An Executive Agency of Defra. Collect samples for the National Surveillance Scheme and carry our follow-up investigations on fish farms in England and Wales. FRS (see below) applies in Scotland.

Coccidiostats- Products that control coccidiosis, a protozoal disease that can cause diarrhoea and dysentery. Control of this infection is particularly important in the poultry industry where the prophylactic use of coccidiostats prevents the diseases from developing.

CSL – Central Science Laboratory – an Executive Agency of Defra. Analyses samples collected under the Non-Statutory Scheme.

CVMP – The Committee For Medicinal Veterinary Products, part of the EMA (see below). CVMP assesses safety data to set MRLs and can set Withdrawal Periods (see below).

DAL (Differential Action Level) - Level agreed by the AGVR (now VRC) as a guideline below which there is no toxicological risk to the consumer. In 1997 the VMD set up an *ad hoc* Group of consumer, industry and retail representatives to consider the incidence and concentration of nicarbazin residues in eggs and to try to develop strategies to reduce them. The Group agreed that the concept of a DAL should be recommended to the AGVR. This was so that the VMD would automatically follow-up a number of positive results which did not pose a risk to the consumer. In 1998 the AGVR endorsed the proposed DAL for nicarbazin in eggs at 100 microgrammes/kg as a guideline, subject to annual review. In 1999 the AGVR agreed that the DAL would also apply to lasalocid.

DARD NI- Department of Agriculture and Rural Development Northern Ireland. Collect and analyse samples for the National Surveillance Scheme in Northern Ireland on behalf of VMD and conduct their own surveys. DARD also carries out follow-up investigations in NI, and attends the VRC as advisors.

Defra - Department for Environment, Food and Rural Affairs

Detection Limit – see LOQ.

Dioxins – The general term "dioxin" collectively refers to a class of structurally and chemically related compounds known as halogenated aromatic hydrocarbons. They include poly-chlorinated dibenzo-p-dioxins (PCDD or Dioxins), polychlorinated dibenzofurans (PCDF or Furans) and the "dioxin-like" Biphenyls (PCBs). The term dioxin-like refers to compounds having basic similarities in molecular structure, chemical properties, environmental persistence, bioaccumulation potential and mechanisms of toxic actions. It must be noted that the compounds encompassed by the term "Dioxin" varies with publications and organisations, which can lead to confusion when defining maximum tolerable or inclusion levels. In general, the term "dioxin" only includes both PCDD and PCDF.

EMA – The European Medicines Agency

EMIs – Egg Marketing Inspectorate of Defra. Collects samples of eggs from packing stations for the National Surveillance Scheme.

EMOs – Egg Marketing Organisations

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EC – European Commission. The Executive of the European Union. It has powers of initiative, implementation, management and control. It is composed of twenty independent members including a President and two Vice-Presidents. It is appointed for a five-year term by the Council, acting by qualified majority in agreement with the Member States. It is subject to a vote of appointment by the European Parliament, to which it is answerable. The Commissioners are assisted by an administration made up of directorates-general and specialised departments whose staff are divided mainly between Brussels and Luxembourg. The EC examines, comments on and approves all National Surveillance Plans.

EU - European Union

FAO – Food and Agriculture Organization of the United Nations, founded in 1945 to raise levels of nutrition and standards of living, to improve agricultural productivity, and to better the condition of rural populations. FAO has 183 member countries plus one member organisation, the European Community

Feeding Stuffs – A product of vegetable or animal origin in its natural state (fresh or preserved), a product derived from the industrial processing of such a product, or an organic or inorganic substance, used singly or in a mixture (whether or not containing additives), for oral feeding to animals

FEMAS - Feed Materials Assurance Scheme. An integral part of UFAS (see below), covering the sourcing and production of feed materials.

FHW - Food Hazard Warning. FHWs are issued by the FSA to inform Local Authorities about problems associated with food and, in some cases, provide details of specific action to be taken. FHWs are also copied to Consultants in Communicable Disease Control, Trading Standards Officers and food trade organisations to alert them to current food issues. FHWs are currently issued under four categories:

A: For Immediate Action
B: For Action
C: For Action as Deemed Necessary
D: For Information

Fluoroquinolones – A subgroup of quinoline compounds having the addition of a fluorine atom and the 7-piperazinyl group. Broad spectrum antibiotics with properties more suited to the treatment of system infections.

FRS- Fisheries Research Service of the Scottish Executive Collects samples under the National Surveillance Scheme and carry out follow-up investigations on fish farms in Scotland.

FSA - Food Standards Agency. Advises on the significance of the results of the Surveillance Schemes and also attends the VRC meetings as advisors.

Growth Promoter – Substances which when given in animal feed increase feed conversion efficiency or result in better daily liveweight gain, or both.

Hormones - Hormones include both naturally occurring and synthetic substances. The use of all hormones to increase the growth rate in food producing animals is banned in the EU. Natural hormones are produced by endocrine glands such as the ovaries, testes, thyroid, adrenal or pituitary and released into the bloodstream to be carried to a particular organ or tissue, where they produce a specific response. Synthetic hormones include stilbenes, gestagens and thyrostats. Gestagens can be used to control animals' breeding cycles and treat threatened abortion.

Ionophores – An agent, such as a chemical or biological material, that inhibits bacterial growth

JECFA – The Joint FAO/WHO Expert Committee on Food Additives. An expert international scientific committee that is jointly administered by the FAO (see above).

LA - Local Authority

LGC – Laboratory of the Government Chemist, Teddington.

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LOD- Limit of Determination (see LOQ)

LOQ - Limit of Quantification: the smallest analyte concentration for which a method has been validated with specified accuracy and precision. Also known as Limit of Determination or Detection Limit.

Macrolides – A group of antibiotics mainly derived from *Streptomyces* species. Thought to act by inhibiting bacterial protein synthesis.

Matrix - The sample of, for example, liver, kidney or animal feed, analysed for the presence of a residue.

MAVIS – Medicines Act Veterinary Information Service. VMD's quarterly newsletter, providing information on VMD's work, plans and general developments in the control of veterinary medicines.

Medicated Feeding Stuffs – Any mixture of a veterinary medicinal product or products and feed or feeds which is ready for marketing and intended to be fed to animals without further processing, because of its curative or preventative properties or other properties as a medicinal product.

MHS - Meat Hygiene Service. An Executive Agency of the FSA. Collects National Surveillance Scheme samples from abattoirs. It also has powers to detain animals that it suspects have been treated with unauthorised substances or contain residues above the MRL.

Mintel – An independent market intelligence company, at the time of writing contracted to VMD to buy retail samples of foods for analysis under the Non-Statutory Scheme.

MRL - Maximum Residue Limit - the maximum concentration of residues resulting from the use of a veterinary medicine that is legally permitted, or recognised as acceptable in or on a food.

MRPL – Minimum Required Performance Limits of analytical methods to be used for substances for which no, or no recent, toxicological assessment has been made and therefore no permitted limit established. An analytical standard which all Member States are required to achieve, being set by the EC through Commission Decision 2002/657/EC. Commission Decision 2003/181/EC (as amended) sets MRPLs for certain residues in food of animal origin.

NBU – National Bee Unit. Delivers the Bee Health Programmes on behalf of Defra in England and the National Assembly of Wales.

Organochlorines - Compounds such as DDT previously used as insecticides. They degrade very slowly in the environment and can be ingested by animals and accumulate in their tissues.

Organophosphorus (OP) - Used as veterinary medicines to control ticks and mites and are currently used in sheep dips. They are also widely used in insecticides.

OVS - Official Veterinary Surgeon - employed by the Meat Hygiene Service to act as leaders of meat hygiene and inspection teams in meat premises in Great Britain, enforce EC standards of structure, operation and hygiene practices as set out in UK legislation. OVSs have responsibility for animal welfare and inspection and hygiene supervision at meat plants and are assisted in this by authorised meat inspectors to whom they can delegate some duties.

PCBs - Polychlorinated biphenyls were produced in the UK and other western countries until the 1970s mainly for use in electrical equipment. PCBs are adventitious environmental contaminants (non-veterinary), and are resistant to degradation by normal environmental processes. They are ubiquitous in the environment and are generally present in low concentrations in foods.

Positive - A 'positive' sample is a sample which confirmatory analysis confirms a concentration of an authorised substance above the MRL or Action Level, or where this has not been set for the substance or the matrix concerned, in excess of the LOQ or the presence of an unauthorised substance - see also DAL. 'Positive' is being replaced by 'non-compliant' in accordance with the new description used in Commission Decision 2002/547.

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Prescribed Confidence Level - The Commission and the expert working group which drafted Council Directive 96/23/EEC on which the national surveillance scheme is based have taken account of the fact that sampling is designed to provide profile information on the occurrence of residues in specified food producing populations on an annual national basis. The numbers prescribed in the annexes to the directive are therefore based on a statistically specified reliability expressed in reference to a confidence level and a prevalence rate as set out for example in the CODEX Alimentarius publications "residues of veterinary drugs in food', volume III.

Primary Processor – Whilst there is no legal definition, for the purposes of this document this refers to the first processing stage following primary production and would include for example, breaking down of carcases into primal cuts and the pasteurisation of milk.

Primary Production – Defined by Council Regulation 178/2002/EC as the production, rearing or growing of primary products including harvesting, milking and farmed animal production after slaughter. It also includes hunting and fishing and the harvesting of wild products.

RASFF- EU Rapid Alert System for Food and Feed. RASFF provides a means for an EU Member State to alert all EU Member States of adverse findings via the European Commission. RASFF alerts are published weekly on the European Commission's website: http://europa.eu.int/comm/food/. The FSA has responsibility for RASFF alerts management in Great Britain.

Residue - That portion of the administered dose of a veterinary medicine or other substance present in the tissues, body fluids, products or excreta of an animal arising from treatment of the animal. Total residue includes the parent compound plus any metabolites.

RPSGB - Royal Pharmaceutical Society of Great Britain. Carry out inspections of feed mills that produce medicated feed. These inspections can be for either the National or Non-Statutory Surveillance Schemes. RPSGB currently has overall responsibility for the AMI.

Sulphonamides – A group of bacteriostatic compounds that interfere with folic acid synthesis of susceptible organisms. They all have similar antimicrobial activity.

SVS - State Veterinary Service of Defra. Collect National Surveillance Scheme samples from stock farmers in Great Britain and carry out follow-up investigations for samples above the MRL or Action Level. SVS attend the VRC meetings as advisors.

TA – Trade Association

Tetracyclines – A group of antibiotics derived from *Streptomyce*s species, usually bacteriostatic at concentrations achieved in the body and act by interfering with protein synthesis in susceptible microorganisms. All have a broad spectrum of activity.

Tranquiliser- A substance used to reduce stress or aggressive behaviour, for example during transport

Trimethoprim – Compounds with a similar action to sulphonamides, acting by interfering with folic acid synthesis, but at a different stage in the metabolic pathway. Display a similar spectrum of activity to, and are often used in combination with sulphonamides.

UFAS – Universal Feed Assurance Scheme. An assurance scheme covering the sourcing and evaluation of feed materials and ingredients, through manufacture, storage, transport and delivery of finished compound feed. The Scheme, run by AIC, covers some 90% of UK commercially manufactured compound feed.

VMD – Veterinary Medicines Directorate – an Executive Agency of Defra, protecting public health, animal health, the environment and promoting animal welfare by assuring the safety, quality and efficacy of veterinary medicines in the UK.

VPC – Veterinary Products Committee. An independent body of experts advising Ministers on the safety, quality and efficacy of veterinary medicines, scrutinising assessors' reviews of applications for the authorisation of veterinary medicinal products

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VRC – Veterinary Residues Committee. An independent committee established in 2001 to replace AGVR. The VRC provides Chief Executives of VMD and FSA with expert scrutiny and advice on the scope and content of agencies' surveillance programmes and on the significance of the results in terms of consumer safety.

WHO – World Health Organization. The United Nations specialised agency for health, established in 1948. WHO is governed by 192 Member States through the World Health Assembly. The Health Assembly is composed of representatives from WHO's Member States. The main tasks of the World Health Assembly are to approve the WHO programme and the budget for the following biennium and to decide major policy questions.

Withdrawal Period - The period following the cessation of treatment during which an animal or its products should not be used for food and provides an assurance of public safety.

Zootechnical Additives - Dietary enhancing additions to feed, currently antibiotic growth promoters and prophylactic coccidiostats, which may in the future include alternatives.

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10. Useful Contacts

It is recommended that each company maintain an up to date crisis contact list to include the following key organisations:-

Agricultural Industries Confederation (AIC)
Confederation House
East of England Showground
Peterborough
PE2 6XE
www.agindustries.org.uk
T: +44 (0) 1733 385230
F: +44 (0) 1733 385270

Animal Medicines Inspectorate (AMI)
Royal Pharmaceutical Society of Great Britain
National Agricultural Centre
Stoneleigh Park
CV8 2LZ
E-mail: ami@rpsgb.org.uk
T: +44 (0) 24 7684 9260
F: +44 (0) 24 7684 9261

Central Science Laboratory (CSL)
Sand Hutton
York
YO41 1LZ
www.csl.gov.uk
T: +44 (0) 1904 462000
F: +44 (0) 1904 462111

Chilled Food Association (CFA)
P O Box 6434
Kettering
NN15 5XT
www.chilledfood.org
T: +44 (0) 1536 514365
F: +44 (0) 1536 515395

Defra
Animal Health and International Trade (Products) Branch
1A Page Street
London
SW1P 4PQ
http://www.defra.gov.uk/animalh/int-trde/

Food Standards Agency (FSA)
Aviation House
Kingsway
London
WC2B 6NH
www.food.gov.uk
T: +44 (0) 20 7276 8000

National Farmers Union (NFU)
Agriculture House
164 Shaftesbury Avenue
London
WC2H 8HL
www.nfu.org.uk
T: +44 (0) 20 7331 7200
F: +44 (0) 20 7331 7313

Pesticides Safety Directorate (PSD)
Mallard House
Kings Pool
3 Peasholme Green
York
YO1 7PX
www.pesticides.gov.uk
T: +44 (0) 1904 640500
F: +44 (0) 1904 455733

Veterinary Medicines Directorate (VMD)
Woodham Lane
New Haw
Addlestone
KT15 3LS
www.vmd.defra.gsi.gov.uk
T: +44 (0) 1932 336911
F: +44 (0) 1932 336618

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11. Sources of Further Information

Butterworths	www.butterworths.co.uk
Central Science Laboratory	www.csl.gov.uk
CODEX	www.codexalimentarius.net
Defra	www.defra.gov.uk
European agriculture legislation links	http://europa.eu.int/eur-lex/en/lif/ind/en_analytical_index_03.html
Food Standards Agency (FSA)	www.food.gov.uk
LGC	www.lgc.co.uk
Medicines Act Veterinary Information Services (MAVIS)	www.vmd.gov.uk/mavis/mavis.htm
National Office for Animal Health (NOAH)	www.noah.co.uk
Responsible Use of Medicines in Agriculture Alliance (RUMA)	www.ruma.org.uk
Veterinary Medicines Directorate	www.vmd.gov.uk
Veterinary Products Committee	www.vpc.gov.uk
Veterinary Residues Committee	www.vet-residues-committee.gov.uk
WHO	www.who.int

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12. Legislation Summary

UK LEGISLATION	EUROPEAN SOURCE LEGISLATION
GENERAL	
Food Safety Act 1990 C16	
Environmental Protection Act 1995	
SUBSTANCE APPROVAL	
Medicines Act 1968 C67	
Marketing Authorisations for Veterinary Medicinal Products 1994 SI No 3142	Directive of the European Parliament and of the Council on the Community Code relating to Veterinary Medicinal Products 2001/82/EC Council Directive 92/74/EEC widening the scope of Directive 81/851/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to veterinary medicinal products and laying down additional provisions on homeopathic veterinary medicinal products
The Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Amendment Regulations 1994 SI 1994 No 2987	
The Medicines (Veterinary Drugs) Prescription Only Regulations 2001 SI No 1646	
Medicines (Exemptions for Merchants of Veterinary Drugs) Order 1998 SI No 1044 (as amended)	
The Medicines (Veterinary Drugs) (General Sale List) Order 2001 SI No 1645	
The Medicines (Pharmacy and General Sale - Exemption) Order 1980 SI No 1924 (as amended)	
Retailers' Records for Veterinary Medicinal Products Regulations 2000 SI No 7	
The Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997 SI No 322	Council Directive 92/74/EEC widening the scope of Directive 81/851/EEC
The Sheep Scab Order 1997 SI No 968	

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UK LEGISLATION	EUROPEAN SOURCE LEGISLATION
FEEDINGSTUFFS	
Agriculture Act 1970	
Medicated Feedingstuffs Regulations 1998 SI No 1046	Council Directive 90/167/EEC laying down conditions governing the preparation, placing on the market and use of medicated feedingstuffs.
The Feeding Stuffs (Zootechnical Products) Regulations SI 1999 No 1871	Council Directive concerning additives in feeding stuffs 70/524/EEC
The Feeding Stuffs (Establishments & Intermediaries) Regulations 1999 SI No 1872	Article 1.10 of Council Directive 96/51/EC amending Directive 70/254/EEC concerning additives in feedingstuffs Article 6.8 and 6.9 of Commission Directive 98/51/EC laying down certain measures for implementing Directive 95/69/EC Council Directive 95/69/EC laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector.
Feeding Stuffs Regulations 2000 SI No 2481 (as amended)	European Parliament and Council Directive 2002/32/EC on undesirable substances in animal nutrition Council Directive 96/25/EC on the circulation of feed materials Council Directive 93/74/EEC on feedingstuffs intended for particular nutritional purposes Commission Decision 91/516/EEC on establishing a list of ingredients whose use is prohibited in compound feedingstuffs Council Directive 99/29/EC on the undesirable substances and products in animal nutrition Council Directive 82/471/EEC concerning certain products used in animal nutrition Council Directive 79/373/EEC on the marketing of compound feedingstuffs Council Directive 70/524/EEC concerning additives in feedingstuffs
Organic Products Regulations 2001 SI No 430	Council Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs

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UK LEGISLATION	EUROPEAN SOURCE LEGISLATION
FOOD	
Fresh Meat (Hygiene and Inspection) Regulations 1995 SI No 539	Council Directive 64/433/EEC on health conditions for the production and marketing of fresh meat
Poultry Meat, Farmed Game Bird Meat and Rabbit Meat (Hygiene and Inspection) Regulations 1994 SI No 1029 (as amended)	Council Directive on health problems affecting trade in fresh poultrymeat
Dairy Products (Hygiene) Regulations 1995 SI No 1086 (as amended)	Council Directive 92/46/EEC, laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products
Organic Products Regulations 2001 SI No 430	Council Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuff
Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations 1997 SI No 1729	Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of ß-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC
Contaminants in Food Regulations 2002 SI No 890	Commission regulation setting maximum levels for certain contaminants in foodstuffs (EC) No 466/2001
IMPORT	
Products of Animal Origin (Third Country Imports) Regulations 2002 SI No 1227	Council Directive 92/118/EEC laying down animal and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A(I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC
Miscellaneous Products of Animal Origin (Import Conditions) Regulations 1999 SI No 157	Council Directive 92/118/EEC laying down animal and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A(I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC
Miscellaneous Products of Animal Origin (Import Conditions) Regulations (Northern Ireland) 1999 Statutory Rule No 189 (as amended)	

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UK LEGISLATION	EUROPEAN SOURCE LEGISLATION
IMPORT (Cont)	
Products of Animal Origin (Import and Export) Regulations 1996 SI No 3124	Council Directive 89/662/EEC concerning veterinary checks in intra-Community trade with a view to the completion of the single market Council Directive 90/675/EEC laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries Council Directive Community rules referred to in Annex A(I) to Directive 89/662/EEC. Commission Decision 2001/556/EC drawing up provisional lists of third country establishments from which Member States shall authorise imports of gelatine for human consumption.
Fresh Meat (Import Conditions) Regulations 1996 SI No 3125	Council Directive 72/462/EEC on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries (as amended) Council Decision 79/542/EEC drawing up a list of third countries from which the Member States authorize imports of bovine animals, swine and fresh meat (as amended) 72/461/EEC on health problems affecting intra-Community trade in fresh meat (as amended) Council Directive 77/96/EEC on the examination for trichinae (Trichinella spiralis) upon importation from third countries of fresh meat derived from domestic swine (as amended)

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13. Guidance WG Membership

Miss Kaarin Goodburn	Chilled Food Association
Dr Wayne Morgan	Northern Foods
Mrs Margaret Williams	Greencore

14. Consultees

* Agricultural Industries Confederation
* British Meat Processors Association
* British Poultry Council
* Food Standards Agency
* Provision Trade Federation
* UK Association of Frozen Food Producers
* Veterinary Medicines Directorate

* Denotes that comments were received

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