MEDITATED FEEDINGSTUFFS AND SPECIFIED FEED ADDITIVES – REGULATION AND APPROVAL OF MANUFACTURERS

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Medicated Feedingstuffs

- Medicated Feedingstuffs are animal feedingstuffs that contain a veterinary medicinal product (VMP) authorised in accordance with EC Regulation 2001/82.
- The Marketing Authorisation must specifically authorise the product for incorporation into animal feed. This VMP is usually referred to a premix.
- A VMP application and supporting data is assessed by VMD assessors and authorised nationally. There are some premixes which are authorised throughout the EU by the centralised procedure.
Medicated Feedingstuffs
EU Regulations

- **Directive 90/167** laying down the conditions governing the preparation, placing on the market and use of medicated feeds in the Community.
- **Regulation 178/2002** laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
- **Regulation 882/2004** on official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare rules.
- **Regulation 183/2005** laying down requirements for feed hygiene. (This does not apply to medicated feeds throughout the EU).

- **Directive 90/167** is under review. A Commission proposal for a new Medicated Feedingstuffs Regulation is expected in 2012.
Medicated Feedingstuffs
UK Regulations

- The Veterinary Medicines Regulations (VMR).
- **Schedule 5** of the VMR relates to the manufacture, supply and use of medicated feedingstuffs.
- **Schedule 5** enforces three EU Regulations and one EU Directive in relation to medicated feeds:

Requirements of Directive 90/167

In General

● Manufacturers **must** be approved to mix medicated feed and distributors must be approved to supply medicated feed.

● Conditions for approval to manufacture and supply medicated feeds including, personnel, equipment, storage and records (Note: approval conditions have been superseded by Regulation 183/2005 in UK legislation).

● Packaging and labelling.

● Prescription rules and requirements.

● Intra-Community trade.
● **Sampling checks by manufacturers** - The feed manufacturers have to carry out regular checks, including laboratory tests for homogeneity to ensure the medicated feedingstuffs comply with requirements in respect of homogeneity, stability and storability.

● The samples are sent to commercial laboratories. For homogeneity, they take 8 or 10 samples of a trace element in the feed, e.g. copper or manganese to check that the mix is the same throughout the feed.

● The feed is also analysed to ensure that the active ingredient stated on the label is present and within tolerance levels. 80% of the sample is analysed straight away and 20% at the end of the shelf life of the product to check stability.

● During an inspection, the VMD will look at the analyses results to check that any deficient samples are investigated and procedures put in place to remedy the problem. They will also check for trends.
Specified Feed Additives (SFAs)

- Specified feed additives are coccidiostats, histomonostats and *growth promoters used as feed additives.
- Feed additives are authorised under separate legislation to medicated feedingstuffs.
- The Report concluded that these products should remain under feed additive legislation.

*These are non antibiotic growth promoters. Antibiotic growth promoters were banned as feed additives from 1 January 2006.
Applications for feed additives (including SFAs), are made in accordance with Regulation 1831/2003. An authorisation must receive a qualified majority vote from Member States (MSs).

The European Food Safety Authority (EFSA) evaluate the application dossiers and provide a scientific opinion to the Commission.

Feed additives are categorised in Article 6 and Annex I of Regulation 1831/2003.

Regulation and enforcement for all non SFA feed additives (the majority of feed additives) is the responsibility of the Food Standards Agency.

SFAs are used routinely. A prescription is not required. However, they must be used strictly in accordance with their conditions of authorisation.
Specified Feed Additives
EU Regulations

- **Regulation 178/2002** laying down the general principles of food law.
- **Regulation 1831/2003** on additives for use in animal nutrition relates to the authorisation, supervision and labelling of feed additives and premixtures containing them.
- **Regulation 183/2005** laying down requirements for feed hygiene.
- **Regulation 767/2009** on the placing on the market and use of feed, sets out rules which include defining complementary feeds, setting tolerances for feed additives and labelling of feedingstuffs containing feed additives.
Specified Feed Additives
UK Regulations (VMR)

- The Veterinary Medicines Regulations (VMR).
- Schedule 5 of the VMR relates to the manufacture, supply and use of SFAs.
- Schedule 5 enforces five EU Regulations in relation to SFAs:
Requirements of Regulation 183/2005 In General

- Manufacturers **must** be approved to mix SFAs into feedingstuffs and distributors must be approved to supply feeds containing SFAs.
- Conditions for manufacture and supply including, facilities and equipment, personnel, production, quality control, storage and transport, record keeping, and complaints and product recall.
Combinations of Veterinary Medicines & Specified Feed Additives into Feedingstuffs

- Inclusion of both a veterinary medicinal product (VMP) and a feed additive is permitted provided it is prescribed by a veterinary surgeon;
- there is no undesirable interaction between the VMP and any feed additive used in the feedingstuff and;
- the active substance of the VMP is not the same as an active substance in any feed additive used in the feedingstuff.
OFFICIAL CONTROLS
The Official Feed and Food Controls Regulation 882/2004

- Official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare rules.
- The rules of this Regulation are predominantly for the enforcement authorities.
- The VMD (Animal Medicines Inspectorate) is the enforcement authority for medicated feedingstuffs and SFAs in GB.
- The Department of Agriculture and Rural Development inspectorate is the enforcement authority in Northern Ireland.
General Requirement of Regulation 882/2004

- General rules for the performance of official controls including:
  - Competence of inspectors;
  - control and verification procedures, methods of sampling and analysis, official laboratories, official checks, inspection reports to business operators,
  - non-compliance;
  - financing of official controls;
  - approval of feed and food business establishments;
  - National Control Plans and Annual Reports, and imports and exports and miscellaneous other requirements.
Official Controls under Regulation 882/2004
Sampling and analysis:

- Sampling and analysis methods for medicated feedingstuffs and SFAs must comply with Community rules.
- In the EU, samples must be taken and analysed in accordance with Council Directive 76/371 (establishing Community methods of sampling for the official control of feedingstuffs).
- Wherever possible, methods of analysis must be characterised by the appropriate criteria set out in Annex III of the Regulation.
- The competent authority must designate suitably designated laboratories that may carry out the analysis of samples taken during official controls.
- The Regulation also sets out the requirement for Community Reference Laboratories and National Reference Laboratories.
PERMITTED TOLERANCES
Medicated Feedingstuffs

The active ingredient in a sample of medicated feedingstuff must be within the following tolerances:

<table>
<thead>
<tr>
<th>Declared Level</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤50mg/kg</td>
<td>± 50%</td>
</tr>
<tr>
<td>&gt;50mg/kg≤500mg/kg</td>
<td>± 40%</td>
</tr>
<tr>
<td>&gt;500mg/kg≤5g/kg</td>
<td>± 30%</td>
</tr>
<tr>
<td>&gt;5g/kg≤50g/kg</td>
<td>± 20%</td>
</tr>
<tr>
<td>&gt;50g/kg</td>
<td>± 10%</td>
</tr>
</tbody>
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# PERMITTED TOLERANCES

Specified Feed Additives

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<tbody>
<tr>
<td>≥1000mg/kg</td>
<td>10%</td>
</tr>
<tr>
<td>≥500mg&lt;1000mg/kg</td>
<td>100mg</td>
</tr>
<tr>
<td>≥1mg &lt;500mg/kg</td>
<td>20%</td>
</tr>
<tr>
<td>≥0.5mg &lt;1mg/kg</td>
<td>0.2mg</td>
</tr>
<tr>
<td>&lt;0.5mg/kg</td>
<td>40%</td>
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ENFORCEMENT OF THE REGULATIONS

ANIMAL MEDICINES INSPECTORATE (AMI)

- AMI is the VMD’s inspectorate who carry out the enforcement of the conditions laid out in Schedule 5 of the VMR regarding medicated feedingstuffs and SFAs.

- Currently comprises of Head of Inspectorate (inspector role) + 5 inspectors and 2 admin staff.

- Requirement for inspectors to possess a formal Agriculture/Science qualification and have extensive knowledge of agriculture with specialist background in animal feedingstuffs and/or animal medicines.
THE ROLE OF THE AMI INSPECTORS

- To approve and inspect premises carrying out the manufacture, and distribution of medicated feedingstuffs and SFAs as defined in Schedule 5 of the VMR.
- Premises include large feed mills, small commercial producers, farmers mixing their own feed and distributors.
- To ensure compliance with Annex II of Regulation 183/2005 through advice and/or enforcement, by carrying out inspections at premises, including:
  - Facilities & Equipment - security, cleanliness, storage facilities, staff facilities, suitability and condition of equipment;
  - Personnel – designated persons responsible for production and quality control with defined roles and responsibilities;
THE ROLE OF THE AMI INSPECTORS (cont)

- Production – in accordance with written procedures to achieve product specification and minimise contamination (Hazard Analysis & Critical Control Point – HACCP - plan);
- Quality Control/Assurance – homogeneity and carryover tests, end product testing (including stability);
- Storage – security of controlled products;
- Documentation – SOPs, purchase & sale records, manufacturing records, MFS prescriptions, labelling;
- Complaints & recall procedures.

- The AMI takes samples from every feed mill inspection and 10% of on-farm mixer inspections to check that the active ingredient is present within the permitted tolerances.
The VMD commissioned Food and Environment Research Agency (FERA) to develop a rapid detection screening technique for AGPs as conventional sampling to find these substances would prove too costly.

Fera made a presentation on the development and progress of the screening project – It clearly shows excellent progress made to rapid detection of AGPs in feed. The data show that a single sample can be assayed for at least six AGPs in one run but full validation is still underway.

The screening technique will be available for the first five compounds by end of April 2011 and we are hoping sampling will commence shortly after.
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ENFORCEMENT METHODS

● Enforcement Strategy published on the VMD website
● Aims to take a progressive approach to enforcement, following policy of ‘inform, insist, enforce’
● Range of measures taken when deficiencies noted, depending on category
  ● Minor
  ● Major
  ● Critical
- Minor - Inspection Report issued after every inspection;
- Major - Inspectors’ Formal Advisory Letter (IFALs);
- Critical - Improvement/Seizure Notice served;
- Right of Appeal against Notices;
- Notices published on VMD website;
- Suspension/revocation of approval/authorisation;
- Referral of cases to DIS for investigation – prosecution
ANY QUESTIONS?