ACAF/11/13

MEDICATED FEEDINGSTUFFS

AN UPDATE ON CURRENT DEVELOPMENTS

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THE REVIEW OF DIRECTIVE 90/167 ON THE PREPARATION, SUPPLY AND USE OF MEDICATED FEEDINGSTUFFS

What form will the new legislation take?

- Commission proposal expected in 2012
- Proposal to be run in tandem with the Veterinary Medicinal Products proposal (review of Directive 2001/82)
- No decision yet on the form of the legislation

Options:

(i) New Directive
(ii) New Regulation
(iii) Amendment of Regulations 183/2005 on Feed Hygiene, Regulation 767/2009 on the marketing and use of feed and Regulation 2002/32 on undesirable substances, to include medicated feed.

- Commission to consider further and will consult with their lawyers

Developments so far

- DG SANCO commissioned a study to evaluate the production and use of medicated feed in the EU.
- Study resulted in a Report* which was published in February 2010.
- The Conclusions of the Report were the basis of a questionnaire/consultation.
- Consultation concluded on 30 May 2011.

*Report can be found on:
http://ec.europa.eu/food/food/animalnutrition/labelling/medicated_feed_report_20100224.pdf

Conclusions of the Report

- Scope for harmonisation within the rules of medicated feed:
  - Standards for manufacture (including mobile mixers)
  - Inclusion rates of medicated premixes
  - Anticipated production of medicated feed
  - On-farm production of MF
  - MF containing several medicated premixes

Commission Aim of the Review

- Commission aim to cut unnecessary administrative burden regarding feed.
- To harmonise the marketing of medicated feed in the EU at an appropriate safety level.
- To reflect technical progress in this field.

UK view in general

- UK welcomes the review.
- The new legislation should continue to safeguard public and animal health.
- Any change should be proportionate and not impose undue burdens on industry.
- The new legislation should be transparent since the existing Directive is, in places, not clear in its intentions.
- The revised legislation should be in harmony with other more recent legislation providing for feed additives, including coccidiostats and histomonostats.

Highlighted issues in Commission consultation

- Transposition of Directive 90/167 has led to significant differences throughout the EU, meaning that not all feed business operators are able to use medicated feed within a comparable playing field:

  (i) Differing national provisions for standards of manufacture for establishments.
  (ii) Anticipated manufacturing of medicated feed. Rapid delivery of MF is crucial for effective treatment once vet surgeon has prescribed.
  (iii) On-farm manufacturing.
  (iv) The approval of distributors to supply medicated feed.
  (v) Concerns regarding the use of Antimicrobials in animals with respect to the development of antimicrobial resistance with negative impacts on public and animal health.
  (vi) Carry-over of VMP at low concentration, with the possibility of contribution to the development of AMR. Some MS have a zero tolerance whilst others have a less strict approach.

Comparisons of results of the *Consultation in the UK

- VMD has carried out a comparison of answers from ourselves and other major contributors. AIC, FEFAC, NOAH and the NFU.
- Almost 100% correlation of answers with AIC/FEFAC/NFU.
- Some minor issue differences with NOAH.

*Consultation document can be found on:
http//ec.europa.eu/food/food/animalnutrition/labelling/docs/online_consultation_medicated_feed_en.pdf

VMD's requests for consideration in the New Legislation

- Manufacturing principles and requirements should be in harmonisation with Annex II of the Feed Hygiene Regulation 183/2005 to include HACCP and with consistent feedingstuffs terminology.
- Labelling requirements for medicated feeds should be clearly laid out.
- The activities and approval of distributors should be clarified.
- The new legislation should specify permitted analytical tolerances.
- Permitted levels of carry-over should be set, but it is important they are set out in the undesirable substances legislation, similar to those issued for feed additives (coccidiostats).

VMD meeting with Commission, Jim Moynagh, (Head of Animal Nutrition, DG SANCO) and Wolfgang Trunk

- VMD met with the Commission post consultation.

- The following is an interpretation of our discussion, but has not been qualified in writing by the Commission.

Main points discussed at the meeting

- Outcome of questionnaire shows there is a vast difference between MS.
- Commission did not indicate where they stood regarding these differences i.e. who did they agree with?
- Commission are convinced that medicated feed is a good route of administration and want it to remain available to farmers.
- Anti-microbial resistance issue very important when considering the proposal. Commission must take into account the perception of risk. Very important politically.
- Commission intimated that anticipated production (in anticipation of a prescription) would be allowed.
- Commission did not appear to want to set analytical tolerances for medicated feed but took on board why the UK thinks this is important.

Antimicrobial Resistance

General Picture

- International concern over the loss of antimicrobial efficacy in human prescribing.
- The development of antimicrobial resistance in veterinary medicine has also led to concerns about continuing availability.
- There are concerns that resistant disease organisms may pass from animals through the food chain and compromise animal health.
- For the revisions to the veterinary medicines legislation, measures to reduce the development of antimicrobial resistance are being considered.

Antimicrobial Resistance

In relation to the review of Directive 90/167

- The Commission's primary concern for the revisions to the medicated feedingstuffs legislation is whether contamination from feed containing antimicrobials to subsequent batches of untreated feed (carry-over) will cause antimicrobial resistance in animals.
- Setting acceptable levels of carry-over are now being debated.
- Ideally these should be based on scientific evidence and provided for in the same way as those set for specified feed additives (coccidiostats).
- The Commission argues that to provide for all possible combinations of in-feed veterinary medicines and target species would be too costly in terms of both time and monetary resource.
- Industry bodies are intending to lobby the Commission further for scientific assessment and setting of carry-over limits. VMD is in support of this initiative.
- Final decision is yet to be made.

Next steps

- Summary of the outcome of the consultation should have been made publicly available once the consultation was over on 30 May. This has not yet been put on the Commission website.
- Commission to submit impact assessment.
- Proposal expected late 2012.

ANY QUESTIONS?