



FOCUS GROUP
FATE OF VETERINARY MEDICINAL PRODUCTS IN MANURE

23 June 2009, EMA, Room 4C

AGENDA

| TIME | AGENDA TOPIC | |
|------------------|---|--------------------------|
| 10.00 | Welcome and Introduction | Kornelia Grein |
| | Background documents: | |
| | - Concept Paper for a Guideline on the Fate of Veterinary Medicinal Products in Manure | |
| | - Comments received during consultation period: | |
| | o IFAH Europe | |
| | o EGGVP | |
| | o Farma Research Animal Health | |
| 10.10 - 11.10 | Introductory presentations | |
| | - Outline & objectives | Alex Tait |
| | - Evaluation of Degradation Studies of Veterinary Drugs in Manures; A Regulatory Viewpoint | Joop de Knecht |
| | - Degradation in poultry manure: how to express concentrations? | Leo van Leemput |
| | - Manure Degradation Studies Experiences – Intervet / Schering-Plough | Gregor Scheef |
| | - The Reference Manure Concept | Robert Kreuzig |
| 11.10 - 13.15 | Design of the studies: the following topic areas were identified in the concept paper: | Coordinator Alex Tait |
| | • Selection and handling of the test manure (e.g., origin, storage, reference manure, tank manure) | |
| | • Matrix characterisation of the manure (parameters to be measured) | |
| | • Establishing test conditions (e.g., temperature, aerobic, anaerobic, moisture, duration, sterile, non-sterile...) | |
| | • Test substance (e.g. labelled, non-labelled) and spiking procedure | |
| | • Extraction and determination of the test substance, metabolites and non extractable residues (e.g. validation of analytical methods, setting criteria for recovery....) | |
| | • Data analysis (e.g. kinetics) | |
| 13.15 - 14.00 | Lunch | |

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| 14.00 | Evaluation and use of the test results | |
| - 16.00 | <ul style="list-style-type: none"> • Extrapolation of biotic and abiotic transformation of VMPs within and between manure types of different target species • Defining realistic and representative storage conditions for standardisation of test results (e.g. temperature, time) • Use of test results to refine PECs (e.g. dealing with non first-order dissipation interpretation, of non-extractable residues) • Identification of relevant metabolites | Coordinator Alex Tait |
| 16:00 | Confirmation of recommendations and action plans | Alex Tait |
| - 17.00 | - Summary slides | |
| 17:00 | <i>Closure of the meeting</i> | |