European Commission

EU legislation on Feed

Directorate Food and Feed Safety, Innovation

Veterinary

DG Health and Food Safety

European Commission

These slides accompany the explanation of the acquis to Albania and North Macedonia and can only be used for that purpose. Their content is subject to further development of the acquis and interpretation by the Court of Justice of the European Union

Health and Food Safety

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Content

1. Feed additives (Reg 1831/2003)
2. Feed Hygiene (Reg 183/2005)
3. Undesirable substances in feed (Dir. 2002/32)
4. Marketing of feed materials & compound feed (Reg 767/2009)
5. Medicated Feed
6. Resume

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Categories of feed (legal base)

FEED (178/2002)

Feed Materials (767/2009)

Feed Additives and Premixtures (1831/2003)

Medicated Feed (90/167)

Compound Feed (767/2009)

Complete Feed

Complementary Feed

Dietetic Feed "*ParNuts*" (767/2009)

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Feed Additive Regulation (EC) No 1831/2003

Ban on antimicrobial growth promoters as additives

pre-marketing authorisation => Principle of a positive list:
only what is in the list can be placed on the market and can be used as additive in feed under conditions clearly established (type of feed, level of addition, animals intended to consume the feed, etc…)

Current Register with 1700 additives

Labelling of additives and premixtures

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Definition of feed additives

- “substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more specific functions”
- 5 Categories are currently established for the different functions:

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1. Technological additives

Preservatives
Antioxidants
Emulsifiers, Stabilisers, Thickeners, Gelling agents, Binders
Substances for control of radionucleides
Anticaking agents
Acidity regulators
Silage additives
Denaturants
Mycotoxin contamination reducers

2. Sensory additives

Colourants
Flavouring compounds

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3. Nutritional additives	*Vitamins and vitamin-like* *Trace elements* *Amino acids* *Urea and derivatives*
4. Zootechnical additives	*Digestibility enhancers* *Gut flora stabilisers* *Substances which favourably affect the environment* *Other zootechnical additives*
5. Coccidiostats and histomonostats	*Substances intended to kill or inhibit protozoa*

General aspects of applications for authorisation

- *Application to the **Commission***
- *Technical dossier to **EFSA***
- *Reference samples and the part of the technical dossier with the methods of analysis to the **EURL***

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EURL for Feed Additives

- COM Regulation 378/2005 details the rules for the implementation of Regulation 1831/2003 and provides the practical conditions for the duties and tasks of the EURL
- Additional tasks are assigned to the EURL by Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. In accordance with this regulation, sampling and analysis in the context of official controls are carried out by official laboratories designated by CAs in each MS
- Guidance documents available on website
- Specific presentation on EURL tasks and activities by Mr De Jong

After EFSA:

European Food Safety Authority

EFSA Journal 2010; 8(6):1635

SCIENTIFIC OPINION

Scientific Opinion on the safety and efficacy of vitamin E as a feed additive for all animal species[1]

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)[2,3]

European Food Safety Authority (EFSA), Parma, Italy

European Commission =>

& Member States

Standing Committee on the Food Chain

L 11/18 EN Official Journal of the European Union

COMMISSION REGULATION (EU) No 26/2011

of 14 January 2011

concerning the authorisation of vitamin E as a feed additive for all animal species

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

(4) The European Food Safety Authorit

R. 183/2005 on Feed Hygiene: key issues

- *Good hygiene practices and feed safety requirements under the responsibility of business operators over the whole chain of feed production except retailing of pet food*
- *Procedures based on HACCP principles except primary production and associated operations*
- *Registration or approval*
- *Guides to good practice*
- *Import conditions: Member States competence*

Exemptions from the scope (I)

Not too many exemptions!

(a) the private domestic production of feed:

(i) for food-producing animals kept for private domestic consumption; and

(ii) for animals not kept for food production;

(b) the feeding of food-producing animals kept for private domestic consumption.

Exemptions from the scope (II)

(c) the feeding of animals not kept for food production;

(d) the direct supply of small quantities of primary production of feed at local level by the producer to local farms for use on those farms

(e) the retailing of pet food.

Definitions

- *'feed hygiene' means the measures and conditions necessary to control hazards and to ensure fitness for animal consumption of a feed, taking into account its intended use;*

- *'feed business operator' means the natural or legal person responsible for ensuring that the requirements of the present Regulation are met within the feed business under their control;*

Examples of activities covered

- ***Farms***
  - **Farms mixing feeds using additives**
  - **Growing and/or selling crops for feed**
  - **Feeding their own animals**

Approval/Registration of Feed Businesses

Approval

- *Businesses (establishments) subject to approval set out in Annex IV - 'higher risk'*
- *Includes certain additive/premixture manufacturers and distributors (vitamins and trace elements, coccidiostats, micro-organisms…)*
- *Prior inspection required before start-up*

Approval/registration

Registration

- *Most feed businesses will be in this category*
- *Registration is mainly a means of identifying establishments for future inspection*
- *But companies can only buy from registered feed businesses*

Obligations on Feed Businesses

- *Feed businesses operating at level of primary production have to comply with provisions in Annex I*
- *Feed businesses engaged in other operations - Annex II applies.*
- *Farmers feeding food producing animals must comply with Annex III.*
- *Application of HACCP (except primary producers).*

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Obligations of Feed Business Operators

Production processing distribution in accordance with law and good practice

Satisfy hygiene rules

Reduce riskof biological, chemical and physical contamination as low as reasonably achievable

Specific requirements in annex

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Hazard Analysis and Critical Control Points
HACCP

- Identify Hazards that must be prevented, eliminated or reduced to acceptable levels
- Identify Critical Control Points where control is essential to reduce Hazard
- Establish Critical Limits at CCPs
- Establish and Implement Monitoring at CCPs
- Establish regular procedures to verify that above working
- Document

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Approval of Feed Businesses

Businesses manufacturing or marketing Feed Additives, Premixes or compound feed containing additives

Fat blenders, biodiesel, oleochemical fatty acids, processors of crude vegetable oil - for feed

Approval only after on-site visit by competent authority

Approval or registration to be suspended or revoked if business no longer fulfills conditions.

Guides of good practices

- *Community and national guides*
- *Good practice and HACCP application*
- *Feed sector*
- *Encourage, develop, disseminate*
- *Voluntary*
- *Notify*

Import from Third Countries - I

Art. 23

- *General Food Law: Art 11: equivalency also for feed*
- *New system: list of countries and establishments, equivalency*

Import from Third Countries - II

- *Continuing the previous system:*
- ***Representative established in the EU ("gatekeeper"):***
  - Declares that the Third-Country-Establishment complies with the EU-legislation
  - Keeps a register of the imported products

NB. No consolidated EU-list of Third-Country representatives

By way of derogation from Article 33 and pending the drawing up of the lists provided for in Article 23(1)(a) and (b), imports shall continue to be authorised under the conditions laid down in Article 6 of Directive 98/51/EC.

R. 183/2005: Import of feed

- *Art 24: interim measures applicable (= Art. 6 of Dir. 98/51/EC)*
- *Representative established in the EU*
  - **informs on establishments he represents;**
  - **declares compliance with EU rules**

  to the national competent authorities who submit overview to EC.

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Directive 2002/32/EC on undesirable substances in animal feed:

- Undesirable substance: any substance or product, with the exception of pathogenic agents, present in … feed which presents a potential danger to human or animal health or the environment or do adversely affect livestock production.
- prohibits the dilution of contaminated feed materials.
- maximum limits for heavy metals such as arsenic, lead, mercury and cadmium as well as for dioxin, aflatoxin, certain pesticides, and botanical impurities in certain feed materials, feed additives and feedingstuffs.

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	Maximum content in mg/kg (ppm) feed with 12% moisture
1. Arsenic (*) (**)	
Feed materials with the exception of:	2
— meal made from grass, from dried lucerne and from dried clover, and dried sugar beet pulp and dried molasses sugar beet pulp,	4
— palm kernel expeller	4
— phosphates and calcareous marine algae	10
— calcium carbonate	15
— magnesium oxide	20

2002/32

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Maximum content in ng WHO-PCDD/ F-TEQ/kg (ppt) in feed with 12% moisture

Dioxins [sum of polychlorinated dibenzo-para- dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) expressed in WHO toxic equivalents, using the WHO-TEFs (toxic equivalency factors, 2005)]

— Feed materials of plant origin	0,75
— Animal fat, including milk fat and egg fat,	1,50
— Other land animal products including milk and milk products and eggs and egg products.	0,75
— Fish oil	5,0
— Feed additives … trace elements & Premixtures	1,0
— Compound feed	0,75
with the exception of compound feed for pet animals and fish	1,75

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Regulation (EC) N° 767/2009 on the placing on the market and use of feed

- Scope: **feed materials & compound feed** (including pet food)
- **Broad definition of labelling**: … any words, … symbol … on any medium … including for advertising purposes AND rules for sale by means of distance communication
- **No** pre-market authorisation procedure for FMs (**"Bio-proteins")**
- But: **some FMs** require **approval** of the manufacturer
- List of materials prohibited/restricted for feed use ("***negative list***")
- Mandatory labelling requirements
- Feed materials not listed in the **EU-Catalogue** must be contained in feed material register
- Chapter on **dietetic feed** ("*ParNuts*")
- **Codes** for good labelling

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"Negative" list (Annex III) with prohibited [and restricted] materials

1. Faeces, urine …
4. Wood, …which has been treated with wood preservatives biocides
7. Packaging from the use of products from the agri-food industry, and parts thereof.

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Catalogue of feed materials with 67 processes and about 600 products listed (Updated Reg 68/2013)

- ***fat/oil derivatives**:*

  *2.19.6 Sunflower seed meal **feed**: Product of oil manufacture, obtained by extraction and appropriate heat treatment of expeller of sunflower seeds from which part or all of the husks has been removed. May contain up to 1 % used bleaching earth and filter aid (e.g. diatomaceous earth, amorphous silicates and silica, phyllosilicates and cellulosic or wood fibres) and crude lecithins from integrated crushing and refining plants Maximum crude fibre 27,5 % in the dry matter*

  13.6.1 Acid oils from chemical refining

  13.6.4 Fatty acid distillates from physical refining

- ***processing aids:** …feed materials shall be **free from** chemical impurities resulting from their manufacturing process and from **processing aids, unless a specific maximum content is fixed in the Catalogue***

767/2009

- **Labelling rules for additives** in feed materials & compound feed
- FM labelling in compound feed
- **Tolerances** for analytical constituents AND **feed additives**
- Feed additive **functions** can be **claimed** for FM and compound feed (scientific substantiation in the moment of marketing)
- The MS-authority … may submit the issue of **doubtful claims** to the Commission who may adopt a decision. Pilot discussion at EU level on a pre-biotic (MOS)

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Additive labelling in feed materials and compound feed

The name of the additive, identification number and the added amount; example for Zinc*:

Compounds of trace elements, mg/kg

Zinc chelate of hydroxy analogue of methionine, 3b6.10: 40; Zinc chelate of amino acids hydrate, 3b606: 40; Zinc sulphate, heptahydrate, 3b604: 20; all Zinc compounds:100

* Voluntary labelling in blue

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Clarification re "grey zone"

- *"non-additive" Regulation 892/2010*
- *Non-binding guidelines for borderlines between feed materials-feed additives-veterinary medicines-biocides (Recommendation 25/2011)*
- *Catalogue of feed materials (Reg 68/2013) "triple" processes and listed FMs*

⇒ *Clarification for the majority of the grey zone products*

⇒ *However, constantly new cases on the radar, not only FM-FA but Feed-VMP-Biocides*

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- EU Code of good labelling practice for compound feed for food producing animals and Code for good labelling practice of pet food published:

  "… *codes assures a harmonised approach: instead of having 27 different national interpretations of the labelling rules, the code gives clear guidance on how the provisions should be applied throughout the EU. National codes or guidelines are no longer foreseen*…."

- Updated 2018: improve re harmonised implementation (***claims***) and modernised labelling rules

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Authorisation of **feed for particular nutritional purposes** = dietetic feed

Parnuts = special "claim" - borderline with vet medicine

“Exclusivity” of parnut with respect to essential nutritional characteristics and animal species? Example:

Parnut: *"Support of renal function in case of chronic renal insufficiency"*

Essential nutritional characteristics:

"- Low level of phosphorus and restricted level of protein but of high quality (dogs and cats) or
- Reduced phosphorus absorption by means of incorporation of Lanthanum carbonate octahydrate (adult cats)"

RASFF

Rapid Alert System for Food and Feed (RASFF)

- to provide food and feed control authorities with an effective tool to exchange information about measures taken responding to serious risks detected in relation to food or feed. This exchange of information helps Member States to act more rapidly and in a coordinated manner in response to a health threat caused by food or feed.
- App 4000 alerts per year => 10% feed
- Alert example:
  INFORMATION NOTIFICATION FOR ATTENTION: 2012.0514
  SUBJECT: HIGH CONTENT OF LEAD IN ZINC OXIDE FROM TURKEY
  Analytical result: 440 mg/kg – ppm (sampled by BE-importer)
  MRL complete feed 5, complementary feed + FM 10, FA 100, ZnO 400

Medicated feed

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- Directive 90/167 -due to “omissions”- outdated
- The trend shows that the route via MF becomes less important resulting in an increased significance of the “less regulated" routes
- Due to national requirements extreme differences between MS concerning manufacturing and use of MF
- This is even more severe due to national systems of veterinary prescription and national VMP authorisations => Not in line with common (internal) market where the animal products can freely circulate (public health standards fully harmonised) and farmers should have equal production conditions (Common Agricultural Policy harmonised)

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New Regulation on Medicated Feed

WHY a revision:

- Directive 90/167/EEC on Medicated Feed has been established before the creation of the internal market and it has never been adapted in substance.
- The national transposition of this legal instrument has given freedom to Member States regarding interpretation and implementation of the legal provisions, but this flexibility has contributed to some problems.
- Need for a holistic approach at EU level to address antimicrobial resistance (AMR) => project launched 2008 - external report - IA

Why a revision?

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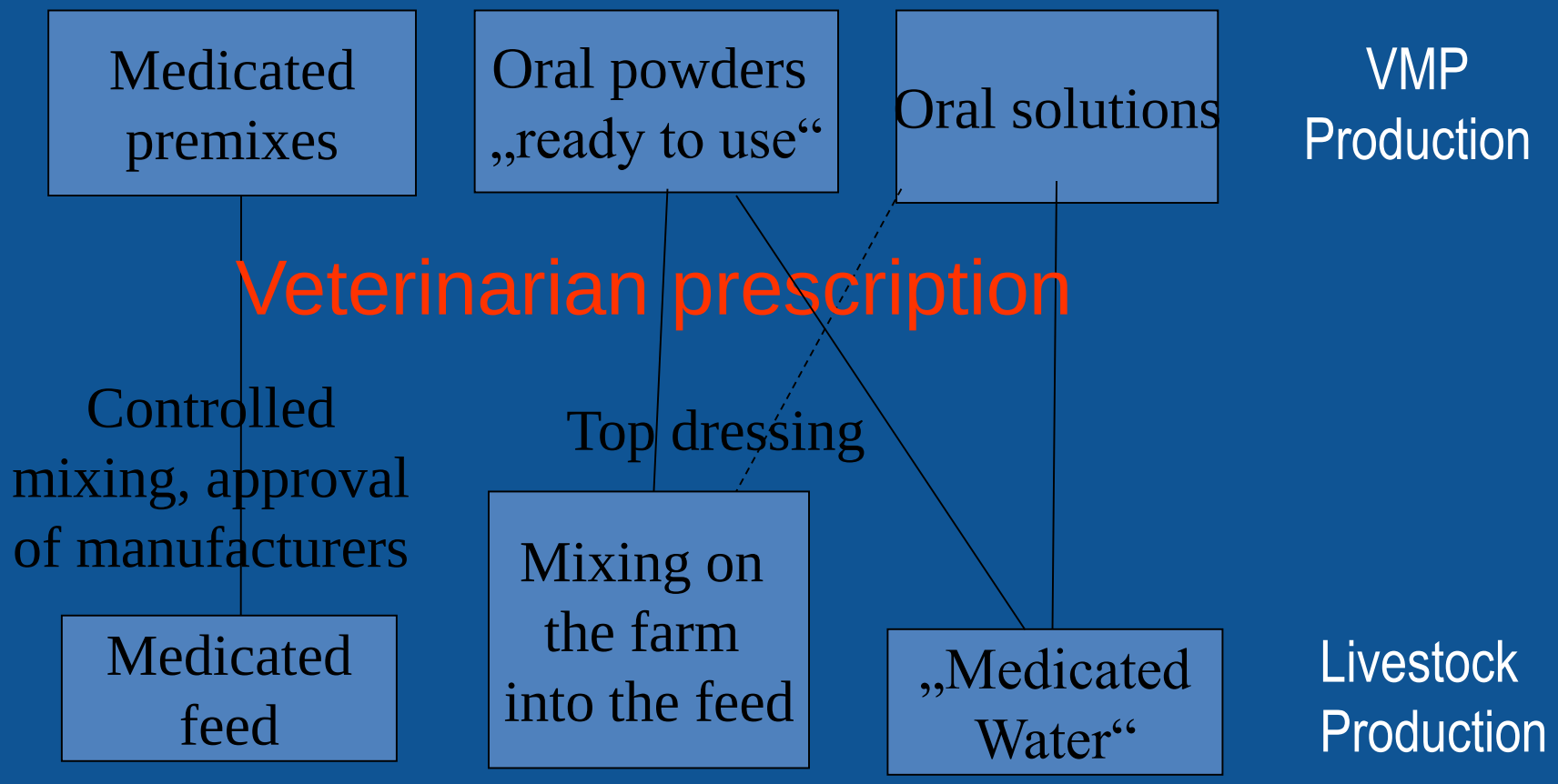
Oral administration of VMPs



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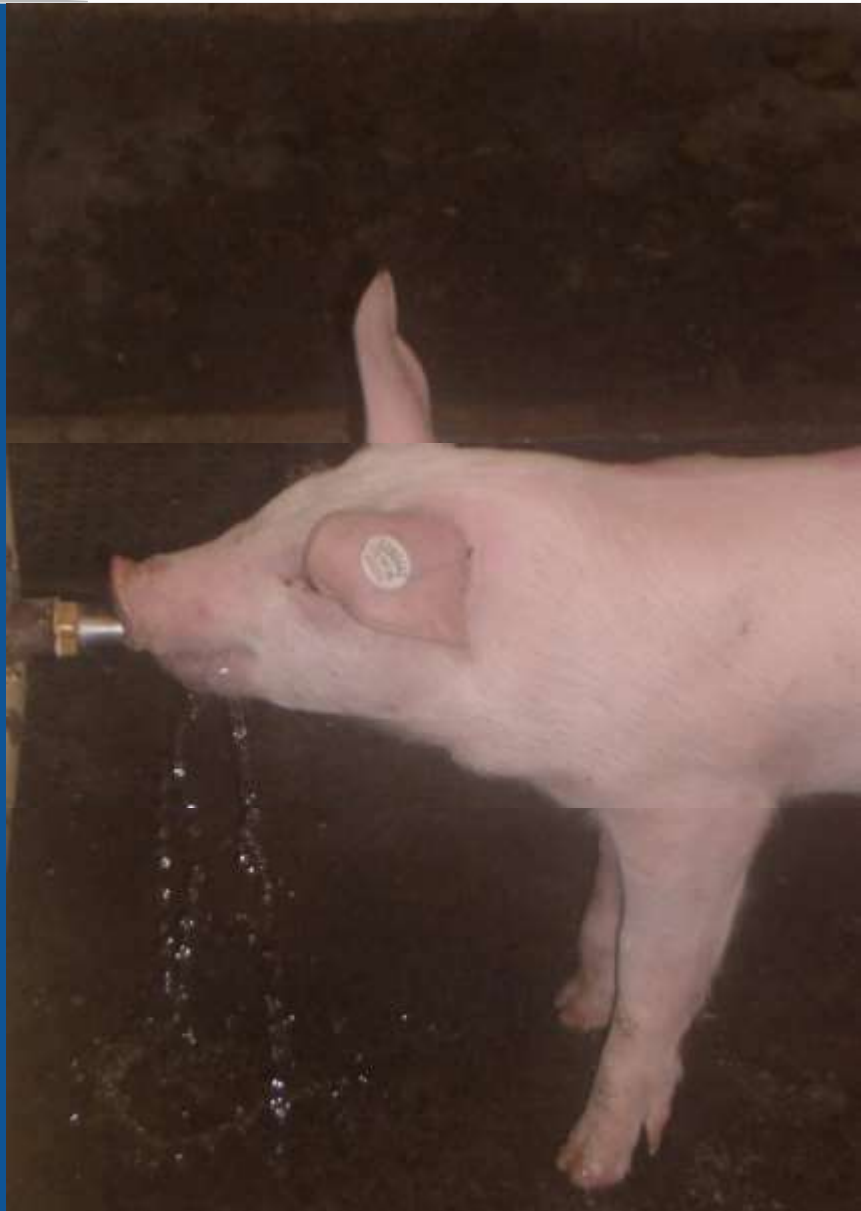
Medication via drinking water ?



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“oral powders”

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Medicated Feed

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I. Antimicrobial resistance (AMR)

1. Carry over limits of veterinary medicines in feed:

   Commission mandate for DA with science based residue limits for 24 antimicrobials in ordinary feed one year after date of application of the Regulation, i.e. 4 years after publication. This deadline is already a big challenge for the Commission as the procedure crucially depends on the European Food Safety Authority (EFSA), for which this will be a new task requiring close cooperation with the EMA.

Goal I

2. Restrictions for veterinary prescriptions of VMPs
   - The validity of veterinary prescriptions for medicated feed with antimicrobials is 5 days.
   - Duration of treatments with antibiotics max two weeks if not specified differently in SPC (link to VMP).

3. Use of antimicrobials in medicated feed for prophylaxis and growth promotion banned:

   In addition to the use restrictions for antimicrobials established for VMPs (reference to Article 107), ban of antimicrobials via MF for prophylaxis (for antiparasitics and immunological VMPs reference to VMP Regulation).

Goal II

II. Level playing field for an economically viable production of safe MF

1. Harmonisation of standards for the manufacturing of medicated feed at the appropriate quality and safety level
2. 3 possibilities for production, in feed mill, mobile mixers and on-farm by animal holder => choice for the best option according to the respective local conditions
3. Anticipated production
   => bigger batch sizes = less production costs
   => less frequently need to change recipe = less risk for cross contamination

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Goal II

4. Incorporation of VMPs “Off label” according to VMP (Art 112-114), but not in anticipated production ex for aquaculture feed
5. Integration of the rules for the involved operators into the horizontal feed legislation including the need to apply the HACCP principle and for registration/approval of the feed business operators.
6. Establishment of labelling rules based on the horizontal feed provisions, supplemented with specific provisions for medicated feed.
   Advertising rules: consistent with VMP
7. Intra-trade and imports: VMP authorisation according VMP in use MS
8. Prescription: consistent with VMP; but: **all** MF requires a vet prescription

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III. Innovative applications of medicated feed, in particularly for chronically diseased pets

1. The explicit permission to use medicated feed for pets offers a new option to treat diseased pets and thus fosters innovation.
2. Based on the specific situation for pets, the legal requirements concerning production, distribution and prescription of veterinary medicines for pets are designed to allow the development of this new sector:
   + *centralised manufacturing*
   + *distribution channels via veterinarians foreseen*
   + *longer validity of prescriptions for VMPs ex antimicrobials*

=> *possibilities to treat (chronically) diseased pets with their* ***regular feed***

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Consistency between oral routes of VMP administration

*Article 106 of the **VMP (not MF!) Regulation** foresees that the Commission shall adopt delegated acts to establish the rules on **appropriate measures to ensure the effective and safe use** of VMPs authorised and prescribed for oral administration via routes other than medicated feed, such as mixing of water for drinking with a veterinary medicinal product or as manual mixing of a veterinary medicinal product into feed and administered by the animal keeper to food-producing animals.*

Resume

1. EU food safety system has been completely reformed since 2000
2. Establishment of the "farm to fork" principle includes in particular feed safety, in concrete by the
   - ✓ 1st responsibility for safe feed with FBO
   - ✓ provisions on feed hygiene (*HACCP, approval of FBOs* …)
   - ✓ marketing rules for feed (*traceability, negative list, catalogue* …)
   - ✓ integration in system for official controls
3. Reg 1831/2003 made
   - ✓ EU system with centralised authorisation procedure based on an independent risk assessment world class
   - ✓ EU a pioneer on reduction of AGPs (*AMR!*)

Resume ctd

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4. 767/2009 - a success story:
   - Simplification - cutting red tape
   - More legal clarity – harmonisation
   - Co-regulation works
   - Sound safety level achieved => focus on transparency, efficiency and truthfulness of labelling
5. Holistic approach by integration of feed in official controls & RASFF
6. New Regulation on medicated feed with concrete measures to fight AMR and to foster innovation

Thank you for your attention!