



Proposal for a Regulation of the European Parliament and of the Council on **Medicated Feed**

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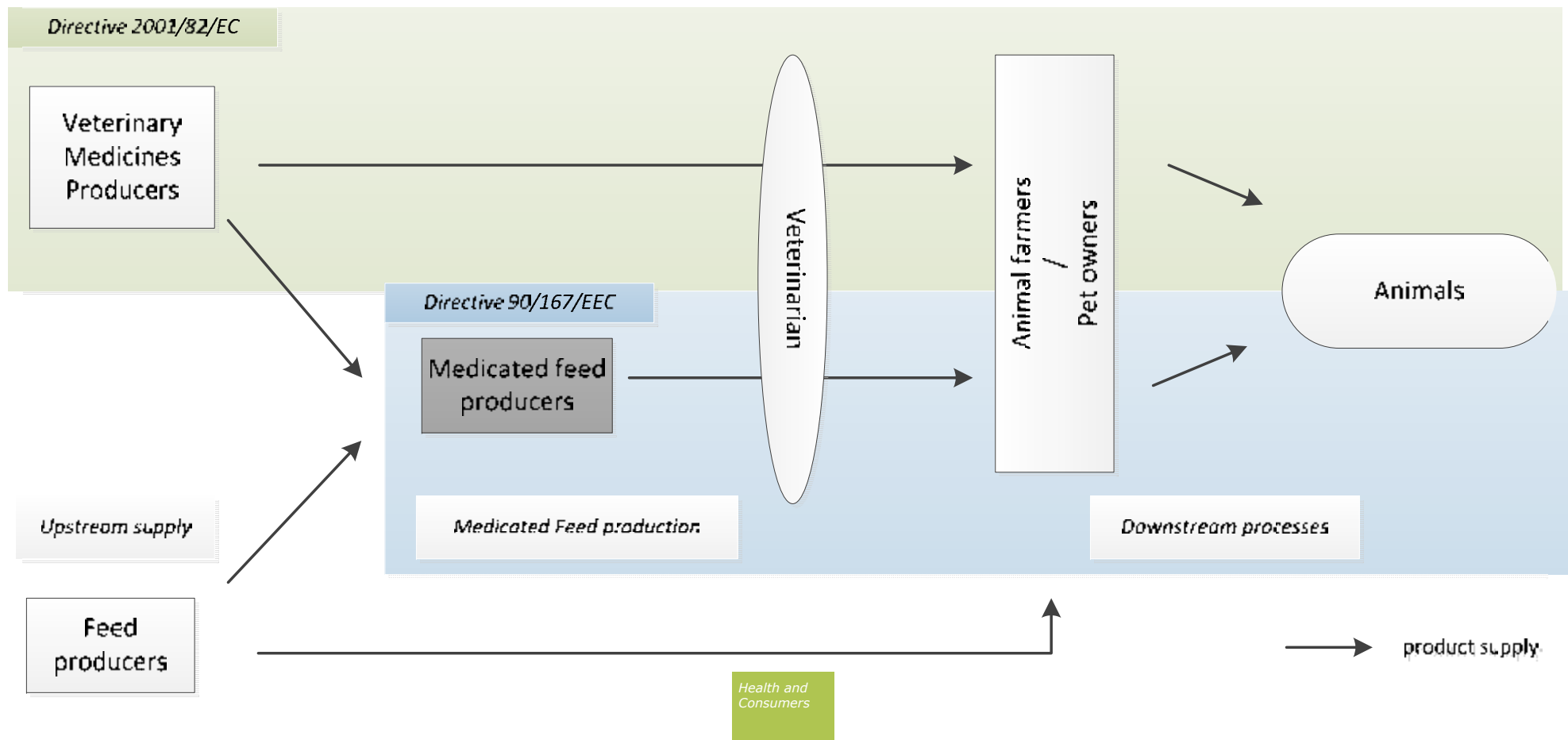


Why a revision?

- Current Directive 90/167/EEC from 1990 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

Upstream-downstream integration of MF





IA structure

1. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES
2. PROBLEM DEFINITION
3. OBJECTIVES
4. POLICY OPTIONS
5. ANALYSIS OF IMPACTS
6. COMPARING THE OPTIONS
7. MONITORING AND EVALUATION



Objectives

General – strategic

- (1) the smooth functioning of a competitive and innovative **internal market**
- (2) ensuring a high level of **protection of animal and public health.**

Specific – operational

1. Overcome the zero-tolerance for unavoidable **carry-over** of VMP
2. Make MF available to farmers and pet owners at a **competitive price**
3. Curb **AMR-risk** from residual and sub-therapeutic administration of antimicrobials
4. Improve animal health **by precise dosage** of oral VMPs
5. Remove **barriers** for innovative, "**novel**" MF



Reasons for EU action

- 1. Protection of public health** => competence given to EU by the Treaty.
With respect to the **AMR** national efforts either contain an explicit call for EU-action or they implicitly hint that EU-action would be sensible
 - + VMP IA and "AMR 5Y action plan": holistic EU-Action
 - + Resolution of the European Parliament
 - + Council conclusions (Doc 10582/12)
 - 2. Directive 90/167** was based on **Art 43** TFEU (implementing CAP).
Evidence that the existing provisions do **not create a level playing** field for EU agriculture **nor assure a functioning internal** market.
- => Choice for a **Regulation** as legal instrument
- => **Articles 43 and 168(4)(b) as legal base** (*same as e.g. feed marketing*)



Problems addressed (1)

1: Imprecise dosage of VMPs + preventive costs for MF production in some MS - Barriers to intra EU trade of MF

- **Manufacturing obligations** including storing, transporting and placing on the market MF and IPs (art 3+4)
 - *adapted from feed hygiene regulation 1831/2003, HACCP*
 - *details laid down in Annex I*
- **... homogenous** incorporation (art 6)!
COM may ... establish **criteria** for the of the VMP into the MF
- *Anticipated production*: MF ... manufactured and stored before the prescription ... is issued (*except on farm mixers and cascade*)
- **Approval** of FBOs manufacturing, storing, transporting or placing on the market MF and IPs by CAs (art 12+13)



Common rules cont

- MF ... shall only be manufactured from VMPs **authorised for the purpose of the manufacture of MF.**
- Parameters for **incorporation** in Annex II (*inclusion rates / mobile and on farm mixers !*)
- **Labelling** (art 9): *synthesis from feed and VMP provisions (annex III)*
tolerances (*technological and analytical!*) for deviation labelling-official controls: annex IV



2: Residues of VMPs in feed – Misuse of AMs – Risk for the development of AMR

- Carry-over limits for VMP in non-target feed:
 - *starting point*: 1% for antimicrobial active substances – 3% for other VMPs
 - to be revised based on scientific risk assessment (*substance based*)
- no preventive use of MF with AMs
- more restrictive rules for prescribing and handling MF with AMs



Problems addressed (3)

3: Limited market access of MF for pets

- Establishment of distributors (*approval*) and anticipated production
- Specific provisions for labelling of medicated pet food
- Specific provisions for prescription and use of medicated pet food



Thank you!

For more information on the revision of the legislation on medicated feed:
http://ec.europa.eu/food/food/animalnutrition/labelling/medicated_feed_en.htm