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

Wolfgang Trunk
European Commission - DG SANTE - Animal Nutrition

Health and Food Safety

Why a revision?

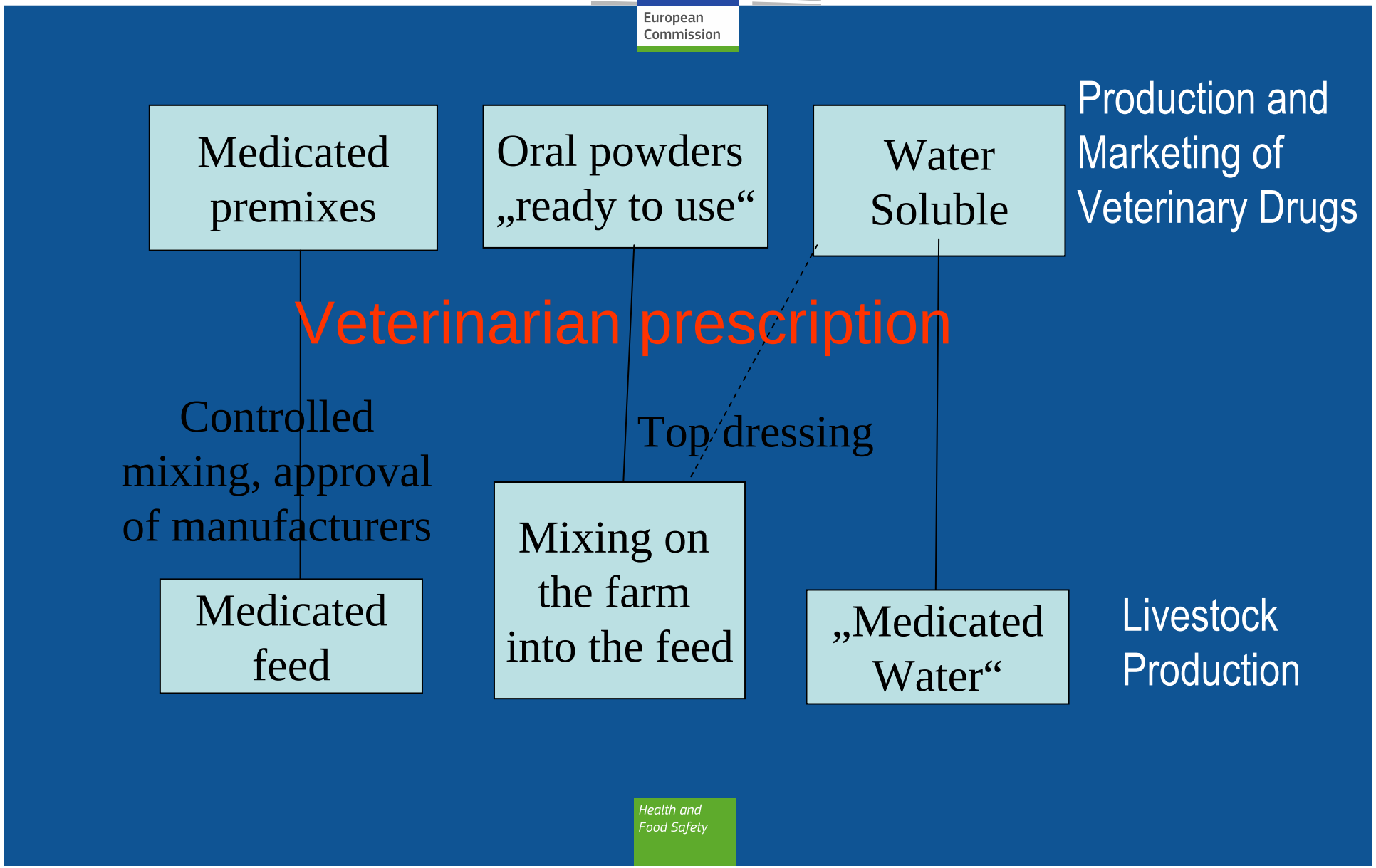
- Current Directive 90/167/EEC from 1990 has been established **before the creation of the internal market** and it has **never been adapted** in substance.

- 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

Oral administration of VMP



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Medication via drinking water ?

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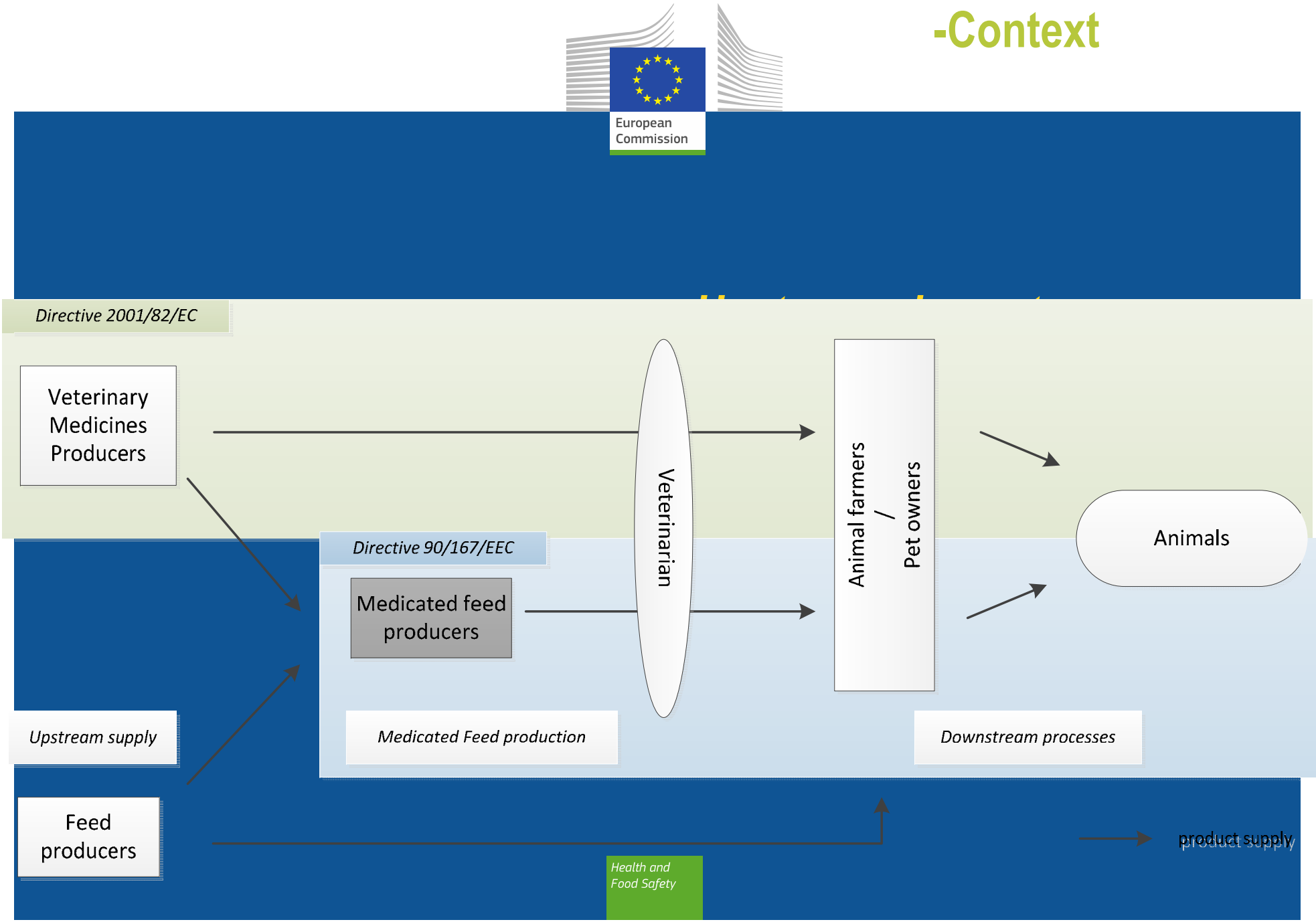
Problems

“oral powders”

Problems

Medicated Feed

-Context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Directive 2001/82/EC
Veterinary Medicines Producers
Veterinarian
Animal farmers / Pet owners
Animals
Directive 90/167/EEC
Medicated feed producers
Upstream supply
Medicated Feed production
Downstream processes
Feed producers
product supply
Health and Food Safety

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

Problems addressed (1)

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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 183/2005, 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

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- 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

Problems addressed (2)

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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

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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

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