EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

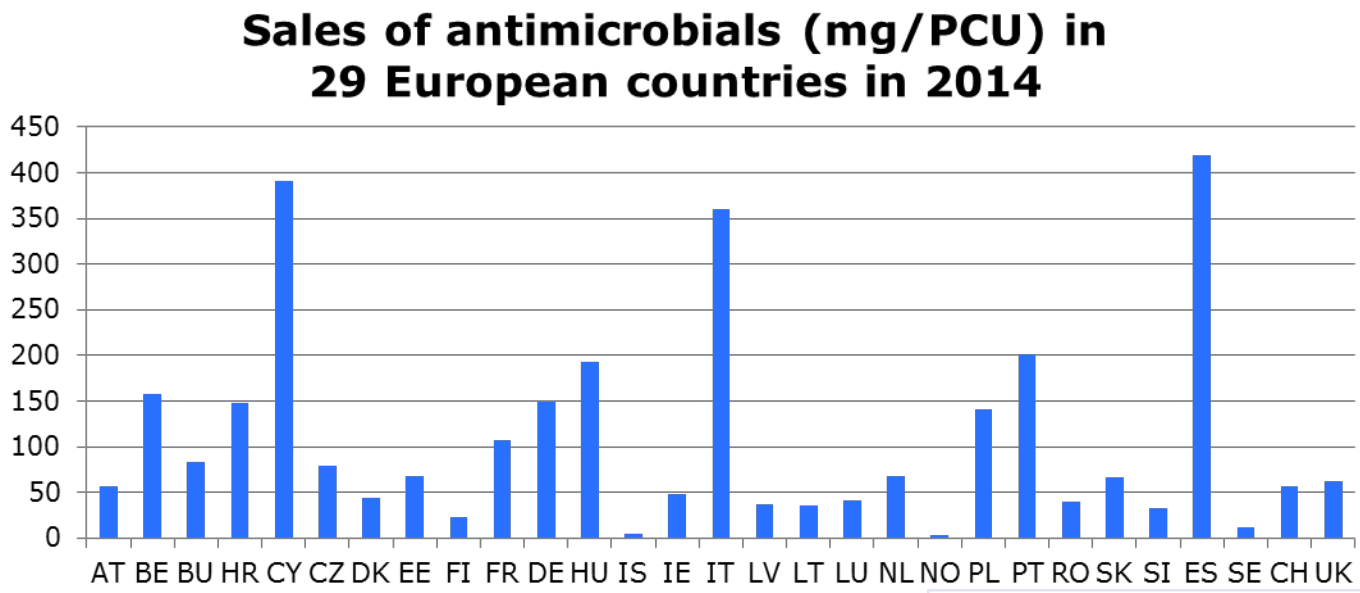
Joint EMA/EFSA scientific opinion of the RONAFA advisory group on measures to reduce the need to use antimicrobial agents in animal husbandry in the EU

ESVAC meeting
3 March, 2017
EMA

Presented by Helen Jukes
Co-chair RONAFA group, chair of the CVMP's Antimicrobials Working Party

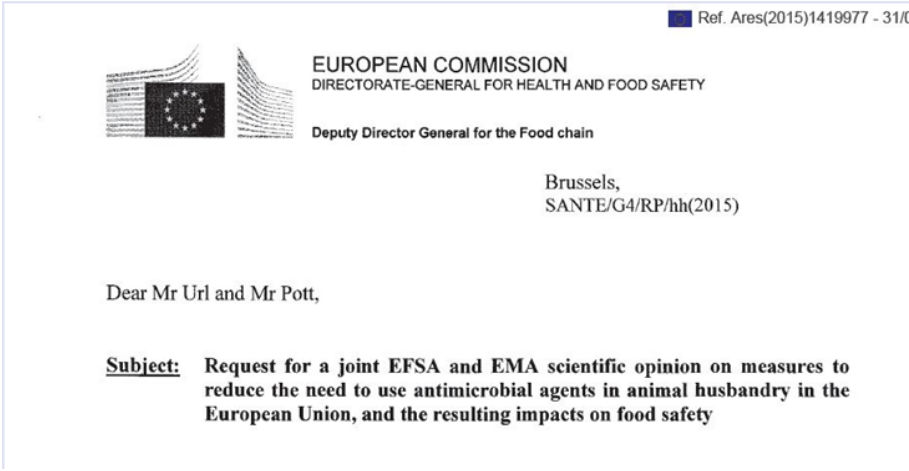
Introduction

ESVAC 2016:



- Lowest user: **3.1** mg/PCU
- Highest user: **418.8** mg/PCU

>100x difference!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EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Deputy Director General for the Food chain

Brussels,
SANTE/G4/RP/hh(2015)

Dear Mr Url and Mr Pott,

Subject: **Request for a joint EFSA and EMA scientific opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the European Union, and the resulting impacts on food safety**

'**RONAFA**': **R**eduction **O**f the **N**eed for **A**ntimicrobials in **F**ood-producing animals and **A**lternatives

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efsa
European Food Safety Authority

Terms of Reference for the opinion provided by the European Commission

- Review the **measures** that have been taken by MSs to **reduce the use** of, and **need to use**, antimicrobials in food-producing animals
- Review **'alternatives'** to the use of antimicrobials
- Assess the **impacts** of the measures and alternatives on the **occurrence of AMR**
- **Recommend options** to **reduce** antimicrobial use and for **responsible use**

Working Group and Data/information

RONAFA group, collaboration between experts from EMA, EFSA

Review of information from:

- **National antimicrobial use and AMR surveillance reports**
- **EU:ESVAC sales report, ECDC/EFSA AMR surveillance reports**
- **Publications in scientific journals, literature reviews *(Alternatives, Organics)***
- **Surveys and questionnaires (FVE, DG SANTE/FVO, food retailers)**
- **Grey literature, hearing expert**

This presentation will focus at high level on a selection of the **eleven recommended options to reduce AMU** and the **supporting information** from the report.

1. Development of **national strategies** and action plans

2. Harmonised integrated **systems for monitoring AMU and AMR** in animals, humans and food

3. Establishing **targets** for reduction of AMU, especially for CIAs

4. **On-farm health management** with professional input

5. Responsibility by **veterinarians for prescribing**

6. Increased oversight of **preventive and metaphylactic** use, especially for groups of animals

7. **Training and education**, raising public awareness

8. Availability of rapid and reliable **diagnostics**

9. Improvement of **husbandry and management** procedures for disease prevention and eradication; use of **vaccination**

10. **Re-thinking of livestock systems**

11. Development of **alternative treatments** to AMs

Option 2: Harmonised systems for monitoring **AMU** and surveillance for **AMR**, **integrating data** from humans, animals, food

- Monitoring impacts of policies on AMU
- Impacts of AMU on AMR
- Transfer of AMR between reservoirs

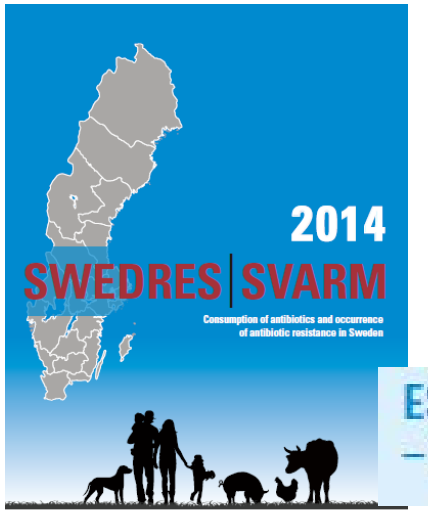
'One Health'

e.g.

SDa Autoriteit Diergeneesmiddelen

Associations between antimicrobial use and the prevalence of resistant micro-organisms

Is it possible to benchmark livestock farms based on resistance data?



ESBL producing *Escherichia coli* – food as a potential dissemination route to humans

Option 3: National (high-level) reduction targets

e.g. Targets set by Dutch government, relative to 2009

2011: 20% reduction

2013: 50% reduction

2015: 70% reduction

By 2014, NL had achieved a **58%** reduction in AMU (MARAN, 2015)

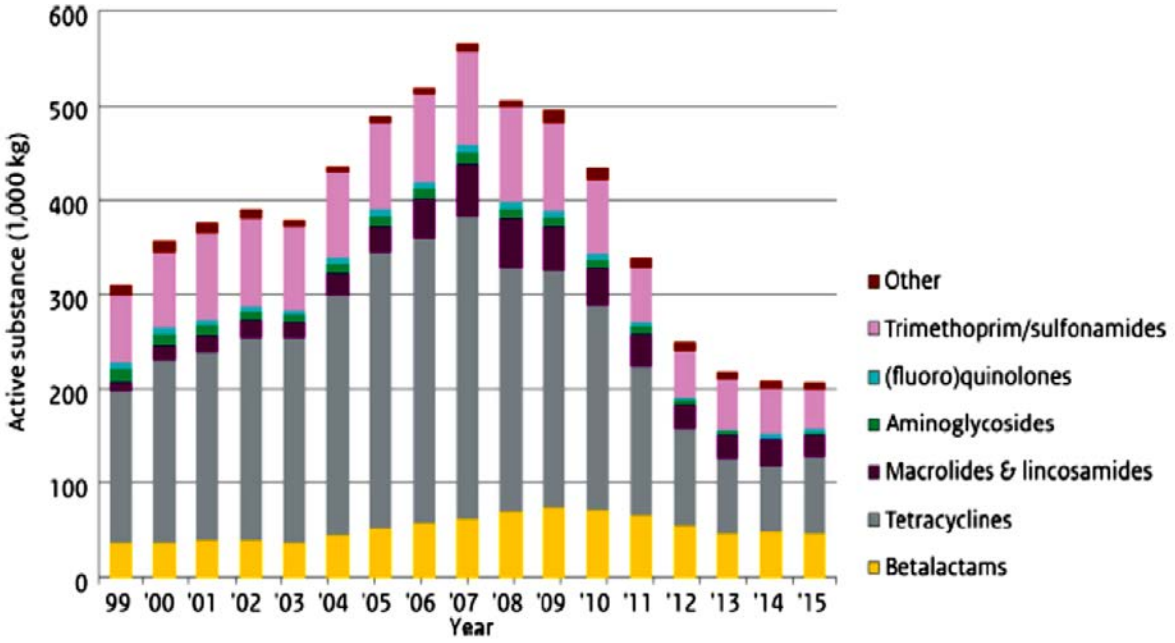


Figure 4: Antimicrobial veterinary medicinal product sales from 1999–2015 in kg (thousands) in the Netherlands (source: MARAN, 2016)

- **Set according to national circumstances**
- **With underlying supporting package of reduction measures**

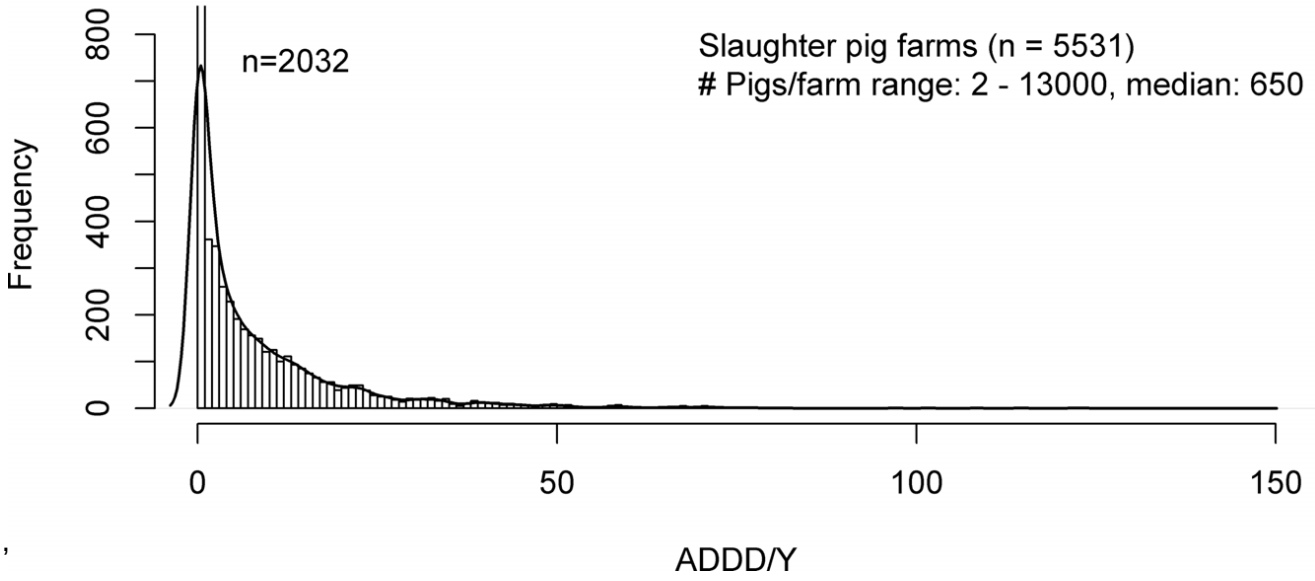
Option 3: Farm level benchmarking

AMU monitoring systems should ideally measure farm level use, and at level of livestock production stage, to allow benchmarking between farms for different sectors

Denmark - 'Yellow Card' initiative (2010) targeted pig farms using >2x the average for the production group

Netherlands – sector specific levels, target farms > 75th percentile

Freq distribution of animal defined daily dosage/year for slaughter pig farms in NL, 2011 (Bos, 2013)



Options 4 & 5: Farm health plans and increasing the **responsibility taken by veterinarians for prescribing** antimicrobials

e.g. Danish pig production–

- **Veterinary Advisory Service Contract** (2010)
- **Treatment guidelines** (2010)
- Yellow card (2010)

→ **25% reduction in AMU per pig produced** in DK from 2009 – 2011 (Jensen, 2014)

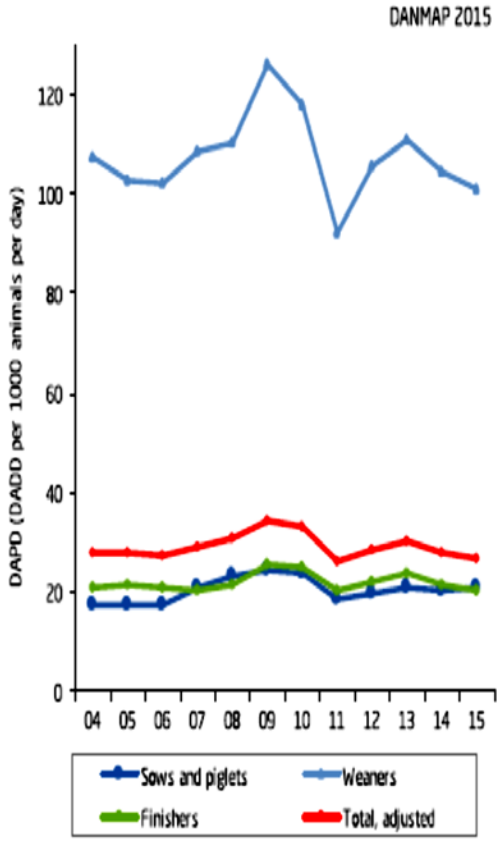
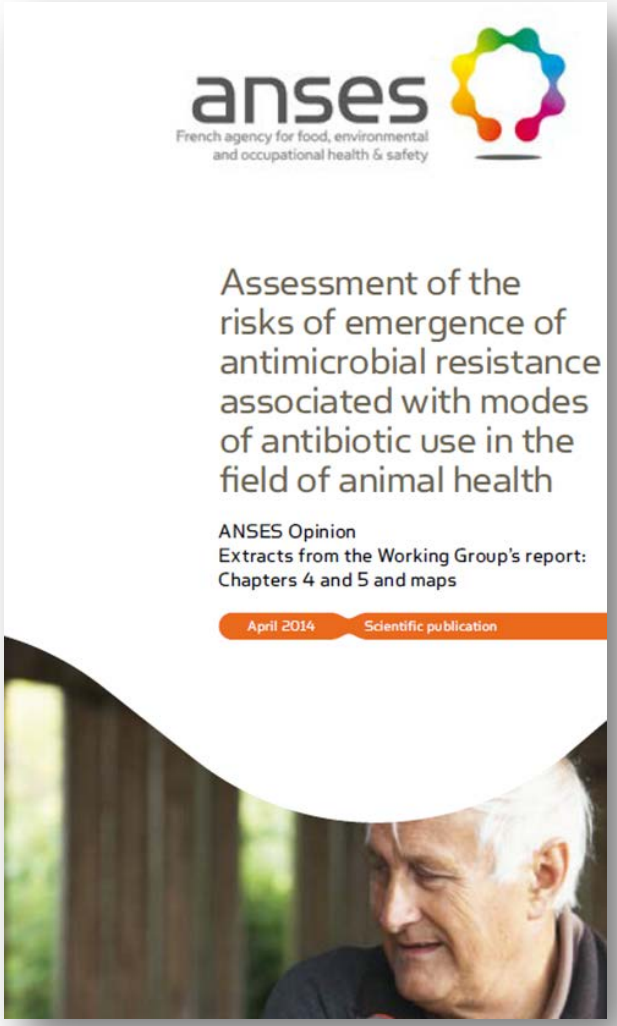


Figure 9: Antimicrobial consumption in the pig production, and the distribution on age groups, Denmark (source: (DANMAP, 2016) – see also original report)

Option 6: Increased oversight of preventive and metaphylactic AMU

- **Preventive use to be phased out** except in exceptional cases.
- Specific conditions given for exceptional cases where prevention may still be needed.
- Phase-out of preventive use based on **review by livestock sector professionals** of endemic diseases, risk factors, local husbandry.
- **Metaphylactic use to be refined**: Principles to be developed at national level. Criteria to be defined for initiation of treatment. Recognised alternatives measures identified.



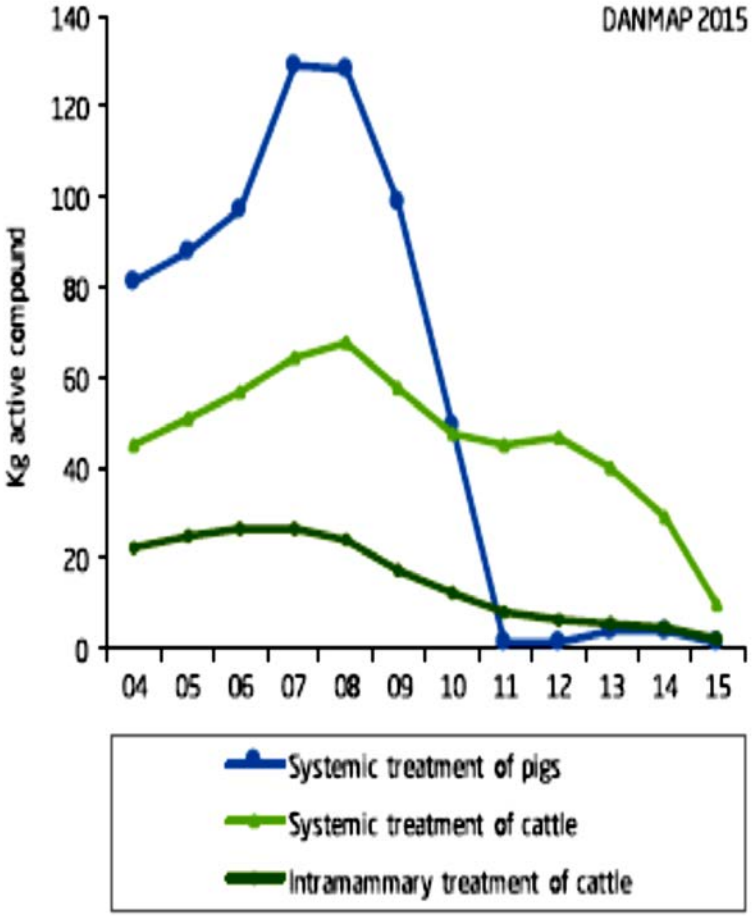
Options 3, 5 & 7: Measures on critically important antimicrobials

- **Livestock sector targets for CIAs, voluntary sector bans**
- **Susceptibility testing prior to use** of high priority **CIAs** (NL, SE, DK) – highly effective
- **Treatment guidelines**

e.g. Denmark, use of 3/4G Cephs in pigs

- **Treatment guidelines** for pigs (2010)
- **Voluntary ban** on use of 3/4G cephs in pig sector (2010)

Consumption of 3/4G Cephalosporins in pigs & cattle in DK



Option 9: Improvement of husbandry for disease prevention, control and eradication

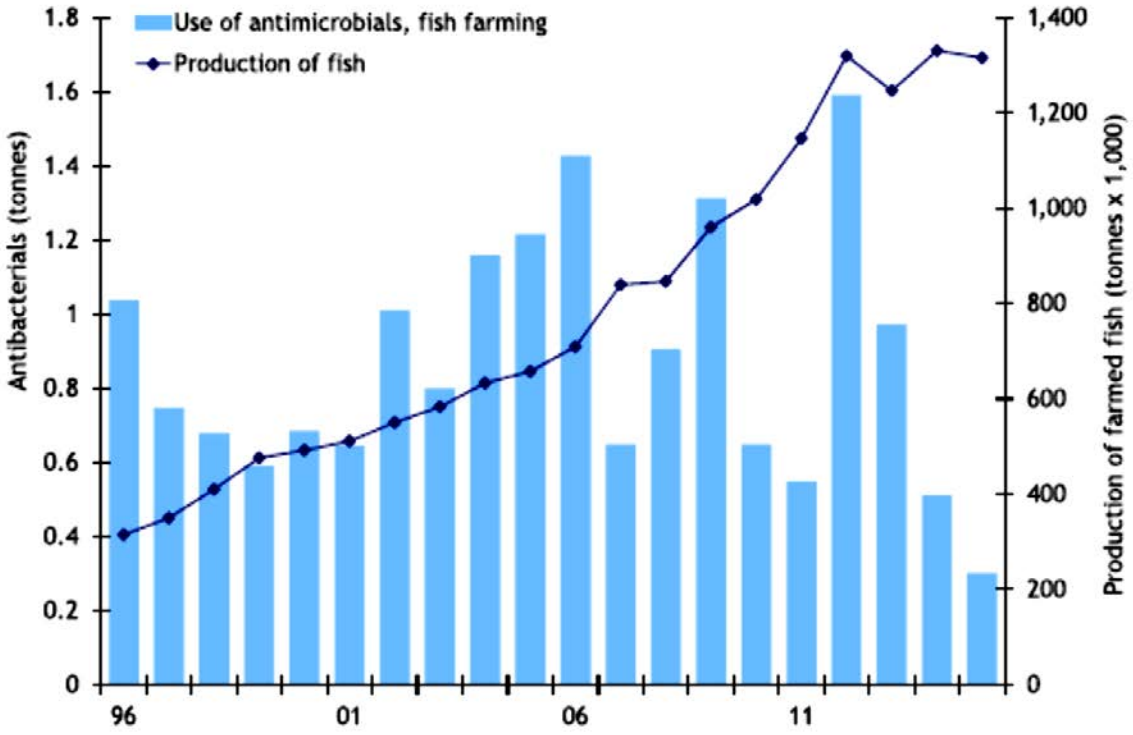
- **Preventing spread of infections between farms**: external biosecurity, compartmentalisation according to health status (e.g. SPF), eradication
  - Eradication of PRRS from pigs in Sweden (Carlsson, 2009)
  - Eradication of BVD from Scandinavian countries (Stahl, 2012)

- **Preventing spread of disease on the farm**: internal biosecurity (biocontainment), housing, production groupings ‘all-in, all-out’

- **Increasing disease resilience**: nutrition, genetics, vaccination, stress reduction

e.g. **Norway: Use of vaccines in fish production**

- Fish production increased >3x from 1996 to 2015 (1.3M tonnes)
- AMU remains c. 1 tonne/year
- Government/industry investment in vaccine development (vibriosis, furunculosis)
- Mandatory use of vaccines (Ronafa, Appendix C)



re D.2: Fish production and use of antimicrobials in fish farming in Norway (1996–2015)

Option 11: Development of treatments which are alternatives to antimicrobials

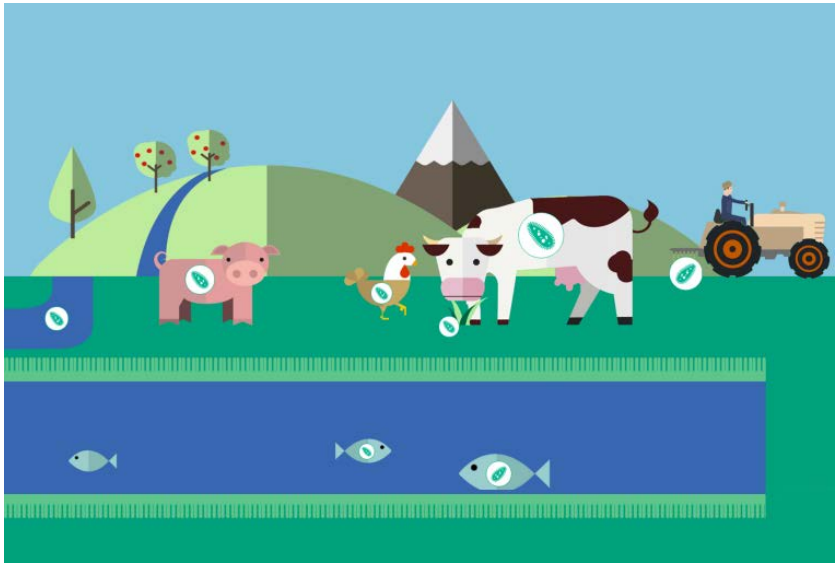
- Literature review: Limited robust scientific evidence of impacts on health parameters
- Some authorised as zootechnical feed additives
- Some show reduction of disease risk; studies rarely in line with veterinary 'medicinal' claims
- Positive impacts on health parameters shown for e.g.
    - **organic acids** (necrotic enteritis in poultry, PWD in pigs)
    - **probiotics** (diarrhoea in calves and piglets)
    - **bacteriophages** (shedding of zoonotic pathogens)
    - **immunomodulators** (aquaculture, intramammary infections)
    - **zinc oxide** (diarrhoea in pigs)
    - **teat sealants** (intramammary infections)

Options

- **an EU regulatory framework for 'alternatives'**
- **Additional research – controlled & meaningful clinical trials**

Features of successful strategies to reduce AMU

- Integrated, multifaceted approach (reflecting multiplicity of factors that underlie AMU)
- Take account of local livestock production systems
- Involve all relevant stakeholders



In conclusion

Setting targets

Increase responsibility of veterinarians

Preventive use should be phased out

Consider alternatives to antimicrobials

Research new alternatives

Develop an EU legal framework for alternatives

Improve disease prevention and control

Consider alternative farming systems

Education and awareness

Thank you for your attention

Further information

See next slide

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References

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Animated infographic:

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