

Mandate 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.

BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION:

Combating antimicrobial resistance is a priority for the European Commission which launched in 2011 a 5-year Action Plan against the rising threats from AMR, based on a holistic approach, in line with the "One Health" initiative. The plan introduced a set of rigorous measures to fight against AMR.

Antimicrobials are necessary for treating human and animal diseases. Any use of antimicrobials, either in human or veterinary medicine, might result in the development of AMR and has an impact on human and animal health, although the specific impact has not been quantified to date. The prudent use of antimicrobials in human and veterinary medicine is therefore a key element of the Action plan to contain resistance for the benefit of both animal and human health.

Antimicrobial agents have been used for many years in animal husbandry mostly for treatment and also for animal production purposes. Their use as feed additives for growth promotion has been banned in the European Union since January 1st 2006. The use of antimicrobial agents in animal husbandry is necessary for the treatment of animal disease. In certain cases antimicrobials are used for prophylaxis.

Figures from the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) Report 2014¹ of the sales of antimicrobial veterinary medicinal products in food producing species in 26 EU/EEA countries accounting for approximately 95 percent of the food-producing animal population in the EU/EEA area, show that in 2012 a total of 7982 tonnes of active ingredients of veterinary medicinal products were sold for use in livestock. The ESVAC report shows that during the last years Member States have taken successful initiatives to reduce antimicrobial consumption, which has resulted on an overall decrease on sales of antibiotics for use in animals by 15% between 2010 and 2012 for the 20 European countries that provided data over this timespan. However the report shows considerable variation in the use of antimicrobial agents between countries and it is of note that antibiotic classes such as 3rd/4th-generation cephalosporins, fluoroquinolones, aminoglycosides and polymyxins, which are classified as Critically Important Antimicrobials by the WHO², are sold, in some Member States, in important amounts for use in animals. Tetracyclines were by far the most common class of antimicrobials used.

The use of antibiotics in food-production animals has come under considerable scrutiny, particularly in recent years. At the request of the European Commission, the European Food Safety Authority (EFSA) has published several opinions on this subject, sometimes independently and at other times in collaboration with the European Centre for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA) and Scientific

¹ http://www.ema.europa.eu/docs/en_GB/document_library/Report/2014/10/WC500175671.pdf

² http://apps.who.int/iris/bitstream/10665/77376/1/9789241504485_eng.pdf

Committee on Emerging and Newly Identified Health Risks (SCENIHR)³. EFSA and ECDC also produce yearly the European Union Summary Report on antimicrobial resistance in zoonotic and indicator bacteria from humans, animals and food⁴. Following a request from the European Commission, the EMA in collaboration with EFSA and ECDC provided a ranking of antibiotics taking into account the risk for Public and animal health⁵.

Further inter-EU agency collaborations have resulted on the ECDC/EFSA/EMA first joint report on the integrated analysis of the consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals.⁶

The use of antimicrobial agents in food-producing animals has an impact on human health, although this cannot be quantified at present. Such problems were highlighted in the EFSA Scientific Opinion on the public health risks of bacterial strains producing extended-spectrum β-lactamases and/or AmpC β-lactamases in food and food-producing animals⁷. Key conclusions from this report were that '*since most ESBL- and AmpC-producing strains carry additional resistances to other commonly-used veterinary drugs, generic antimicrobial use is a risk factor for ESBL/AmpC and it is not restricted specifically to the use of cephalosporins. Prioritisation is complex, but it is considered that a highly effective control option would be to stop all uses of cephalosporins/systemically active 3rd/4th generation cephalosporins, or to restrict their use (use only allowed under specific circumstances). As co-resistance is an important issue, it is also of high priority to decrease the total antimicrobial use in animal production in the EU*'.

Because of these concerns for public health, and the possible consequences for animal health and welfare, there is increasing focus on measures to reduce antimicrobial usage in animal husbandry by promoting prudent use initiatives, as well as exploring alternative management aspects to the use of antimicrobials in farms. In addition there is great interest to deploy possible alternatives to the use of such agents in livestock production. Such measures range from changes in husbandry practices, improved biosecurity, to more direct interventions such as the use of vaccines, immune modulation, interventions aimed to influence gut microbiome, bacteriophage therapy and competitive exclusion, to name a few examples.

TERMS OF REFERENCE AS PROVIDED TO EFSA AND EMA:

The European Commission requests jointly to the EFSA and the EMA, taking into account the impact on public health and animal health and welfare, to:

³ <http://www.efsa.europa.eu/en/efsjournal/doc/765.pdf>; <http://www.efsa.europa.eu/en/efsjournal/doc/1372.pdf>; www.efsa.europa.eu/en/efsjournal/doc/2322.pdf.

⁴ <http://www.efsa.europa.eu/en/search/doc/3196.pdf>

⁵ http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000385.jsp&mid=WC0b01ac058080a586

⁶ <http://www.efsa.europa.eu/en/efsjournal/pub/4006.htm>

⁷ <http://www.efsa.europa.eu/en/efsjournal/pub/2322.htm>

- Review the measures that have been, or are being taken, to reduce the use of antimicrobials in animal husbandry in the EU.
- Assess the impact of such measures regarding the occurrence of antimicrobial resistance in bacteria from food-producing animals and food.
- Review the recent scientific developments in the area of possible alternatives to the use of antimicrobials in animal husbandry in the EU.
- Assess the potential impact of such alternative measures on the occurrence of antimicrobial resistance in bacteria from food-producing animals and food.
- Recommend options to reduce antimicrobial usage in animal husbandry in the EU, including consideration of the advantages and disadvantages of the different alternatives. Where a continued need is identified to use antimicrobials in the interests of animal health and welfare, recommend how such use can continue with the minimum possible risk to human health.