



BTSF on Antimicrobial resistance ‘one health’ approach

LECTURES FOR THE TRAINING COURSE

EU

- Commission Website on AMR with all related issues:
https://ec.europa.eu/health/amr/antimicrobial-resistance_en
- 2017 EU AMR Action Plan
https://ec.europa.eu/health/amr/sites/amr/files/amr_action_plan_2017_en.pdf
- Progress report on EU AMR Action Plan – last update: Q2 2019
http://ec.europa.eu/health/amr/sites/amr/files/amr_2018-2022_actionplan_progressreport_en.pdf

Political commitments addressing AMR in the EU

- Council Recommendation of 9 June 2009 on the prevention and control of health-care associated infections <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32009H0703%2801%29>
- European Parliament Resolutions:
 - 12 May 2011 on antibiotic resistance on the public health threat of antimicrobial resistance
<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.CE.2012.377.01.0131.01.ENG&toc=OJ:C:2012:377E:FULL>
 - 27 October 2011 on the public health threat of antimicrobial resistance
<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+TA+P7-TA-2011-0473+0+DOC+PDF+Vo//EN>
 - 19 May 2015 on safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance (2014/2207(INI))
<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+TA+P8-TA-2015-0197+0+DOC+PDF+Vo//EN>
- Council conclusions:
 - on the next steps under a One Health approach to combat antimicrobial resistance (2016/C 269/05): [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52016XG0723\(02\)](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52016XG0723(02))
 - on the impact of antimicrobial resistance in the human health sector and in the veterinary sector - a "One Health" perspective - 22 June 2012
[http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52012XG0718\(01\)](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52012XG0718(01))
- European Parliament resolution of 11 December 2012 on the Microbial Challenge — Rising threats from Antimicrobial Resistance (2012/2041(INI))
<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52012IP0483>

EU Legislation

- EU related legislation on AMR – human sector:
 - Implementation report on the Council recommendation on patient safety including healthcare associated infections – adopted 13 November 2012



- https://ec.europa.eu/health/sites/health/files/patient_safety/docs/council_2009_report_en.pdf
- Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health
https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/decision_serious_crossborder_threats_22102013_en.pdf
 - Council Recommendation (2002/77/EC) of 15 November 2001 on the prudent use of antimicrobial agents in human medicine
<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32002H0077>
 - EU guidelines for prudent use of antimicrobials in human health
https://ec.europa.eu/health/amr/sites/amr/files/amr_guidelines_prudent_use_en.pdf
[http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52017XC0701\(01\)&from=EN](http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52017XC0701(01)&from=EN)
- EU related legislation on AMR – veterinary sector:
 - Directive 2001/82/EC Veterinary medicinal products <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32001L0082>
 - Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32003R1831>
 - Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feeding stuffs in the Community https://ec.europa.eu/food/safety/animal-feed/medicated-feed_en
 - Regulation (EC) No 470/2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council
<http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM:2015:56:FIN>
 - Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC
<https://eur-lex.europa.eu/eli/reg/2019/6/oj>
 - Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 1831/2003 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2019.004.01.0001.01.ENG
 - Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs
 - Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents
 - Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC. <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003L0099&from=EN>
 - 2013/652/EU: Commission Implementing Decision of 12 November 2013 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:303:0026:0039:EN:PDF>
 - EU guideline for prudent use of antimicrobials in veterinary medicine
https://ec.europa.eu/health/sites/health/files/antimicrobial_resistance/docs/2015_prudent_use_guidelines_en.pdf



https://ec.europa.eu/health/sites/health/files/files/veterinary/vet_2014-09/amending_726_2004/act_part1_en.pdf

EU Agencies

ECDC – antimicrobial resistance

- <https://ecdc.europa.eu/en/antimicrobial-resistance>
- EU protocol for harmonised monitoring of antimicrobial resistance in human *Salmonella* and *Campylobacter* isolates
<https://ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/antimicrobial-resistance-Salmonella-Campylobacter-harmonised-monitoring.pdf>

EMA:

- EMA – AMR in the veterinary sector:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001686.jsp&mid=WC0b01ac05807a4e0d
- EMA – AMR in the public health sector:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001689.jsp&mid=WC0b01ac058002d4e9
- ESVAC: Activities on collection of data on sales/use of veterinary antimicrobials
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2017/02/WC500221116.pdf

EFSA:

- EFSA – AMR website:
<https://www.efsa.europa.eu/en/topics/topic/antimicrobial-resistance>
- EFSA – Guidance documents:
 - EFSA. 2012 - Technical specifications on the harmonised monitoring and reporting of antimicrobial resistance in *Salmonella*, *Campylobacter* and indicator *Escherichia coli* and *Enterococcus* spp. bacteria transmitted through food.
<http://www.efsa.europa.eu/en/efsajournal/pub/2742.htm>
 - EFSA. 2012 - Technical specifications for the analysis and reporting of data on antimicrobial resistance (AMR) in the European Union Summary Report.
<http://www.efsa.europa.eu/en/efsajournal/pub/2587.htm>
 - EFSA. 2014 - Technical specifications on randomised sampling for harmonised monitoring of antimicrobial resistance in zoonotic and commensal bacteria.
<http://www.efsa.europa.eu/en/efsajournal/pub/3686.htm>
 - EFSA. 2015 - Data dictionaries-guidelines for reporting data on zoonoses, antimicrobial resistance and food-borne outbreaks using the EFSA data models for the Data Collection Framework (DCF) to be used in 2015, for 2014 data.
<http://www.efsa.europa.eu/en/supporting/doc/776e.pdf>
 - EFSA. 2015 - Manual for reporting on antimicrobial resistance within the framework of Directive 2003/99/EC and Decision 2013/652/EU for information deriving from the year 2014.
<http://www.efsa.europa.eu/en/supporting/pub/771e.htm>
 - EFSA 2013 - Scientific Opinion on Carbapenem resistance in food animal ecosystems; EFSA Panel on Biological Hazards (BIOHAZ); 17 December 2013
<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2013.3501/epdf>



Agency reports and scientific opinions:

- **JACRA**
 - JACRA I:
<https://ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/antimicrobial-resistance-JACRA-report.pdf>
 - JACRA II: https://ecdc.europa.eu/sites/portal/files/documents/efs2_4872_final.pdf
- **AMEG:**

First scientific request: Request for scientific advice on the impact on public health and animal health of the use of antibiotics in animals (EMA/363834/2013)
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/07/WC500146812.pdf

 - Use of colistin in food-producing animals in the European Union: development of resistance and impact on human and animal health EMA/755938/2012:
http://www.ema.europa.eu/docs/en_GB/document_library/Report/2013/07/WC500146813.pdf

Revised advice on colistin:

 - Updated advice on the use of colistin products in animals within the European Union: development of resistance and possible impact on human and animal health
EMA/CVMP/CHMP/231573/2016.
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2016/07/WC500211080.pdf
 - Scientific advice on impact on public health and animal health of the use of antibiotics in animals
 - Answer to the Request for scientific advice on the impact on public health and animal health of the use of antibiotics in animals EMA/381884/2014
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/07/WC500170253.pdf
- **RONAFA:**
 - EMA and EFSA published their joint opinion in response to the Commission's request in January 2017 (also known as the 'RONAFA' opinion): EMA and EFSA joint scientific opinion on measures to reduce the need to use antimicrobials agents in animal husbandry in the EU and the resulting impact on food safety
- **Outcome indicators** as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals
<https://ecdc.europa.eu/sites/portal/files/documents/AMR-indicators-joint-report-Oct-2017.pdf>
http://www.ema.europa.eu/docs/en_GB/document_library/Report/2017/10/WC500237745.pdf

National Strategies and Action Plans on AMR

- <https://ecdc.europa.eu/en/publications-data/directory-guidance-prevention-and-control/antimicrobial-resistance-strategies>



International organisation actions on AMR

- United Nations
<http://www.un.org/apps/news/story.asp?NewsID=55011#.WfsMro8m6-s>
- WHO Global Action Plan to combat AMR
http://apps.who.int/iris/bitstream/10665/193736/1/9789241509763_eng.pdf?ua=1
- WHO guidelines on use of medically important antimicrobials in food-producing animals
http://www.who.int/foodsafety/publications/cia_guidelines/en/
- Worldwide country situation analysis: response to antimicrobial resistance
http://apps.who.int/iris/bitstream/10665/163468/1/9789241564946_eng.pdf?ua=1&ua=1
<http://www.who.int/antimicrobial-resistance/national-action-plans/library/en/>
- Antimicrobial Resistance: developing National Action Plans
http://apps.who.int/iris/bitstream/10665/204470/1/9789241549530_eng.pdf?ua=1
- Global framework for development and stewardship to combat AMR
<http://apps.who.int/medicinedocs/en/d/Js23198en/>
- WHO list of Critically Important Antimicrobials in human medicine Integrated Surveillance on AMR
<http://www.who.int/foodsafety/publications/cia2017.pdf?ua=1>
- Antimicrobial Resistance: developing National Action Plans
http://apps.who.int/iris/bitstream/10665/204470/1/9789241549530_eng.pdf?ua=1
- Global Antimicrobial Resistance Surveillance System (GLASS)
http://apps.who.int/iris/bitstream/10665/188783/1/9789241549400_eng.pdf?ua=1
- FAO Action Plan on AMR (2016-2020)
<http://www.fao.org/3/a-i5996e.pdf>
- OIE Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobial 2016
http://www.oie.int/fileadmin/Home/eng/Media_Center/docs/pdf/PortailAMR/EN_OIE-AMRstrategy.pdf
- OIE Annual report on the use of antimicrobials agents in animals
http://www.oie.int/fileadmin/Home/fr/Our_scientific_expertise/docs/pdf/AMR/Survey_on_monitoring_antimicrobial_agents_Dec2016.pdf
- CODEX
<http://www.fao.org/fao-who-codexalimentarius/roster/detail/en/c/433592/>
- Global Health Security Agenda
<https://www.ghsagenda.org/>
- Transatlantic Taskforce on Antimicrobial Resistance (TATFAR)
<https://www.cdc.gov/drugresistance/tatfar/>
- G20 - Health Ministers' Meeting: Fighting Antimicrobial Resistance



<http://www.oecd.org/about/secretary-general/g20-health-ministers-meeting-fighting-antimicrobial-resistance.htm>

- G7 – AMR in G7 countries and beyond: Economic issues, policies and options for action
<http://www.oecd.org/els/health-systems/Antimicrobial-Resistance-in-G7-Countries-and-Beyond.pdf>

Antimicrobial resistance and the Environment

AMR – EMA

- CVMP -Committee for Medicinal Products for Veterinary Use Environmental Risk Assessment Working Party
http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/CVMP/people_listing_000037.jsp&mid=WCob01ac0580028e2b

Articles:

- Andrew C. Singer^{1*}, Helen Shaw², Vicki Rhodes³ and Alwyn Hart³ Review of Antimicrobial Resistance in the Environment and Its Relevance to Environmental Regulators. *Frontiers in Microbiology*. Published: 01 November 2016 doi: 10.3389/fmicb.2016.01728
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5088501/>
- Study on the environmental risks of medicinal products
https://ec.europa.eu/health/sites/health/files/files/environment/study_environment.pdf
- Venter H¹, Henningsen ML², Begg SL².: **Antimicrobial resistance in healthcare, agriculture and the environment: the biochemistry behind the headlines**. *Essays Biochem*. 2017 Mar 3;61(1):1-10. doi: 10.1042/EBC20160053. Print 2017 Feb 28.
<https://www.ncbi.nlm.nih.gov/pubmed/28258225>