29 April 2020
EURL AMR

EFSA Update

Pierre-Alexandre Beloeil
Beatriz Guerra
Karoline Noerstrud

Trusted science for safe food

European Food Safety Authority

Satisfaction Survey on the EU SRs (2019)

- **Stakeholders generally positive about all aspects of the EUSR on AMR**
  - provides an **adequate assessment of sources** and a **clear overview of trends** of AMR
  - an essential and unique source for the collation of national data
  - a repository of information all in one place
  - appropriate size and format of the report: necessary for a comprehensive analysis
  - aligns with **'One Health' approach** and demonstrates alignment between ECDC/EFSA's joint objectives
- **Report satisfies the needs of stakeholders, in particular the EC and the MSs**
  - adheres to the Founding Regulation
  - Is **useful**, adequate, relevant **for decision-making needs**

Figure 3.11 Usefulness for developing strategies to AMR[14]

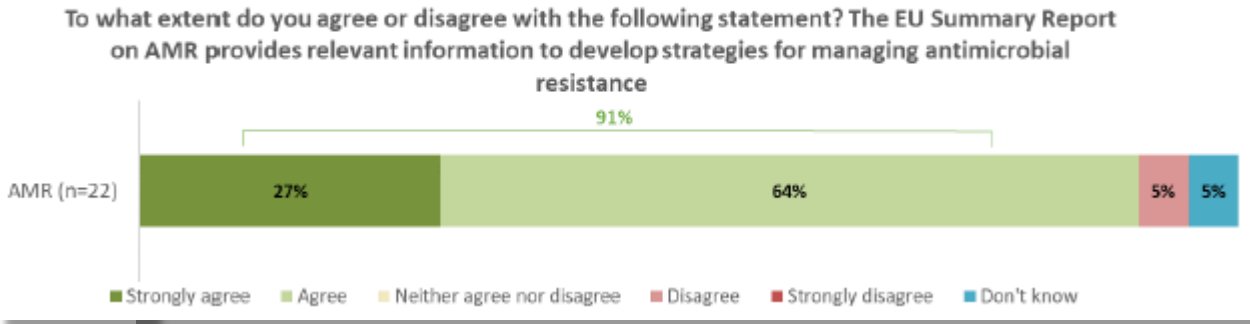
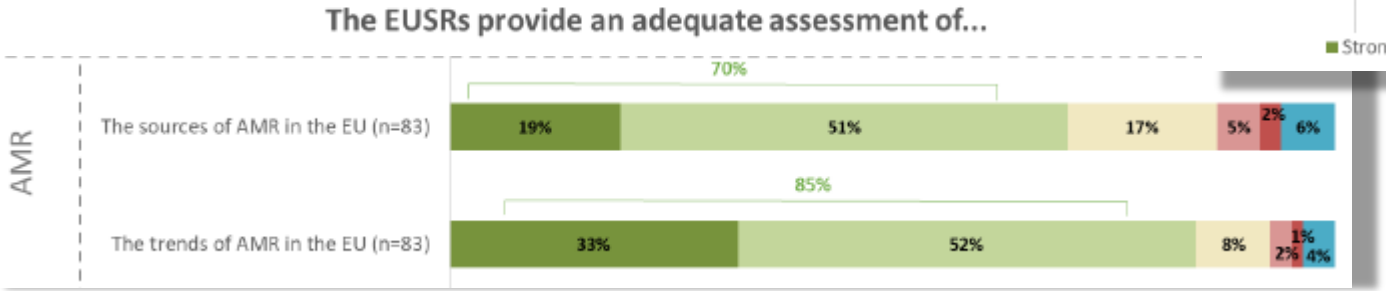


Figure 3.5 EUSR adequacy assessing sources and trends[8]



New format of the EUSR on AMR

AMR monitoring performed on a rotating basis

AMR monitoring foreseen on a rotating basis

2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
2014 EU SR on Broilers, Turkeys + meat	2015 EU SR on Pigs, Calves + meat	2016 EU SR on Broilers, Turkeys + meat	2017 EU SR on Pigs, Calves + meat	Monitoring on Poultry	Monitoring on Pigs, Calves	Monitoring on Poultry	Monitoring on Pigs, Calves	Monitoring on Poultry	Monitoring on Pigs, Calvess	Monitoring on Poultry

Data on Pigs, Calves + **Data on Broilers, Turkeys** + **meat**

AMR data on zoonotic bacteria from humans

2017-2018 Overview Report on AMR

❖ Overview Report on AMR

- More concise and synthetic report
- Still covering all food-producing animals + meat
- Focusing on the main findings at the EU level
- Presenting primary 'Key Indicator': complete susceptibility
- Still addressing the variability among the MSs through maps and graphs
- Focusing on Temporal Trends
- Including Scientific Discussion and Interpretative Analysis

+

- **Tabulated data on occurrence of resistance,**
- **Materials and methods,**

... published on the **EFSA website** as **Supporting**

Review of the harmonised monitoring of AMR

EFSA Tech. Spec. on the harmonised monitoring and reporting of **AMR** in ***Salmonella***, ***Campylobacter***, **indicator commensal *E. coli*** and *Enterococcus* spp. transmitted through food

EFSA Tech. Spec. on the harmonised monitoring and reporting of **MRSA** in food-producing animals and food

EFSA Tech. Spec. on **randomised sampling** for harmonised monitoring of AMR in zoonotic and commensal bacteria

New EFSA Tech. Spec. on the harmonised monitoring of AMR in bacteria transmitted through food ***by July 2019***

2019-2020: Drafting of the legislation by the EC

2020: Negotiation EC - MSs

2012

2014

2019

Directive 2003/99/EC

Art. 7(3) and 9(1) + Annexes II (B) IV

Decision 2013/652/EU

2014 - 2020

New Decision

2021 - ...

European Food Safety Authority

European Commission

2011-2016
Action Plan against the rising threats of AMR

June 2017
The European 'One Health' **Action Plan** against AMR

2016 – 2017 - 2018
Audits of implementation in the MSs by **Dir. F of DG SANTE of the EC**

EURL Campylobacter

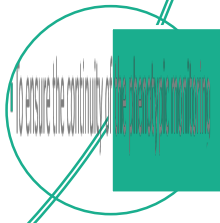
European Union Reference Laboratory Antimicrobial Resistance

Guiding Principles for the Proposals

To ensure the continuity of the phenotypic monitoring

To ensure comparability with historical data

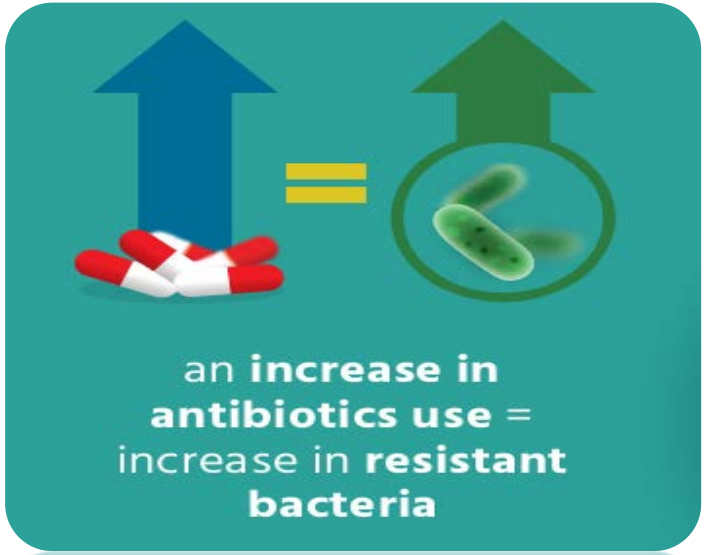
To account for recent scientific developments and AMR trends



To account for recent technological developments

JIACRA III project

- Joint project for ECDC, EMA and EFSA
- Mandate from the European Commission
- To analyse the relationship between data on use of antimicrobials and data on antimicrobial resistance in humans and animals for the years 2016, 2017 and 2018.
- To consider in particular the Key Outcome Indicators



EC Mandate

Scientific Opinion to evaluate the specific maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed below which there would not be an effect on antimicrobial resistance, and the levels for which there would be growth promotion/increase yield

(EFSA-Q-2019-00221, M-2019-0080)

Deadline 30 September 2021

3. Apramycin	Aminoglycosides
10. Neomycin	Aminoglycosides
11. Spectinomycin	Aminoglycosides
16. Paromomycin	Aminoglycosides (antiparasitic)
1. Amoxicillin	Beta-lactams
17. Penicillin V	Beta-lactams
12. Sulfonamides	Folate synthesis inhibitor
21. Trimethoprim	Folate synthesis inhibitor
2. Amprolium	Ionophores (coccidiostats, inhibits the active transport of thiamine)
9. Lincomycin	Lincosamide
20. Tilmicosin	Macrolide
22. Tylosin	Macrolide
24. Tylvalosin	Macrolide
7. Florfenicol	Phenicols
19. Tiamfenicol	Phenicols
18. Tiamulin	Pleuromutilin
23. Valnemulin	Pleuromutilin
5. Colistin	Polymixin
8. Flumequine	Quinolones
15. Oxolinix Acid	Quinolones
4. Chlortetracycline	Tetracyclines
6. Doxycycline	Tetracyclines
13. Tetracycline	Tetracyclines
14. Oxytetracycline	Tetracyclines

- *Ad **hoc*** **WG** composed of **14 experts**
- **EFSA (BIOHAZ+ AHAW+ FEEDAP Panels) + EMA**

MANDATE

The EC requests **to assess the impact of the presence of low-level concentration in feed of 24 antimicrobial active substances … on animal health, human health and, where possible, on the environment.**

- **ToR1**: To assess the **specific concentrations of antimicrobials** resulting from **cross-contamination in non-target feed for food-producing animals, below which there would not be an effect on the emergence of and/or selection for resistance in microbial agents relevant for human and animal health**
  - i.e. the **endpoint** for this assessment should be the **excretion of resistant bacteria** from the animals.
  - However, the assessment should **also consider the impact on the environment of the low-level concentrations in feed**, where possible.

- **ToR2**: To assess which **levels of the antimicrobials have a growth promotion/increase yield effect**.

AMR GP FEED Residues: expertise needed

- **Antimicrobial resistance** (AMR) in zoonotic bacteria, commensals, pathogens: phenotypes, resistance mechanisms (BIOCONTAM, AHAW, EMA)
- Predicted minimal inhibitory concentrations (**PMECs**) of antimicrobials, effect of **low-levels and subinhibitory antimicrobial concentrations** in resistance development (BIOCONTAM)
- **Maximum residue levels** (**MRLs**) (EMA)
- **Veterinary pharmacology** (**PK/PD**) (EMA, BIOCONTAM)
- **Feed residues** (EMA)
- **Animal health** (AHAW, EMA)
- **Animal gut microbiota** (AHAW, FEEDAP)
- **Animal production systems: food-producing animals** (AHAW, BIOCONTAM)
- **Animal Nutrition and production methodologies** (FEEDAP)
- **Feed production** (FEEDAP)

- Methodology agreed. Pilot assessments Tetracycline and Trimethoprim.
- **Public consultation methodology probably end of July.**

BIOHAZ Panel self-task Mandate

Self-tasking mandate for a scientific opinion on the role played by the environment in the emergence and spread of antimicrobial resistance (AMR) through the food chain

(EFSA-Q-2019-00343, M-2019-0109)

Deadline 31 December 2020

- *Ad **hoc*** **WG** composed of **8 experts**
- **EFSA (BIOHAZ) + ECDC (1 WG expert) + EMA (observers) + EEA (observers) + EC (observers)**

ToRs

The BIOHAZ Panel is requested to address the following terms of reference:

- **ToR1**: To **identify** the **main environmental sources and transmission routes leading to the contamination of foods** of animal and non-animal origin **with antimicrobial-resistant bacteria and/or resistance determinants**.

- **ToR2**: Among **antimicrobial-resistant bacteria and/or resistance determinants contaminating food** through the **routes identified** above, to **identify** the **ones of highest priority for public health**, if possible their **relative importance**, and the **main risk factors** influencing their **occurrence and persistence in food-producing environments and food**.

ToRs

- **ToR3**: To **review** and, if possible, **assess** the **impact** of existing or new possible **strategies and options to mitigate the risk** of **emergence, spread** and **food-borne transmission** of the **antimicrobial-resistant bacteria** identified above.

- **ToR4:** To **identify data gaps influencing the assessment** of the **food chain-related AMR risks posed by the environment** and **provide recommendations** to inform future EU research priorities on this topic.

ACKNOWLEDGEMENTS

- The FWD Network / EFSA Network on AMR
- The EC
- CAs, NRLs-AR and the laboratories involved
- The EURL-AR

Thank you for your attention!