



# Better Training for Safer Food *Initiative*

*Antimicrobial Resistance One Health approach*

**EU AGENCIES AND THEIR  
COOPERATION**

# BTSEF

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Food safety

**Malaga, Spain – 25-28 November 2019**



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH



European Food Safety Authority

## SUMMARY

1. EFSA
2. ECDC
3. EMA
4. Interagency cooperation

■ RONAFA

■ AMEG

■ JIACRA

■ Outcome indicators



European  
Commission

**Member  
States**

**European  
Commission**

**European  
Parliament**

**decision makers  
scientific advice**



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH



**Risk  
Assessment**

- Biological Hazards
- Genetically modified organisms
- Feed

**Hazard &  
progress  
monitoring**

- Biological Monitoring
- Task Force on Zoonoses Data Collection

Food safety

# European Food Safety Authority



## Scope and purpose

Set up in 2002

Under General Food Law – Regulation 178/2002

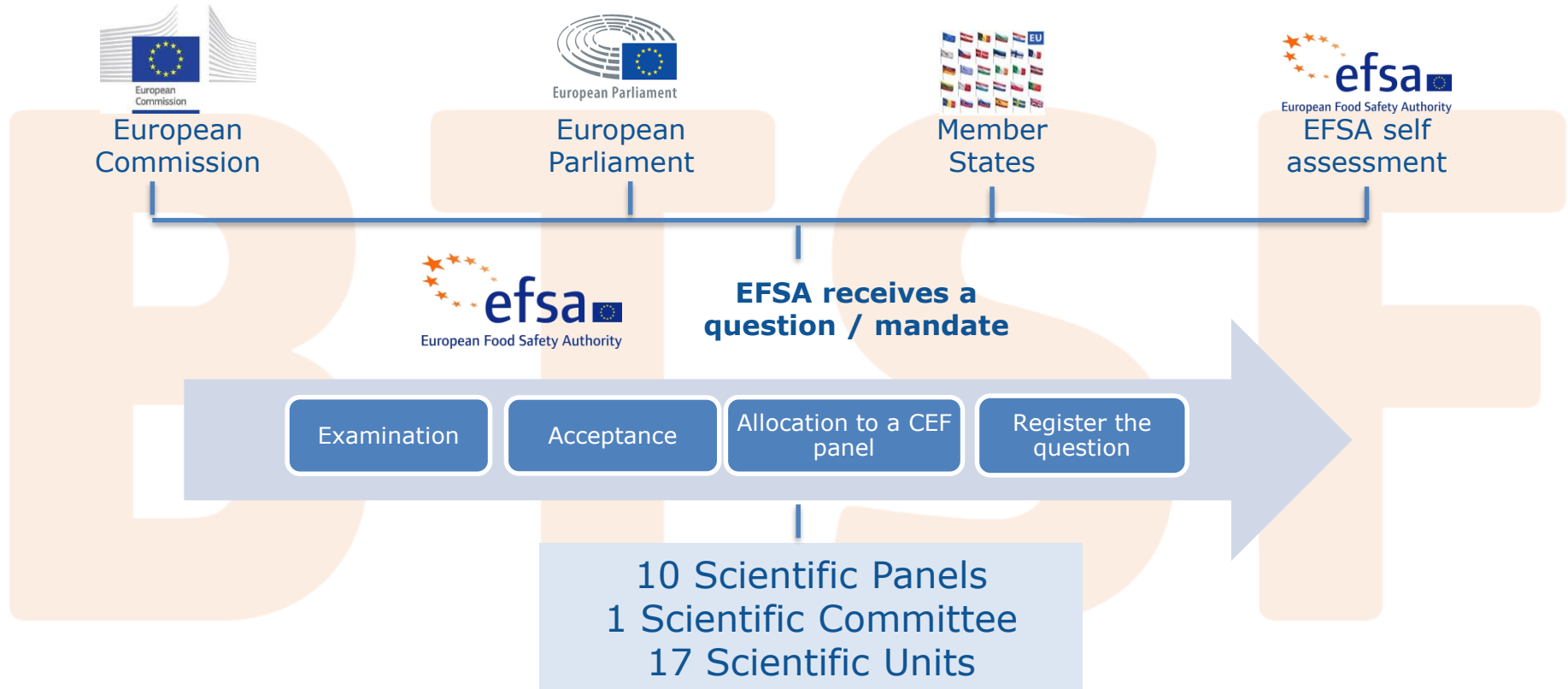
**Risk assessment on** food and feed safety

- Independent scientific advice
- Scientific and technical support
- Clear communication on existing and emerging risks



<https://www.efsa.europa.eu/en/howwework/workingpractices>

## How EFSA works



**Risk assessment**

**Risk communication**

## Panels

- Animal Health and Welfare
- Food Additives and Nutrient Sources Added to Food
- Food Contact Materials, Enzymes, Flavourings and Processing Aids
- Contaminants in the Food Chain
- Additives and Products or Substances used in Animal Feed
- Genetically Modified Organisms
- Dietetic Products, Nutrition and Allergies
- Plant Health
- Plant Protection Products and their Residues
- .....and Panel on Biological Hazards...



# EFSA's role in Monitoring and Risk Assessment

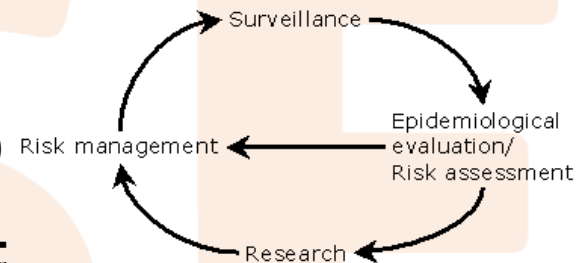
## To detect emergence and to understand dissemination of AMR

Technical specifications on AMR-monitoring  
Data collection on AMR at EU-level  
Baseline surveys (e.g. MRSA in pig production)

## To provide data relevant for risk assessment

Scientific Opinions on AMR  
Clear communication on existing and emerging risks

## To plan interventions and measure their effects





# European Centre for Disease Prevention and Control



# The role of ECDC among the UE Agencies for the surveillance of Antimicrobial Resistance

The European Centre for Disease Prevention and Control (ECDC) gather and analyse data and information on emerging public health threats



Purpose

Protect the public health in the European Community

The collection of data related to antimicrobial resistance and antimicrobial consumption is included as part of the European Surveillance System (TESSy) through several networks.

# EARS-NET: the EUROPEAN ANTIMICROBIAL RESISTANCE SURVEILLANCE NETWORK

EARS-Net was started in 1999 by the Dutch National Institute for Public Health and the Environment (RIVM) and transferred to ECDC in 2010.



The aim of this network is:

- to collect comparable and accurate data on antimicrobial resistance in each Member State. An AMR national focal point is who leads the national AMR network;
- to provide guidance on the AMR surveillance methodology, the external quality assessment;
- to provide AMR data for policy decisions;
- to encourage the implementation, maintenance and improvement of national AMR surveillance programmes.

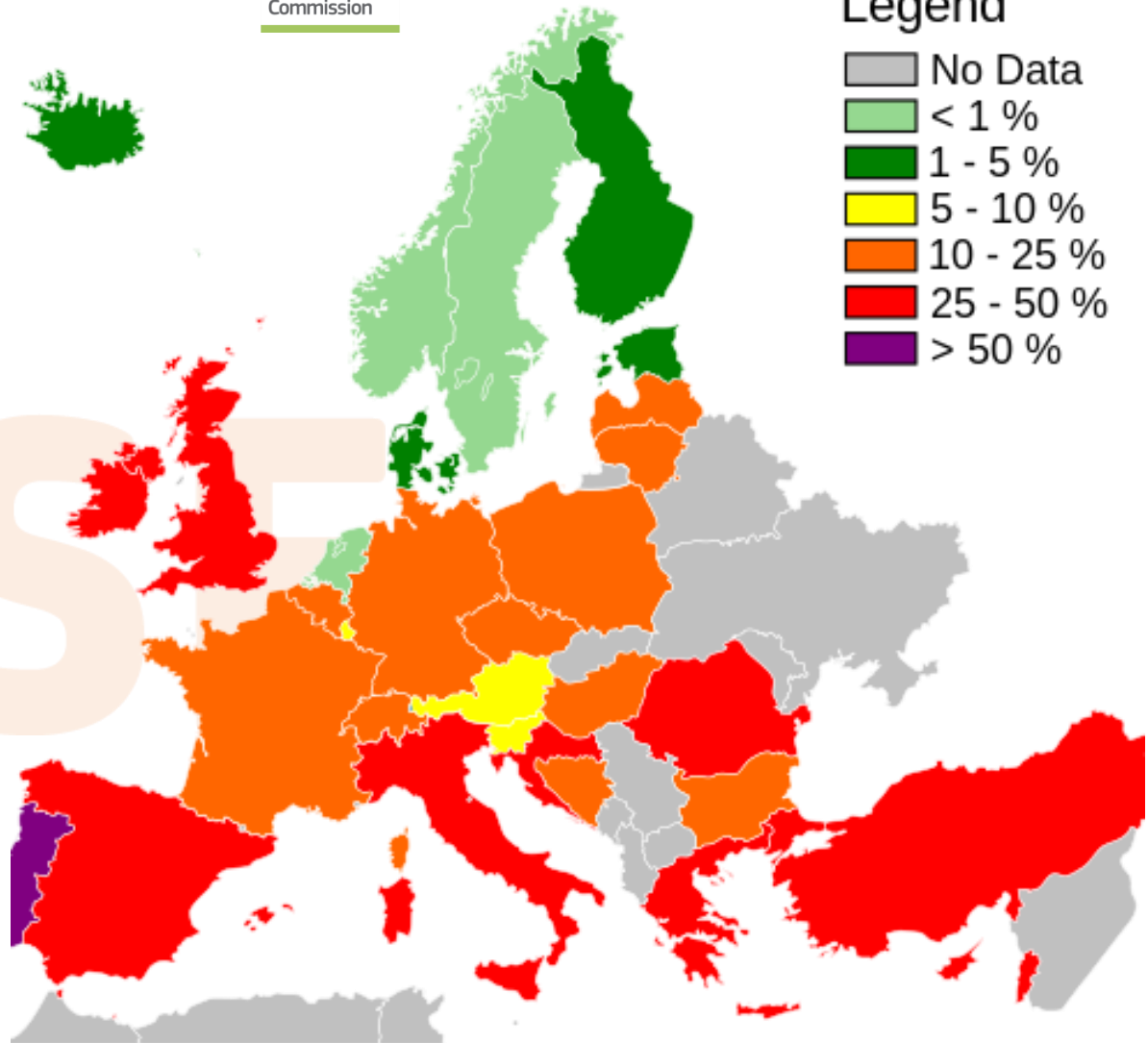


European  
Commission

**MRSA**

## Legend

- No Data
- < 1 %
- 1 - 5 %
- 5 - 10 %
- 10 - 25 %
- 25 - 50 %
- > 50 %



Food safety

# FWD-Net: the FOOD and WATERBORNE DISEASES and ZOO NOSES NETWORK

## Zoonoses

Zoonoses are diseases that can be transmitted directly or indirectly between animals and humans, for instance by consuming contaminated foodstuffs or through contact with infected animals.

Most zoonotic infections have mild symptoms and do not require medical treatment. However, they can also turn into life-threatening conditions.



- Created in the UK as a surveillance network for enteric pathogens (Enter-net), this survey was transferred to ECDC in 2007.
- The scope of the disease network was broadened to cover 21 food-and waterborne diseases and zoonoses.
- Coordinating Competent Bodies (CCB) are in charge to collect the data.
- ECDC produces technical documents.

# ESAC-Net: the EUROPEAN SURVEILLANCE of ANTIMICROBIAL CONSUMPTION NETWORK



ESAC-Net (formerly ESAC) is a Europe-wide network of national surveillance systems, providing European reference data on antimicrobial consumption. ESAC-Net collects and analyses data on antimicrobial consumption from EU and EEA/EFTA countries, both in the community and in the hospital sector.

Started in 2001 and initially coordinated by the University of Antwerp and transferred to ECDC in 2011.

Appointment of a focal point in each MS, responsible for national data collection and collaboration with ESAC-Net.

ECDC provides guidance on methodology, collects and analyses data separately in the ambulatory and the hospital sectors.

## **HAI-Net: the HEALTHCARE- ASSOCIATED INFECTIONS SURVEILLANCE NETWORK**

Initially dedicated to the surveillance of HAIs in hospitals, this network is now incorporating the collection of data on antibiotic prescription during the point-prevalence surveys in the MS.

The HALT-2 project is now collecting data on antimicrobial use in long-term care facilities.

# European Medicines Agency



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH



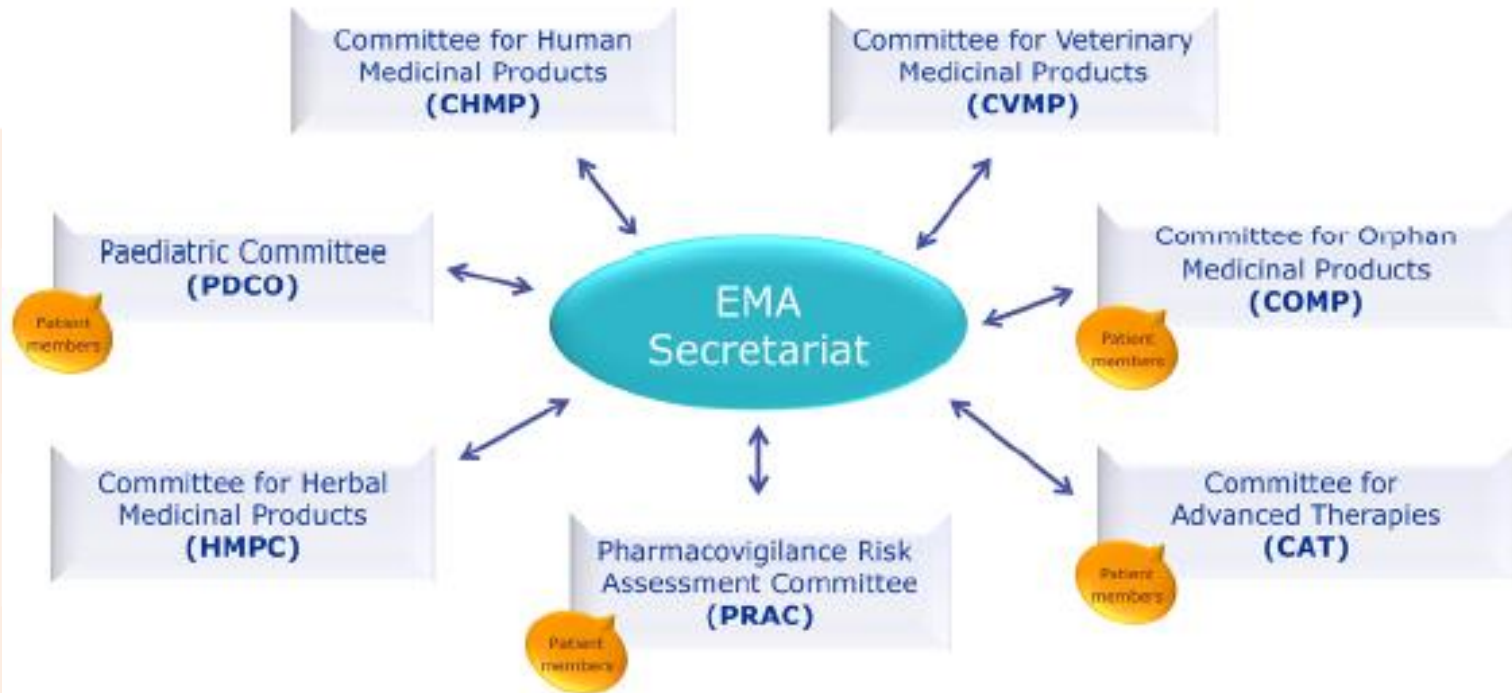
## What does EMA do?



EMA's main responsibility is the **protection and promotion** of public and animal health, by carrying scientific evaluation of medicines for human and veterinary use.

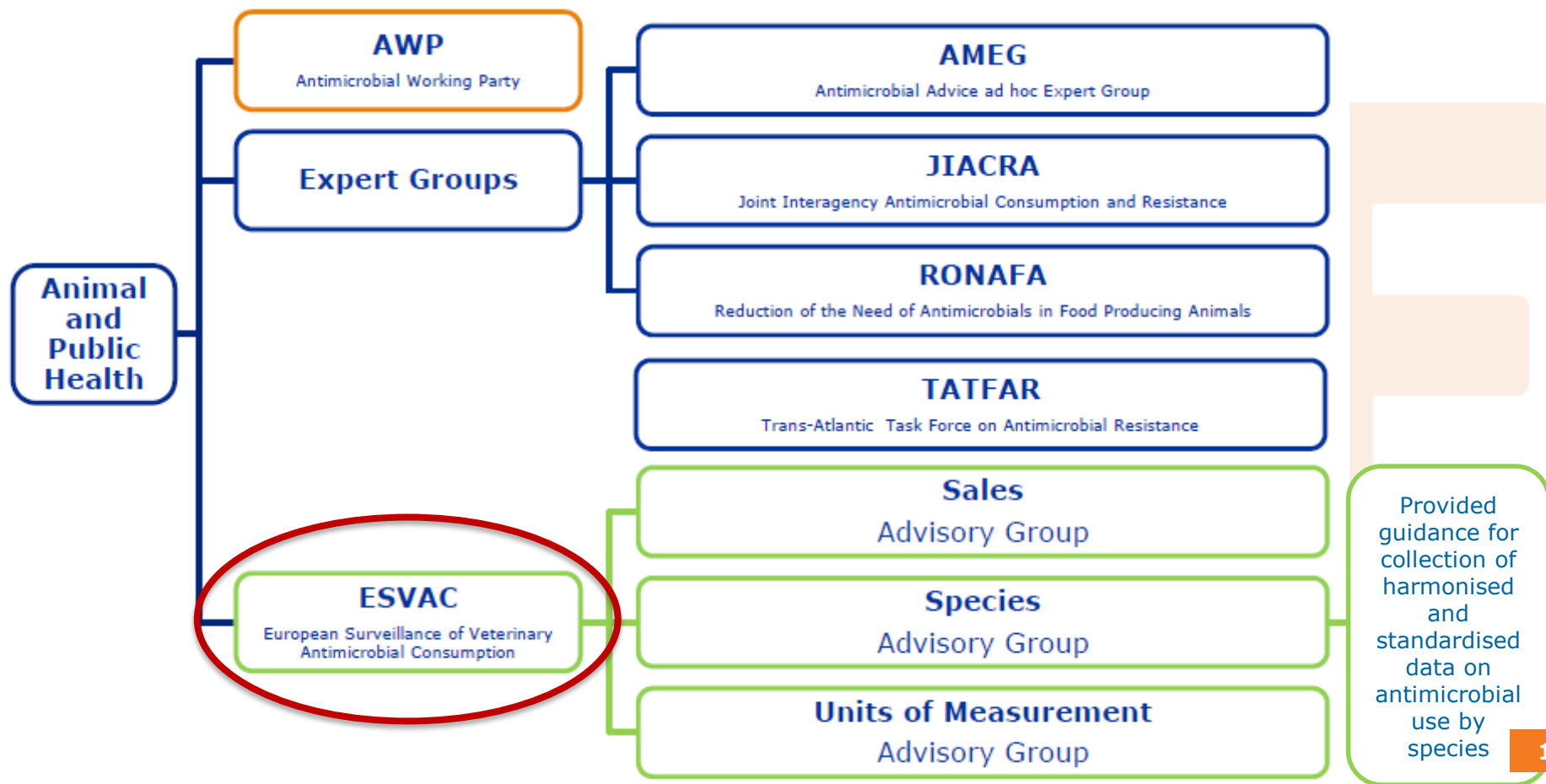
The Agency also **supervises the safety** of medicines in the EU after they have been authorised. It can also give scientific opinions on medicines at the request of MMSS or the European Commission.

## EMA and its scientific committees



There are 7 scientific committees that evaluate medicines at the EMA- 6 of these are for medicines for human use and one, the CVMP is for veterinary products. The Agency secretariat supports the work of these committees both in a scientific and logistical capacity.

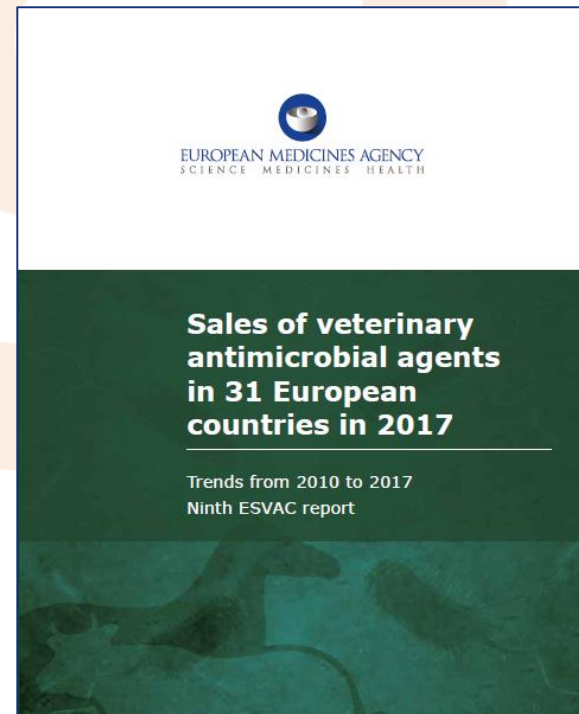
# Medicine and Veterinary Groups and Projects



# European Surveillance of Veterinary Antimicrobial Consumption

**ESVAC** collects and analyses information on how antimicrobial medicines for animal use are sold across the European Union and European Economic Area countries.

It serves to develop a harmonised approach for collection and reporting of data on use of antimicrobial agents based on national sales figures, as well as estimates on consumption in at least the major groups of animal species.



# Interagency Cooperation

AMEG  
RONAFA  
JIACRA

Outcome indicators

# AMEG

## Scientific advice on the impact on public health and animal health of the use of antibiotics in animals

AMEG:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general\\_content\\_000639.jsp](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000639.jsp)



# Antimicrobial Advice ad hoc Expert Group - AMEG

Answers to 4 questions:

- **Question 1:** Advice on **use in animals of 'old' antibiotics** that have been **re-introduced to human medicine** to treat multi-resistant infections: tigecycline, colistin.  

Advice on colistin was updated in 2016 following the discovery of a new, plasmid-borne, resistance mechanism (mcr-1)
- **Question 2:** **Categorisation of the WHO's critically important antimicrobials** according to the risk that their use in animals in the EU poses to human health.
- **Question 3:** Advice on the potential **impact of authorising new antimicrobials for use in animals on the treatment of resistant bacteria in humans**; if their use should be restricted.
- **Question 4:** Advice on **risk management measures for the use of CIAs** in animals.

## Factors considered in the AMEG categorisation:

The **need** for the antimicrobial **in human medicine in the EU**: sole therapy or few alternatives

**Probability of resistance transfer** from animals to humans (mechanisms of resistance, possibility of food-borne transmission)

## Uses of the categorisation:

Development of **Treatment Guidelines** where there is a need to consider impacts on public health (although other factors also need to be taken into account, e.g. local AMR situation and product availability, route of administration, animal welfare needs).

## Policy measures on CIAs





European  
Commission



EUROPEAN MEDICINES AGENCY  
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4 February 2019  
EMA/CVMP/CHMP/682198/2017  
Committee for Medicinal Products for Veterinary use (CVMP)  
Committee for Medicinal Products for Human Use (CHMP)

Answer to the request from the European Commission for  
updating the scientific advice on the impact on public  
health and animal health of the use of antibiotics in  
animals - Categorisation of antimicrobials

Draft

Agreed by the Antimicrobial Advice ad hoc Expert Group (AMEG)	29 October 2018
Adopted by the CVMP for release for consultation	24 January 2019
Adopted by the CHMP for release for consultation	31 January 2019
Start of public consultation	5 February 2019
End of consultation (deadline for comments)	30 April 2019

## Update to AMEG Guidance

- Draft for consultation - February 2019.  
Final version expected to be published end of 2019
- Now ranked into 4 categories (A to D) replacing categories 1 to 3
- Balance human and animal health needs and public health considerations
- Additional "C" category allows for greater distinction in ranking between substances and prevents too many antimicrobials being placed in the highest category

<https://www.ema.europa.eu/en/veterinary-regulatory/overview/antimicrobial-resistance/advice-impacts-using-antimicrobials-animals>

**A**

### **AVOID**

- Carbapenems, fosfomicina, Cephalosporins of last generation, Glycopeptides,
- Glycylcyclines, Lipopeptides, Monobactams, Oxazolidinones, Riminofenazines, Sulfones
- Drugs used solely to treat tuberculosis or other mycobacterial disease

**B**

### **RESTRICT**

- Cephalosporins, 3rd and 4th generation
- Fluoroquinolones and other quinolones
- Polymyxins

**C**

### **CAUTION**

- Aminoglycosides and aminocyclitol, Aminopenicillins in combination with  $\beta$ -lactamase inhibitors (e.g. amoxicillin-clavulanic acid, co-amoxiclav), Amphenicols (florfenicol & thiamphenicol), Cephalosporins, 1<sup>st</sup>- and 2<sup>nd</sup>-generation and cephamycins, Macrolides, Lincosamides, Pleuromutilins, Rifamycins

**D**

### **PRUDENCE**

- Aminopenicillins, without  $\beta$ -lactamase inhibitors, Cyclic polypeptides (bacitracin), Nitrofurantoin derivatives (e.g. nitrofurantoin), Nitroimidazoles, Penicillin: Anti-staphylococcal penicillin ( $\beta$ -lactamase-resistant penicillin), Penicillin: Natural, narrow spectrum penicillin ( $\beta$ -lactamase-sensitive penicillin), Steroid antibacterial (fusidic acid), Sulphonamides, dihydrofolate reductase inhibitors and combinations, Tetracyclines

# RONAFA

Request from the Commission for an opinion on **measures to reduce the need to use antimicrobials in animal husbandry in the EU, and the impacts on food safety**

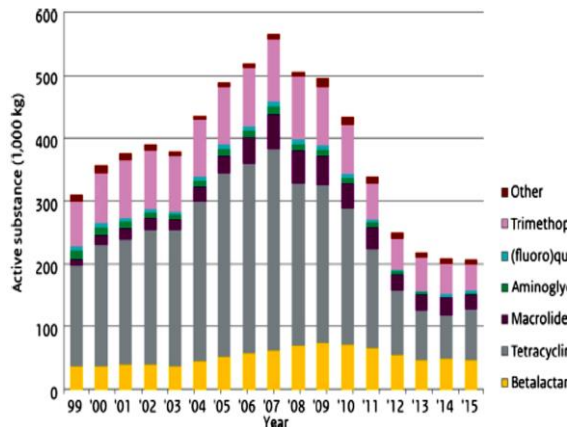
RONAFA = Reduction Of the Need for Antimicrobials in Food animals and Alternatives

<https://www.efsa.europa.eu/en/efsajournal/pub/4666>



# Terms of reference for the RONAFA

Review the **measures that have been taken by MS to reduce the use of 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**

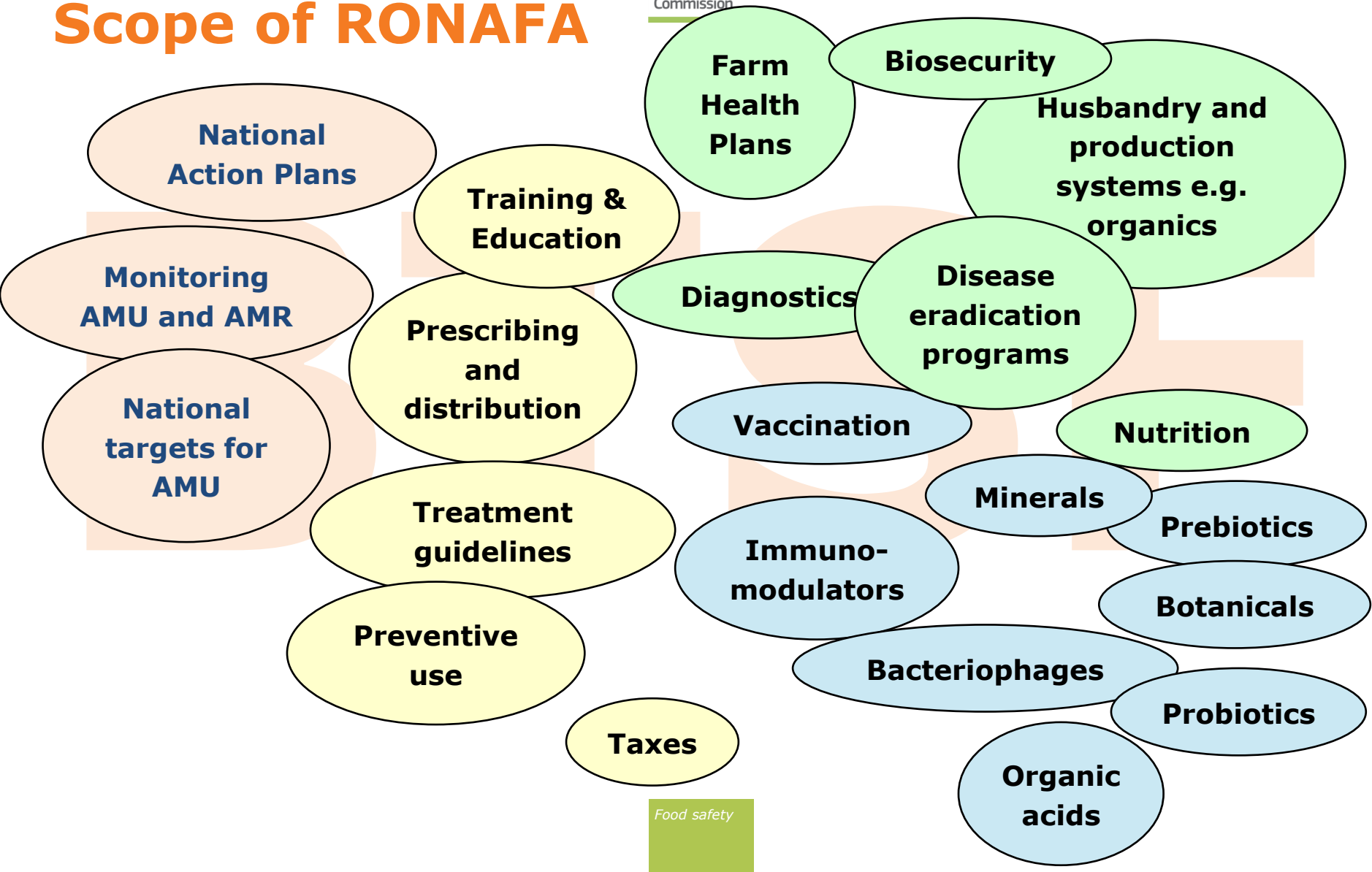
**Recommend options to reduce antimicrobial use and for responsible use**

**DANMAP  
2014**

DANMAP 2014 - Use of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from food animals, food and humans in Denmark



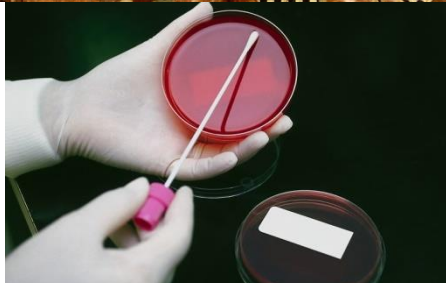
# Scope of RONAFA



# Conclusions and recommended options

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**





# RONAFA Recommended Options



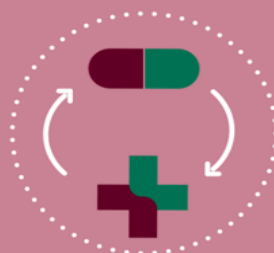
**reduce**

the use of antimicrobials

**Setting targets,**

**Increase responsibility  
of veterinarians,**

**Preventive use should  
be phased out.**



**replace**

antimicrobials with alternative treatments

**Consider alternatives  
to antimicrobials,**

**Research new  
alternatives,**

**Develop an EU legal  
framework for  
alternatives.**



**rethink**

the livestock production system

**Improve disease  
prevention and  
control,**

**Consider alternative  
farming systems,  
Education and  
awareness.**

# JIACRA

## **JIACRA I:**

<https://ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/antimicrobial-resistance-JIACRA-report.pdf>

## **JIACRA II:**

[https://ecdc.europa.eu/sites/portal/files/documents/efs2\\_4872\\_final.pdf](https://ecdc.europa.eu/sites/portal/files/documents/efs2_4872_final.pdf)



## JIACRA reports

Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA) Report - request from the Commission for advice on:

- **ECDC/EFSA/EMA the integrated analysis of the consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals**
- **Analysis of antimicrobial use and resistance from human and food producing animals**

**JIACRA I – Report on 2011-12**

**JIACRA II – Report on 2013-15**

**JIACRA III – Report on 16-18 *(due to be finalised by end of 2020)***

# OUTCOME INDICATORS

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Report/2017/10/WC500237745.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Report/2017/10/WC500237745.pdf)

## Outcome indicators

- EMA, EFSA and ECDC networks
- List of harmonised outcome indicators to assess progress in reduction of use and resistance
- Indicators for human and animal sectors
- Indicators for AM consumption and resistance
- Indicators for community, in hospitals and in food producing animals

## Indicators for AMC in food-producing animals

		2017 Result
Primary Indicator	Overall sales of AM (mg/PCU)	<b>107 mg/PCU</b> (range 3.1- 423.1)
Secondary Indicators	Sales of 3 <sup>rd</sup> /4 <sup>th</sup> generation cephalosporins (mg/PCU)	<b>0.2mg/PCU</b> (range <0.01 – 0.8)
	Sales of polymyxins (mg/PCU)	<b>3.6 mg/PCU</b> (range 0 – 14.9)
	Sales of all quinolones (mg/PCU) specifying % fluoroquinolones	<b>All = 2.8 mg/PCU</b> (range = 0.1 – 15.3) <b>Fluoroquinolones = 2.4mg/PCU</b>

<https://www.ema.europa.eu/en/veterinary-regulatory/overview/antimicrobial-resistance/european-surveillance-veterinary-antimicrobial-consumption-esvac>

# Indicators of AMR in food-producing animals (EFSA)

## Primary indicator:

Proportion of indicator *E. coli* from broilers, fattening turkeys, fattening pigs and calves, weighted by PCU, fully susceptible to a predefined panel of antimicrobials.

## Secondary indicator:

- Proportion of samples positive for presumptive ESBL-/AmpC-producing indicator *E. coli* from broilers, fattening turkeys, fattening pigs and calves weighted by PCU.
- Proportion of indicator *E. coli* from broilers, fattening turkeys, fattening pigs and calves, weighted by PCU, resistant to at least three antimicrobials from different classes included in a predefined panel of antimicrobials.
- Proportion of indicator *E. coli* from broilers, fattening turkeys, fattening pigs and calves, weighted by PCU, resistant to ciprofloxacin.

## Indicators of AMC in humans (ECDC)

		2017 Result
<b>Primary Indicator</b>	Total consumption of all antimicrobials for systemic use (DDD per 1,000 inhabitants and per day).	<b>21.8 DDD per 1000 inhabitants per day</b> (range 11 – 33.1)
<b>Secondary Indicators</b>	Community - ratio of consumption of broad-spectrum penicillins, cephalosporins, macrolides (except erythromycin) and fluoroquinolones to the consumption of narrow-spectrum penicillins, cephalosporins and erythromycin.	<b>2.3</b> (range 0.1 – 22.2)
	Hospital sector - proportion of glycopeptides, third- and fourth-generation cephalosporins, monobactams, carbapenems, fluoroquinolones, polymyxins, piperacillin and enzyme inhibitor, linezolid, tedizolid and daptomycin within the total hospital consumption of antibacterials for systemic use.	<b>30%</b> (range 16% -59%)

<https://www.ecdc.europa.eu/en/antimicrobial-consumption/surveillance-and-disease-data/report-protoco>

# Indicators of AMR in humans (ECDC)

## Primary indicator:

Proportion of methicillin resistant *Staphylococcus aureus* (MRSA) and proportion of *E. coli* resistant to 3<sup>rd</sup> generation cephalosporins (3GCR *E. coli*).

## Secondary indicators:

- Proportion of *K. pneumoniae* isolates with combined resistance to aminoglycosides, fluoroquinolones and 3<sup>rd</sup> generation cephalosporins.
- Proportion of penicillin-resistant *S. pneumoniae* and proportion of macrolide-resistant *S. pneumoniae*.
- Proportion of carbapenem-resistant *K. pneumoniae*.



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## AENOR INTERNACIONAL

6, Genova street. 28004. Madrid, SPAIN

Tel: +34 91 432 61 25

Mail: [20169607\\_amr@aenor.com](mailto:20169607_amr@aenor.com)

[www.btsf-aenor.com](http://www.btsf-aenor.com)



## Better Training for Safer Food BTSF

• *European Commission  
Consumers, Health, Agriculture and Food Executive Agency  
DRB A3/042  
L-2920 Luxembourg*