

New EU Regulations on Veterinary Medicinal Products (VMPs) and Medicated Feed (MF)

Fighting Antimicrobial Resistance!

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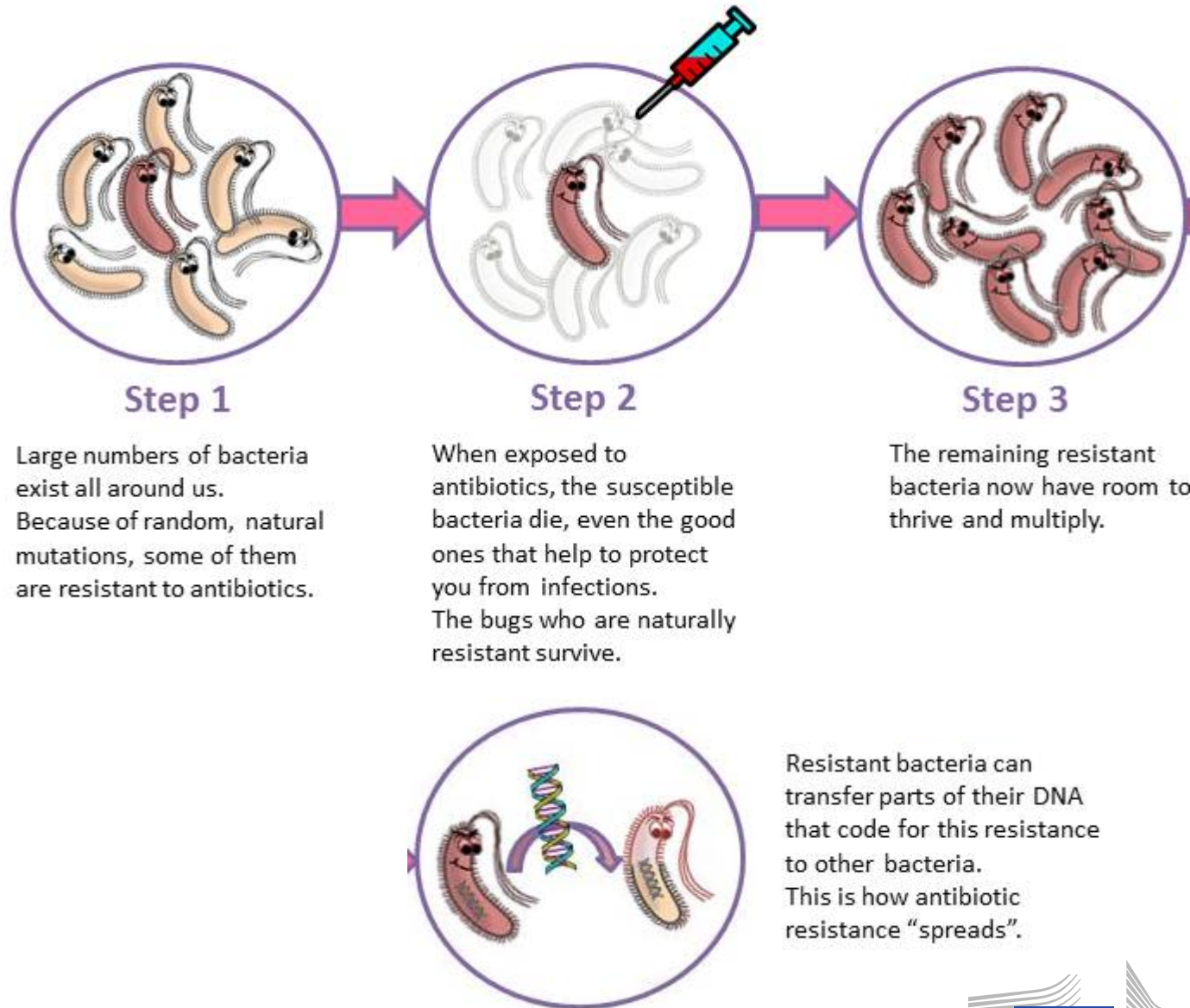
*GREX meeting
Brussels, 10 February 2020*

Antimicrobial Resistance (AMR)

- a few key figures -



What is antimicrobial resistance (AMR)?



Adapted from: <http://antibiotic-action.com/>

Antibiotic Action was established in 2011 and is wholly funded by the [British Society for Antimicrobial Chemotherapy](#) (BSAC)

AMR: need for a **'One Health'** approach!

- *Human health*
- *Animal health*
- *Environment*

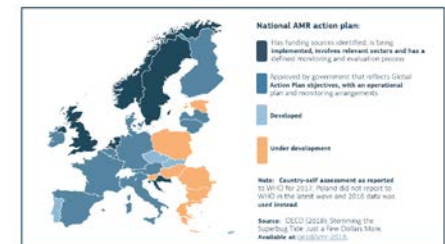
Potential routes of transmission of antibiotic-resistant bacteria



Source: bioMérieux

Examples of existing initiatives to fight AMR

- Ban on the use of antibiotics as feed additives for growth promotion (2006)
- Guidelines for the prudent use of antimicrobials in veterinary medicine (2015)
- EU Action Plans against AMR (2011 & 2017)
- National Action Plans against AMR
- Other targeted initiatives at EU level, at Member States level, at stakeholders level



Significant progress in reducing antimicrobial use in the EU

Oct.2019



9th European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) Report

- **32.5% ▼ overall sales across Europe (2011-2017),**
162.0 mg/PCU in 2011; 109.3 mg/PCU in 2017
- *heterogeneous situation among European Countries.*



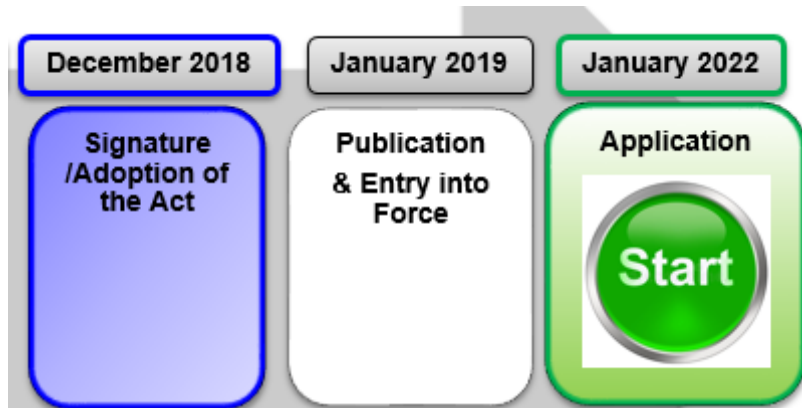
BUT there is still much to achieve!

https://www.ema.europa.eu/en/documents/report/sales-veterinary-antimicrobial-agents-31-european-countries-2017_en.pdf



European
Commission

New EU Regulations on Veterinary Medicinal Products & Medicated Feed will help increase the fight against AMR!



(EU) 2019/6: Veterinary Medicinal Products (VMPs)

<https://eur-lex.europa.eu/eli/reg/2019/6/oj>

(EU) 2019/4: Medicated Feed (MF)

<https://eur-lex.europa.eu/eli/reg/2019/4/oj>

The new EU Regulations on VMP and MF

Concrete Measures to fight AMR applicable to EU operators

- ban on preventive use of antibiotics in groups of animals
- ban on preventive use of antimicrobials via medicated feed
- restrictions on metaphylactic use
- possibility to reserve certain antimicrobials for humans only
- reinforced ban on the use of antimicrobials for promoting growth (in addition to the 2006 EU ban of using antibiotics as growth promoters in feed)
- obligation for EU Member States to collect data on sales & use per species of antimicrobials
- other measures: prudent & responsible use

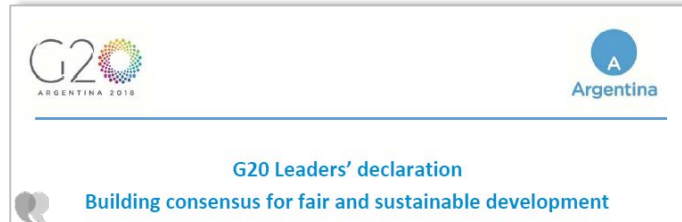
The new EU Regulations on VMPs

Concrete Measures to fight AMR
relevant to **Third Country operators** exporting to the EU

- possibility to reserve certain antimicrobials for humans only
- ban on the use of antimicrobials for promoting growth

Keeping the political momentum to fight AMR at Global level

G7 / G20



15. We encourage the activities of World Health Organization (WHO), together with all relevant actors, to develop an action plan for implementation of health-related aspects of SDGs by 2030. We commend the progress made by the international community in developing and implementing National and Regional Action Plans on Anti-Microbial Resistance (AMR) based on One-Health approach. We recognize the need for further multi-sectoral action to reduce the spread of AMR, as it is increasingly becoming a global responsibility. We note the work done by the Global AMR R&D Hub and, drawing on this, we look forward to further examine practical market incentives. We will tackle



33. We will accelerate efforts based on the One-Health approach to tackle antimicrobial resistance (AMR). Recognizing the UN Secretary-General's report on AMR, which was informed by the recommendations of the UN Interagency Coordination Group on AMR and other relevant initiatives, we encourage all stakeholders including international organizations to act and coordinate on those items relevant to their missions that contribute to global efforts to combat AMR. We recognize the need for policy measures for infection prevention and reduction of excessive antimicrobial usage. Further action should be taken to promote stewardship of and access to antimicrobials. Noting the ongoing work done by Global AMR R&D Hub, we will promote R&D to tackle AMR. We call on interested G20 members and Global AMR R&D Hub to analyze push and pull mechanisms to identify best models for AMR R&D and to report back to relevant G20 Ministers.

United Nations



<https://www.who.int/antimicrobial-resistance/interagency-coordination-group/final-report/en/>

Call for action: International Fora

EU



WHO



Codex



FAO



OIE



European Green Deal & Farm to Fork Strategy

Reducing the overuse and misuse of antibiotics


What is the European Green Deal?

December 2019
#EUgreenDeal

The European Green Deal is about **improving the well-being of people**. Making Europe climate-neutral and protecting our natural habitat will be good for people, planet and economy. No one will be left behind.

The EU will:

-  Become climate-neutral by 2050
-  Protect human life, animals and plants, by cutting pollution
-  Help companies become world leaders in clean products and technologies
-  Help ensure a just and inclusive transition

"The European Green Deal is our new growth strategy. It will help us cut emissions while creating jobs."

Ursula von der Leyen, President of the European Commission

 *"We propose a green and inclusive transition to help improve people's well-being and secure a healthy planet for generations to come."*


Frans Timmermans, Executive Vice-President of the European Commission

 **93%** of Europeans see climate change as a serious problem

 **93%** of Europeans have taken at least one action to tackle climate change

 **79%** agree that taking action on climate change will lead to innovation






From Farm to Fork

The European Green Deal





December 2019
#EUgreenDeal

European food must remain safe, nutritious and of high quality. It must be produced with minimum impact on nature.

In EU budget 2021-2027




-  **40%** of Common Agriculture Policy should contribute to climate action
-  **30%** of the maritime fisheries fund should contribute to climate objectives

In spring 2020, the Commission will present a Farm to Fork Strategy to:

-  make sure Europeans get affordable and sustainable food
-  tackle climate change
-  protect the environment
-  preserve biodiversity
-  increase organic farming

Farmers and fishermen are key to managing the transition






The European Commission will work with Member States and stakeholders to:


-  **Ensure the transition is fair and just** for everyone working in the European agricultural and maritime sector;
-  **Reduce significantly the dependency, risk and use of chemical pesticides**, as well as of **fertilisers, antibiotics**;
-  **Develop innovative farming and fishing techniques** that protect harvest from pests and diseases.


Farm to fork will also help **combat food fraud** by preventing, detecting and fighting it through coordination with Member States and non-EU countries.

Imported food products from third countries must **comply with the EU's environmental standards**.

Farm to Fork will contribute to achieving a circular economy – from production to consumption:

-  Better informed citizens
-  More efficient food production systems
-  More sustainable processing and farm transport
-  Better storage and packaging
-  Healthy consumption and reduce food loss and waste



 Working with Member States is key: national strategic plans for agriculture should fully reflect the ambition of the European Green Deal and the Farm to Fork Strategy.

 EUROPEAN COMMISSION


Brussels, 11.12.2019
COM(2019) 640 final

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE EUROPEAN COUNCIL, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

The European Green Deal


Farmers and fishermen are key to managing the transition


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-  **Reduce significantly the dependency, risk and use of chemical pesticides, as well as of fertilisers, antibiotics;**



Food and Agriculture
Organization of the
United Nations

 <https://www.youtube.com/watch?v=lxzvOSKVGdQ>




0:28 / 1:36

We all can take action now to keep antimicrobials working as they should!

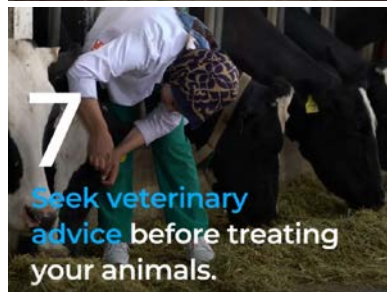
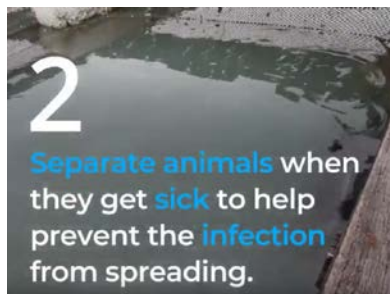
1,022 views • Nov 19, 2019

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 Food and Agriculture Organization of the United Nations
60.4K subscribers

The misuse and overuse of antimicrobials, including antibiotics, is causing antimicrobial resistance (AMR).

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European
Commission


The future CAP & AMR



CAP SPECIFIC OBJECTIVES

...explained

– Brief No 9



Health, Food & Antimicrobial Resistance

This is part of a series of Briefs summarising the facts and addressing the policy relevance around the 9 proposed specific objectives of the future CAP.

KEY MESSAGES

- ✓ Some of the key challenges facing EU agriculture include improving the response to society's demands on food and health, including safe, nutritious and sustainable food, reducing food waste, and improving animal health and welfare.
- ✓ **Antimicrobial resistance (AMR)** is a challenge for which the CAP is called to respond and support Community action. A sense of urgency related to AMR warrants increased attention regarding the use of antimicrobials in animal husbandry.
- ✓ AMR is a serious public health threat. It is responsible for an increasing number of deaths, both in the EU and globally, a significant economic burden (healthcare costs and productivity losses), and an unknown cost to animal production.
- ✓ The safety of the food chain is indirectly affected by the welfare of animals, particularly those farmed for food production, due to the close links between animal welfare, animal health and food-borne diseases.
- ✓ The future CAP, in synergy with the new EU regulations on veterinary medicinal products and on medicated feed and with research, can support farmers and the Member States in the fight against AMR.

This brief is based on contributions from Aurora Ierugan, Jean-Charles Cavitte, Gebhard Seiwald, Nicola Britta Holsten, Florence Buchholzer, Krzysztof Sulima and Aisling Redmond.

Disclaimer: The contents of the publication do not necessarily reflect the position or opinion of the European Commission.

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More information on the new EU Regulations on VMPs and MF:

https://ec.europa.eu/food/animals/health/veterinary-medicines-and-medicated-feed_en

EU RULES ON VETERINARY MEDICINAL PRODUCTS AND MEDICATED FEED

VETERINARY MEDICINAL PRODUCTS: WHAT'S NEW?

- **FIGHTING ANTIMICROBIAL RESISTANCE**
- BAN** preventive use of antibiotics in groups of animals
- EXPAND THE BAN** on the use of antibiotics promoting growth and increasing yield to the use of antimicrobial medicines
- RESTRICT** antimicrobial use in groups of animals ahead of an expected disease outbreak (metaphylaxis)
- Possibility to **RESERVE** certain antimicrobials for humans only
- COMMIT** Member States to collect data on the sale and use of antimicrobials

BAN on growth-promoting antimicrobials and antimicrobials reserved for human use in **ANIMAL AND ANIMAL PRODUCTS IMPORTED FROM OUTSIDE THE EU**

- **PROMOTING AVAILABILITY OF VETERINARY MEDICINAL PRODUCTS THROUGH INNOVATION AND COMPETITIVENESS**
- **ESTABLISHING A MODERN FIT-FOR-PURPOSE LEGAL FRAMEWORK**

MEDICATED FEED: WHAT'S NEW?

- **FIGHTING ANTIMICROBIAL RESISTANCE**
- BAN** preventive use of antimicrobials in medicated feed (similar to veterinary medicine restrictions)
- RESTRICT** prescriptions of antimicrobials in medicated feed
- **EU-WIDE RULES FOR THE ECONOMICALLY VIABLE PRODUCTION OF SAFE MEDICATED FEED**

Health and Food Safety

WHY IS IT IMPORTANT?

- It promotes **prudent and responsible antimicrobial use**
- It promotes **innovation and availability** of veterinary medicines and **medicated pet food**
- It **fight**s antimicrobial resistance in animals and **prevents** the spread of antibiotic-resistant bacteria into the food chain
- It **reduces the red tape** for pharmaceutical and feed companies and strengthens the internal market

PREVENTING THE SPREAD OF ANTIMICROBIAL RESISTANCE

- In the EU, the majority of antimicrobials are consumed by animals (JIACRA Report, 2017)
- Of 130 countries recently assessed worldwide, over 85% have no legislation for the import, manufacture, distribution and/or use of veterinary medicines (OIE, 2016)
- Though the situation differs per Member State, between 2011 and 2017, the sales of veterinary antibiotics across Europe dropped by more than 32% (EMA, 2019)

TIMELINE

- September 2014**
Proposal by the European Commission
- December 2018**
Adoption by Parliament and Council
- Adoption of additional legal acts to prepare implementation of the new legislation**
- 28 January 2022**
Application of the new legislation

<https://europa.eu/YU99vd>
@Food_EU #EUAMRAction