



The new EU Regulations on Veterinary Medicinal Products & Medicated Feed in support of the Farm to Fork Strategy

AMR One Health Network Meeting, 25 March 2021

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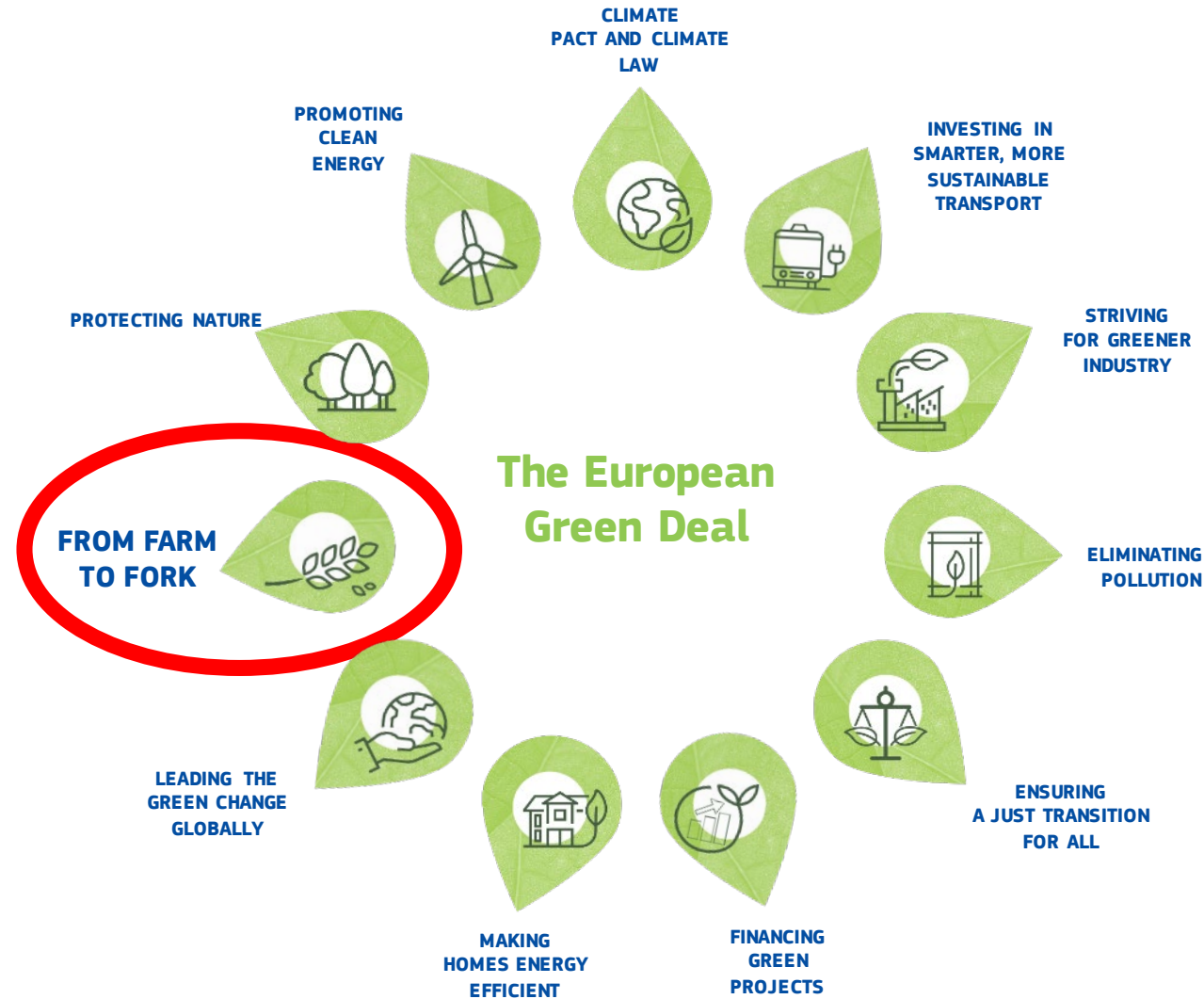
Head of Unit E5 'Animal nutrition & veterinary medicines'

Directorate General for Health and Food Safety

The European Green Deal & the Farm to Fork Strategy

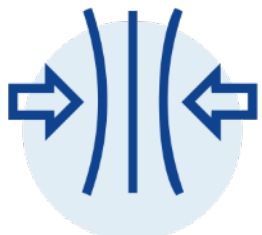
to fight AMR

The European Green Deal & Farm to Fork (F2F) Strategy



F2F Strategy

for a fair, healthy and environment-friendly food system



Create a **robust and resilient** food system



Reduce the **environmental and climate footprint** of the food system



Tap into **new opportunities**



Lead a **global transition** towards competitive sustainability from farm to fork

F2F Strategy



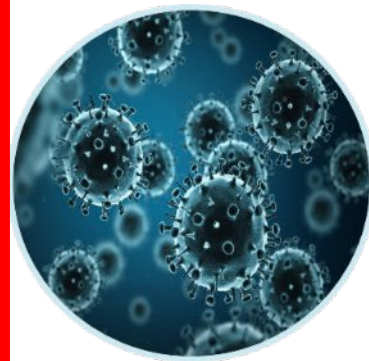
2030 targets for sustainable food production



Reduce by 50% the overall use and risk of **chemical pesticides** and reduce use by 50% of more hazardous **pesticides**



Reduce **nutrient losses** by at least 50% while ensuring no deterioration in soil fertility; this will reduce use of **fertilisers** by at least 20 %



Reduce sales of **antimicrobials** for farmed animals and in aquaculture by 50%



Achieve at least 25% of the EU's agricultural land under **organic farming** and a significant increase in **organic aquaculture**

New EU Regulations on Veterinary Medicinal Products & Medicated Feed

to fight AMR & support the
achievement of the F2F target

New EU Regulations

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

7.1.2019 EN Official Journal of the European Union L 4/43

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
(Text with EEA relevance)

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

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

7.1.2019 EN Official Journal of the European Union L 4/1

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
(Text with EEA relevance)

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

Official Journal of the European Union L 4

English edition Legislation Volume 62 7 January 2019

Content

1 Legislative acts

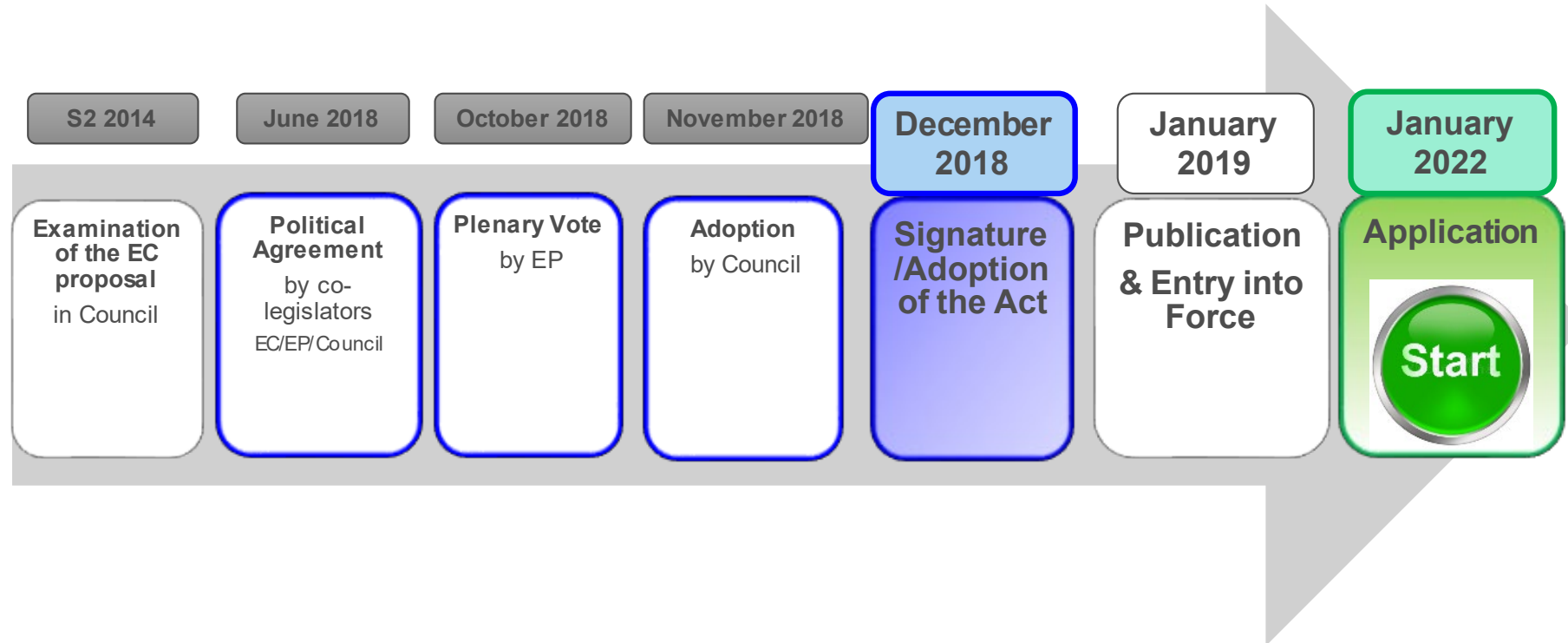
REGULATIONS

- 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 (*) 1
- Regulation (EU) 2019/5 of the European Parliament and of the Council of 11 December 2018 amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Regulation (EC) No 1963/2006 on medicinal products for paediatric use and Directive 2001/82/EC on the Community code relating to medicinal products for human use (*) 24
- 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 (*) 41

(*) Text with EEA relevance

EN Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period. The titles of all other acts are printed in bold type and preceded by an asterisk.

New EU Regulations on VMPs and MF



New EU Regulations on VMPs and MF

Concrete Measures to fight AMR & support achievement of the F2F Strategy target

Applicable to EU operators

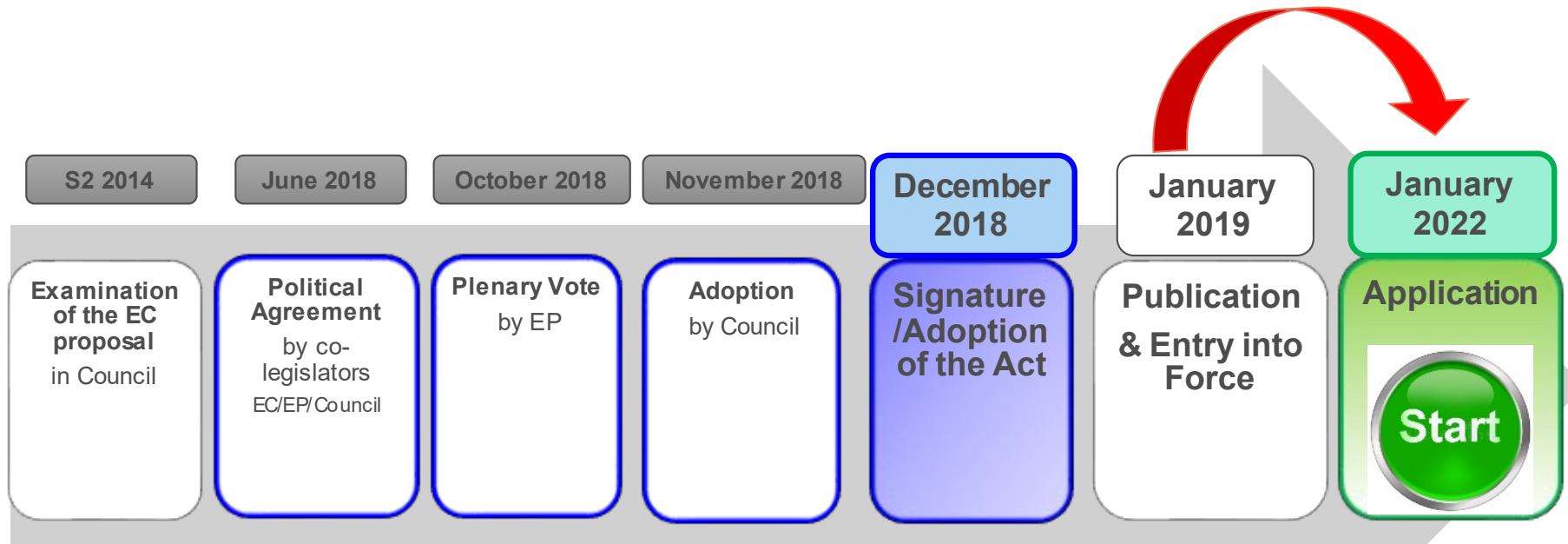
- ban on the preventive use of antibiotics in groups of animals
- ban on the preventive use of antimicrobials via medicated feed (MF)
- restrictions on metaphylactic use
- ban on the use in animals of antimicrobials designated in the EU as reserved to human medicine
- enlarged ban on the use of antimicrobials for growth promotion and yield increase
- compulsory data collection on sales & use per species of antimicrobials
- other measures: prudent & responsible use

Relevant to Third Country operators, exporting animals or products of animal origin to the EU

- ban on the use of antimicrobials for growth promotion and yield increase
- ban on the use in animals of antimicrobials designated in the EU as reserved to human medicine

New EU Regulations on VMPs and MF

on the way to application...
ADDITIONAL TERTIARY LEGISLATION
to allow for appropriate application of the Regulation:



Tertiary Legislation

7 Delegated and Implementing Acts to draft, that directly impact the fight against AMR

4 Delegated Acts (DA)

supplement/amend the Regulation in its non-essential elements

Requirements for the collection of data
on antimicrobials sold and used in animals
Art.57(3) - VMP

Criteria for the designation of
antimicrobials reserved for use in humans
Art.37(4) - VMP

Rules on imports from third countries
Art.118 - VMP

Max. levels of cross-contamination for 24 antimicrobial
active substances **in non-target feed**
Art.7(3) - MF

3 Implementing Acts (IA)

Implement the Regulation

Format of the data to be collected
on antimicrobials sold and used in animals
Art.57(4) - VMP

List of
antimicrobials reserved for use in humans
Art.37(5) - VMP

List of antimicrobials:
- **not to be used outside the terms of MA**
- **which may be used outside the terms of MA,**
subject to certain conditions
Art.107(6) - VMP

Tertiary Legislation

State-of-Play

LEGAL ACTS	Type	To be adopted by	Current Status
Requirements for the collection of data on antimicrobials sold and used in animals	DA Art.57(3)	27.01.2021	Adopted ✓
Format of the data to be collected on antimicrobials sold and used in animals	IA Art.57(4)	27.01.2022	Drafting legal text
Criteria for the designation of antimicrobials reserved for use in humans	DA Art.37(4)	27.09.2021	Public Consultation on draft legal text
List of antimicrobials to be reserved for use in humans	IA Art.37(5)	27.01.2022	Scientific Advice under preparation
List of antimicrobials: - not to be used outside the terms of their MA - which may be used outside the terms of their MA, subject to certain conditions	IA Art.107(6)	No deadline, as per the Regulation	Scientific Advice under preparation
Rules on imports from third countries	DA Art.118	27.01.2022	Internal Consultation
Max. levels of cross-contamination in non-target feed for 24 antimicrobial active substances	DA Art.7(3) - MF	28.01.2023	Scientific Advice under preparation

Follow our work progress on Tertiary Legislation

The screenshot shows the European Commission website interface. At the top left is the European Commission logo. A search bar is located at the top right. Below the logo is a breadcrumb trail: Home > Food, farming, fisheries > Food Safety > Animals > Animal health > Veterinary Medicines and Medicated Feed >. The main heading is 'Animals'. On the left is a navigation menu under 'ANIMAL HEALTH' with items: Animal health law, Veterinary Medicines and Medicated Feed (highlighted), Veterinary Medicinal Products, Medicated feed, Maximum residue limits, Implementation of EU 2019 Regulations (highlighted), EU Strategy 2007-2013, Relations with the World Organisation, Regulatory committee, Advisory committee, and Expert group. The main content area features the title 'Implementation of Regulation (EU) 2019/6 on veterinary medicinal products and Regulation (EU) 2019/4 on medicated feed'. Below the title is a paragraph: 'As part of their implementation, the two Regulations require the European Commission to adopt delegated and implementing acts. Below is a list of the acts the European Commission will adopt in the coming years. The relevant documents regarding the progress of the work on this legislation will be published here as they become available.' There are three dropdown menus: 'Delegated Acts' (selected), 'Implementing Acts', and 'Delegated Acts' (selected). The text 'Regulation (EU) 2019/6 on veterinary medicinal products' and 'Regulation (EU) 2019/4 on medicated feed' is visible. On the right is a 'QUICK LINKS' section with icons and text for: European Food Safety Authority (EFSA), European Medicines Agency, Health and food audits and analysis, Trade Control & Expert System (TRACES), Travelling with pets, Better Training for Safer Food (BTSF), E-News, Press Releases, and Events.

https://ec.europa.eu/food/animals/health/veterinary-medicines-and-medicated-feed/imp-regs-2019_en

Thank you



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