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

AMR One Heath Network Meeting, 25 March 2021

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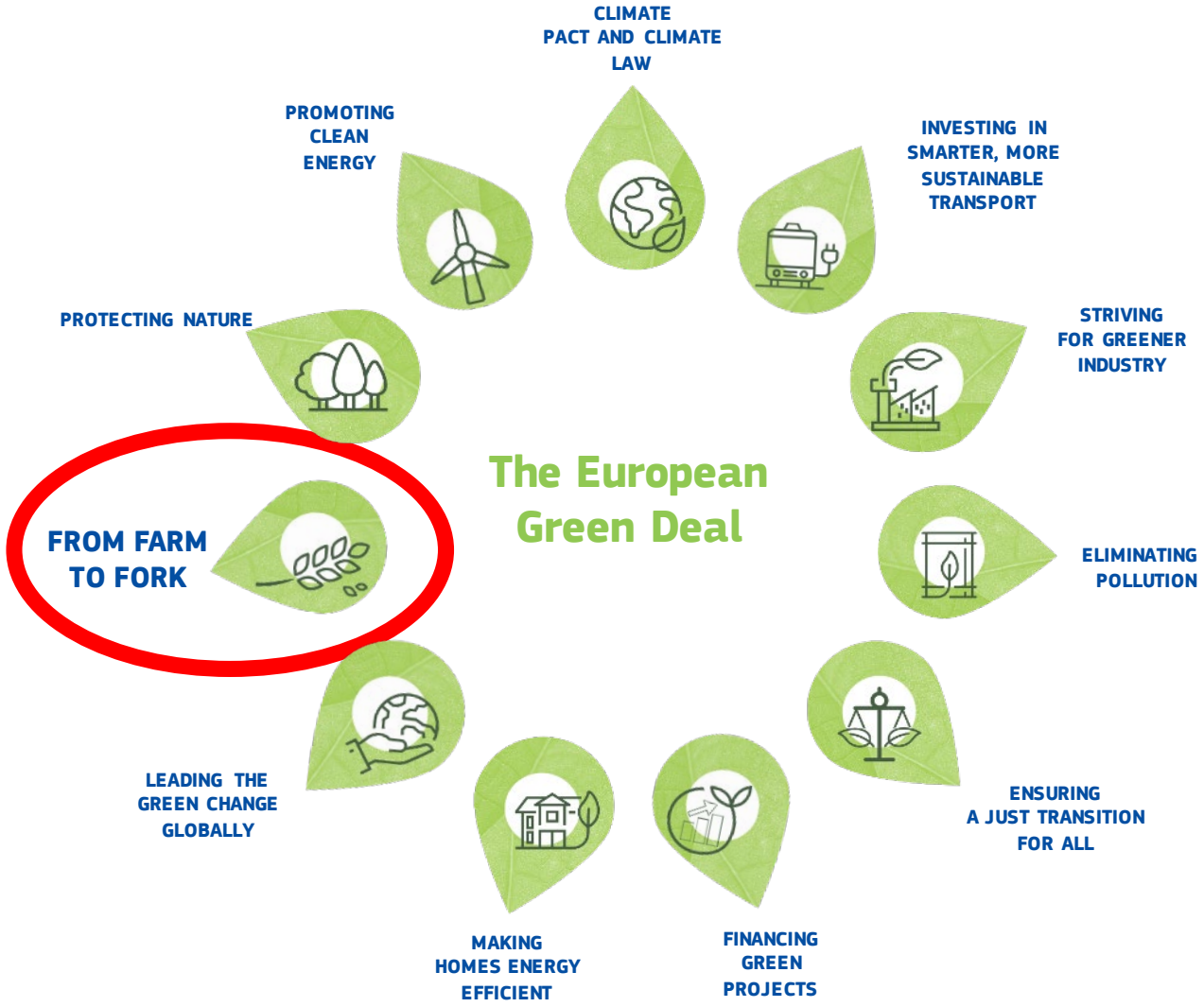
The European Green Deal & the Farm to Fork Strategy

to fight AMR

European Commission

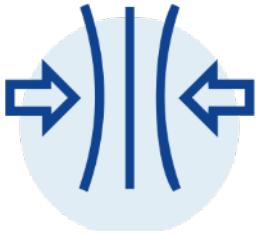
The European Green Deal & Farm to Fork (F2F) Strategy



European Commission

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

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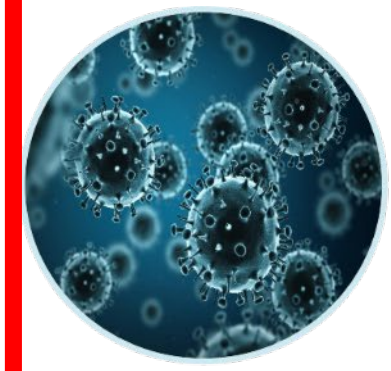
F2F Strategy

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**

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New EU Regulations on Veterinary Medicinal Products & Medicated Feed

to fight AMR & support the achievement of the F2F target

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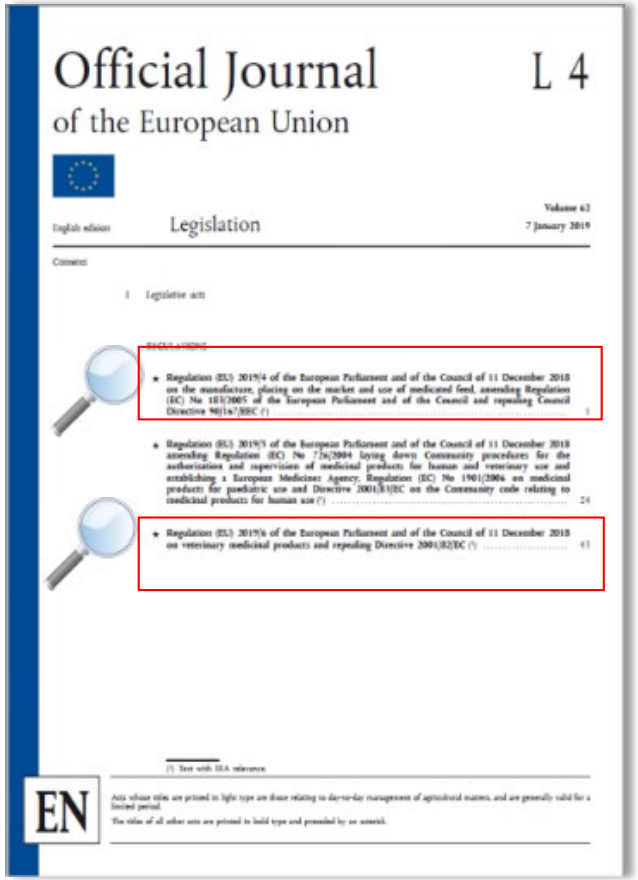
New EU Regulations

(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 183/2005 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

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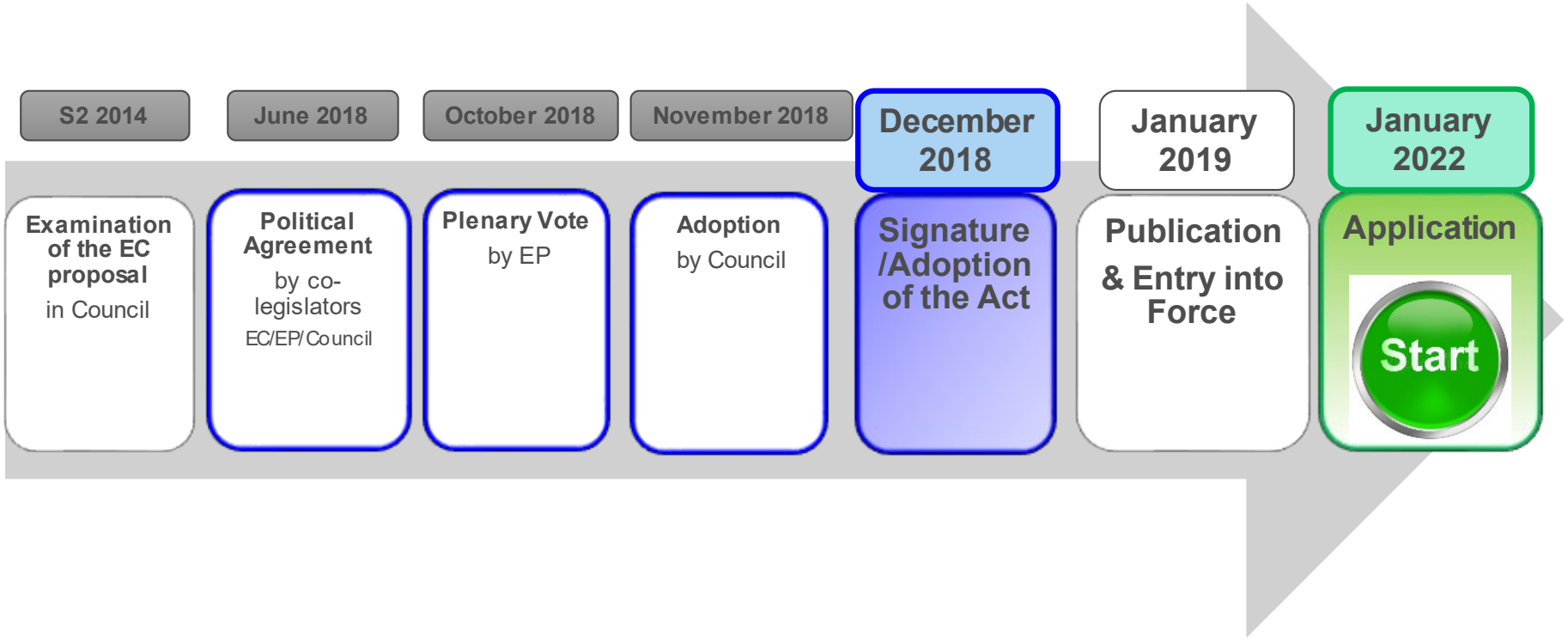
New EU Regulations on VMPs and MF



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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

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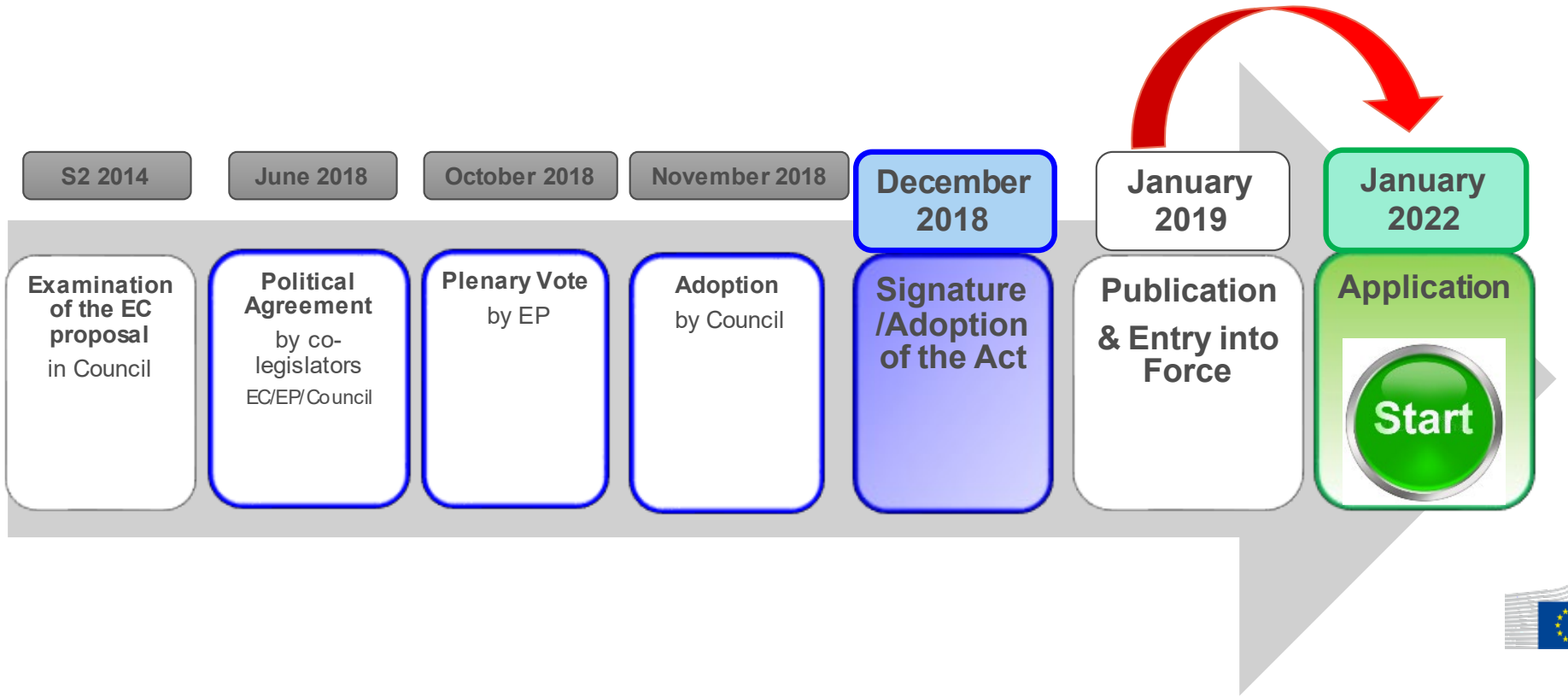
New EU Regulations on VMPs and MF

on the way to application…

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



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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

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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

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

Thank you

European Commission