



Federation  
of Veterinarians  
of Europe

# The Veterinary Medicines Regulation: A New Toolbox For Veterinarians In The Fight Against AMR

Nancy De Briyne, FVE Executive Director

VMP Regulation Event, 20 June 2022





The FVE Network

Members Observers



# Federation of Veterinarians of Europe

- 46 national associations
- 38 European countries
- 4 Sections

- UEVP (*Practitioners*)
- UEVH (*Hygienists – Public Health Officers*)
- EASVO (*Veterinary State Officers*)
- EVERI (*Education, Research, Industry*)

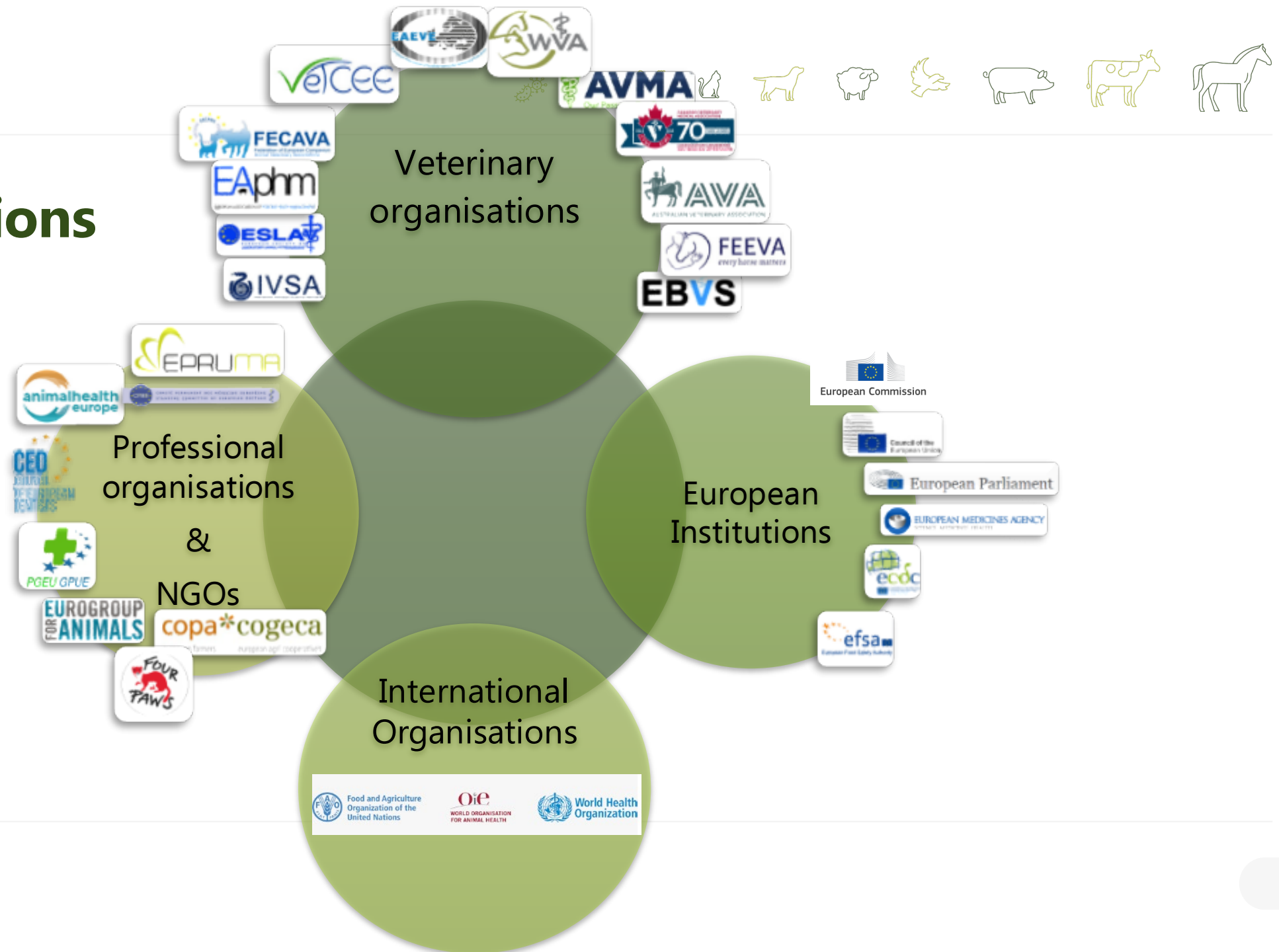
## FVE's mission

The European veterinary profession, embodied by FVE, **enhances animal health, animal welfare, public health and protect the environment** by promoting the veterinary profession.



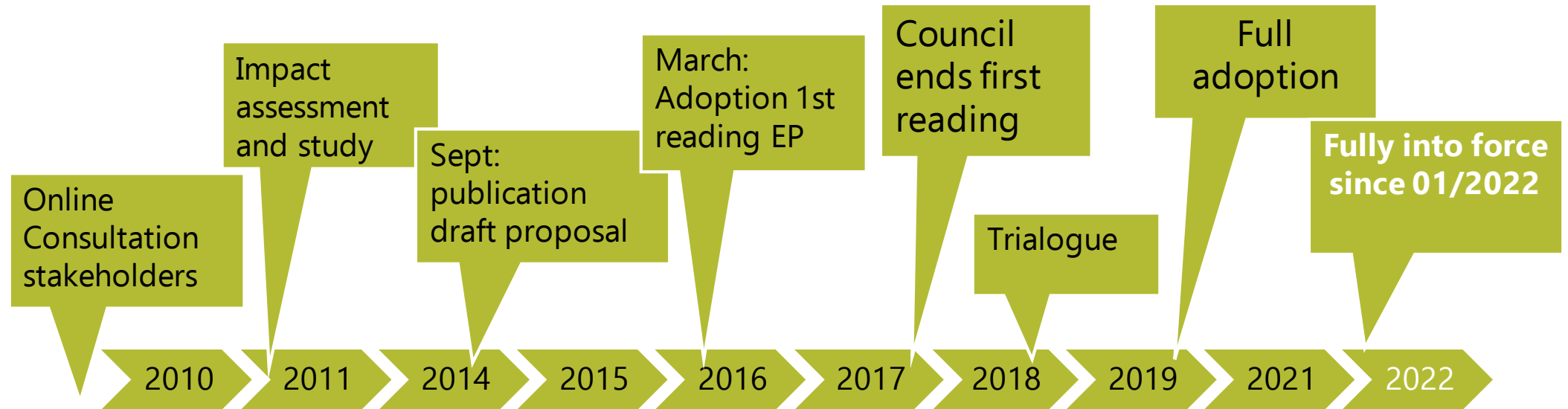
Together with its members, FVE supports veterinarians in delivering their professional responsibilities to the best possible standards and ensures that veterinary expertise is recognised and valued by society.

# FVE Affiliations & Liaison





# Timeline EU Medicines legislation revision: 2019/6



**FVE and national delegations input!**

All FVE position papers on [www.fve.org](http://www.fve.org)

## Aims new legislation:

- **Address** the public health risk of **antimicrobial resistance** (AMR)
- Increase **availability of veterinary medicinal products**; and Improve the functioning of the internal market
- Reduce administrative burden
- Stimulate competitiveness and innovation

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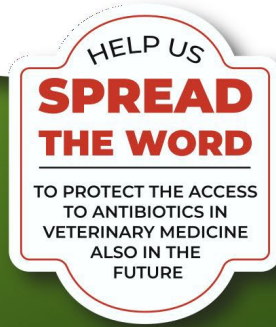
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# New Reg provides excellent tools to fight AMR

- Veterinary profession has & is further committed to fight AMR by a scientific One Health approach → Regulation follows this
- Even animals who are kept in the best conditions can become sick, and animals deserve treatment too



• **VETERINARIANS KNOW, CARE AND CONTRIBUTE** •



VETERINARIANS NEED ANTIBIOTICS  
TO TREAT OTHERWISE INCURABLE  
BACTERIAL DISEASES IN ANIMALS

USING ANTIBIOTICS AS *LITTLE AS POSSIBLE,*  
AS *MUCH AS NECESSARY,* HELPS TO AVOID  
PREVENTABLE SUFFERING







## Reg provides extensive toolbox to fight AMR e.g.



Veterinary antimicrobials = on prescription + quantity/amount prescription



ESVAC collection of Use Data per Species



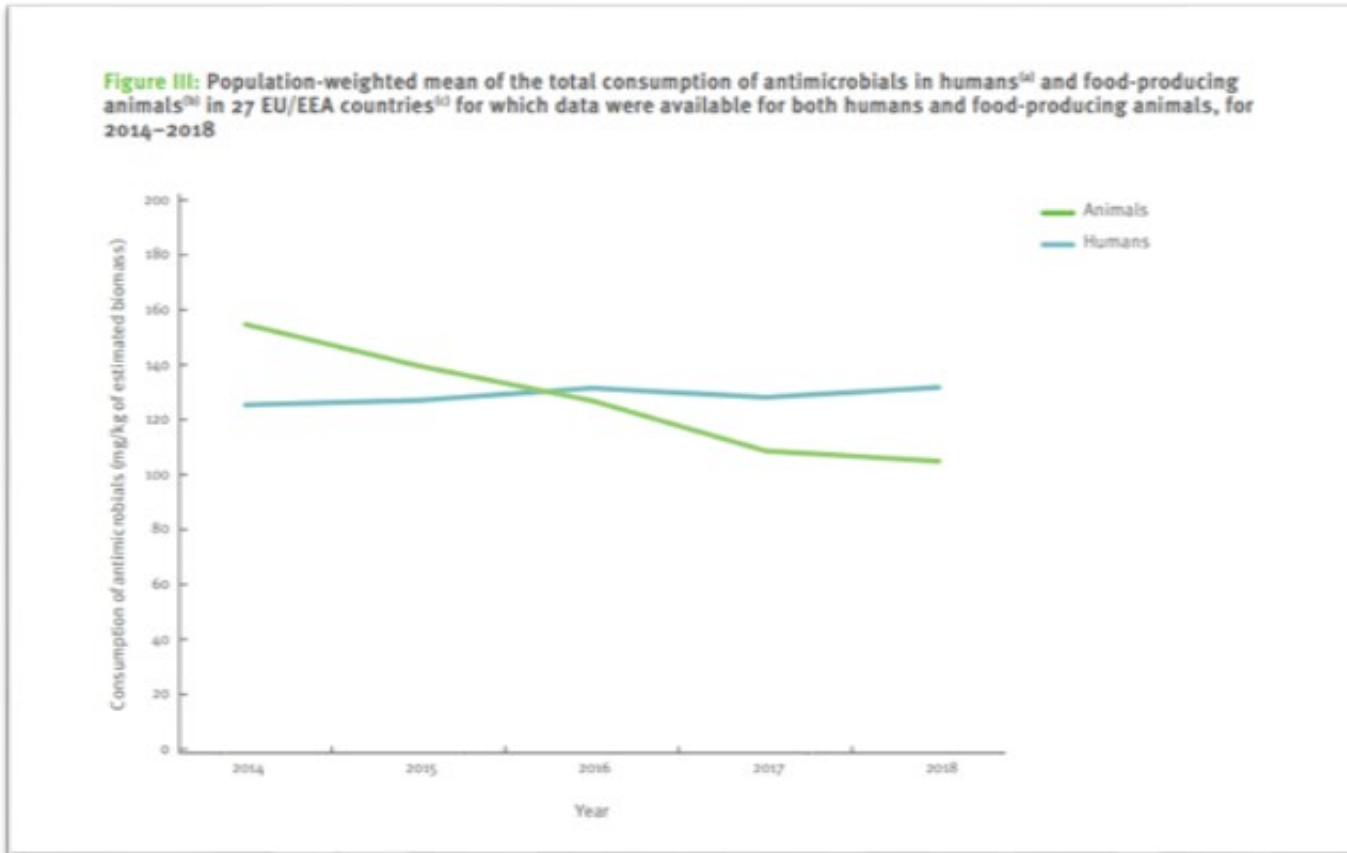
Routine prophylactic & metaphylactic use will not be allowed anymore



List of reserved antimicrobials for human use only



Import rules



**Europe is on the right track to fight antibiotic resistance...**

**2011-2020**  
Sales of antibiotics for veterinary use are declining

**↓ 43%**  
overall sales in 25 of the 31 countries in the ESVAC network

**↓ 60%**  
in some countries

**↓ 77%**  
for polymyxins

**↓ 33%**  
for 3rd- and 4th-generation cephalosporins

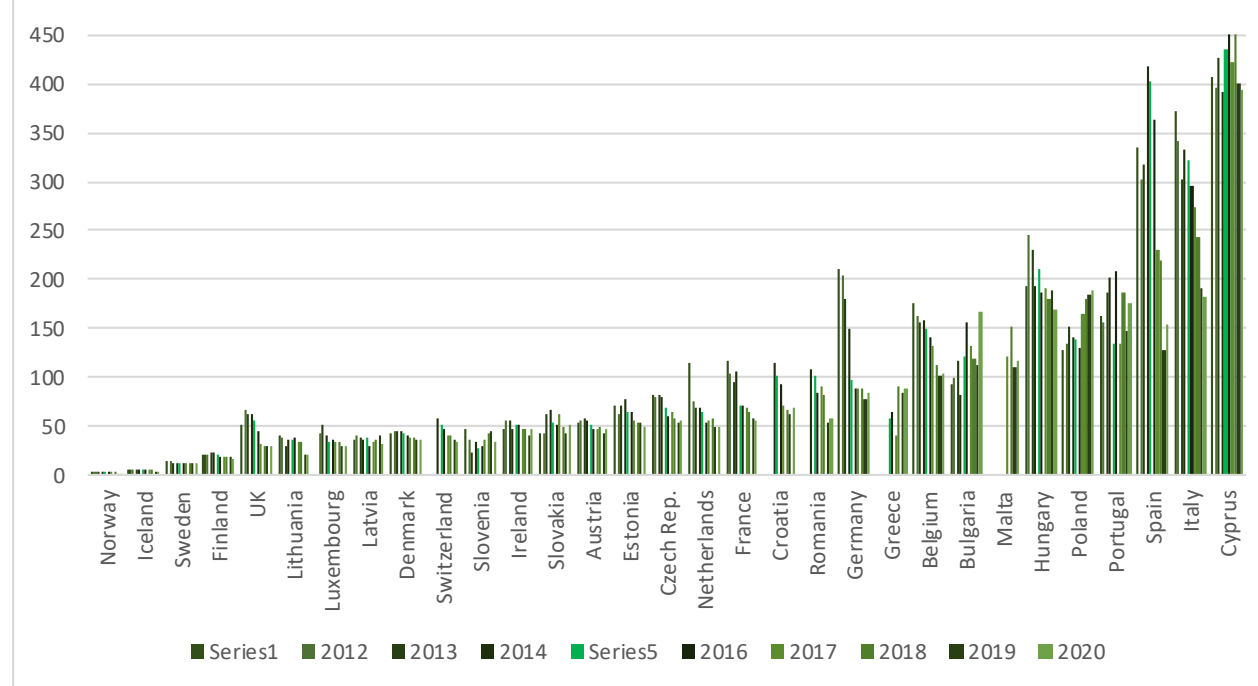
**Animal sector has reached important achievements**



- F2F goal: EU sales of antimicrobials for animals minus 50% by 2030
- Reduce gap between MSs
- Enhance 'One Health Approach'



**Antimicrobial sales in mg/PCU for food-producing animals (2011-2020)**



**Our ambitions go further.**

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# New regulation has potential to increase availability



Veterinary medicines =  
many species/sub-  
species → needs  
flexibility



Increased  
flexibility of  
prescription  
cascade



Stimulate  
innovation incl.  
new medicines



Union Product Database  
& easier import of  
medicines from other EU  
MSs; prescriptions valid  
throughout the EU



Extension  
centralized  
authorization  
procedure



# We need to ensure that this potential is used to increase availability

- Huge concerns that veterinarians are no longer able to deviate from the dose and duration in the SPC (Art 106.1).
- Shortages, supply problems, lack of incentives for investment, national restrictions, more stringent regulatory requirements, etc all influence availability.
- Important for regulators to use flexibility (risk-benefit)
- Important to monitor availability e.g. ANSES example



## 3 to 5 MAJOR gaps in producing animal sectors



27/04/21

- Ocular infections with corneal lesions & teat injuries
- Respiratory mycoplasmosis
- Oral antipyretics
- Oral tranquilizers
- Paramphistomosis
- Dicrocoeliosis



16/04/21

- Digestive strongylosis and increased resistance to parasiticides
- Cryptosporidiosis
- Neonatal colibacillosis
- Sheep scabies
- Myiasis due to *Wohlfahrtia*
- Border disease
- 



16/04/21

- Digestive strongylosis and increased resistance to parasiticides
- Respiratory pasteurellosis (*P. multocida*)
- Mycoplasma mastitis
- Paratuberculosis
- Cryptosporidiosis
- Neonatal colibacillosis
- 
- 

# Mapping done together with profession

<https://www.reseau-francais-sante-animale.net/le-rfsa/cartographie-des-gaps-therapeutiques/>

## 4<sup>TH</sup> EMA FVE WEBINAR ON NEW VETERINARY MEDICINAL PRODUCTS REGULATION

**27 JUNE 2022**  
**11:30-13:00 CET**

**SPECIAL FOCUS:**  
**UNION PRODUCT DATABASE BENEFITS, FUNCTIONALITIES AND  
UPCOMING IMPROVEMENTS**

**TARGET AUDIENCE:**  
**VETERINARIANS, ANIMAL HEALTH PRACTITIONERS,  
COMPETENT AUTHORITIES**

**REGISTRATION OPEN**





# Continuation of the close collaboration

- Example of nice collaboration of regulators, industry and stakeholders
- Ensures legislation which is effective and applicable.
- Let's continue this!

**THANK YOU!**



## CONTACT US

E-mail: [info@fve.org](mailto:info@fve.org)

Website: <https://fve.org/>

## WHERE WE ARE

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