



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



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*)

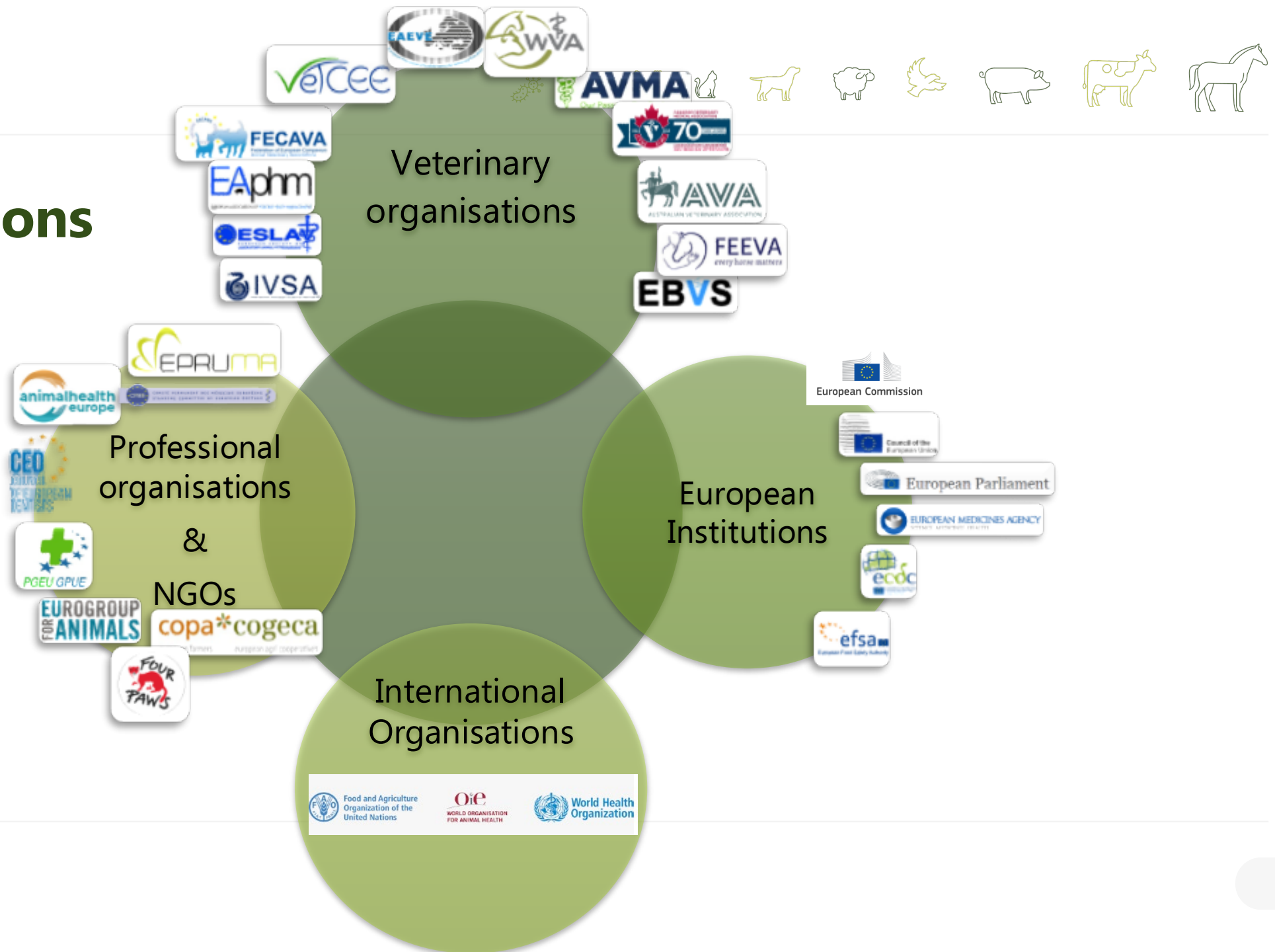
FVE's mission

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



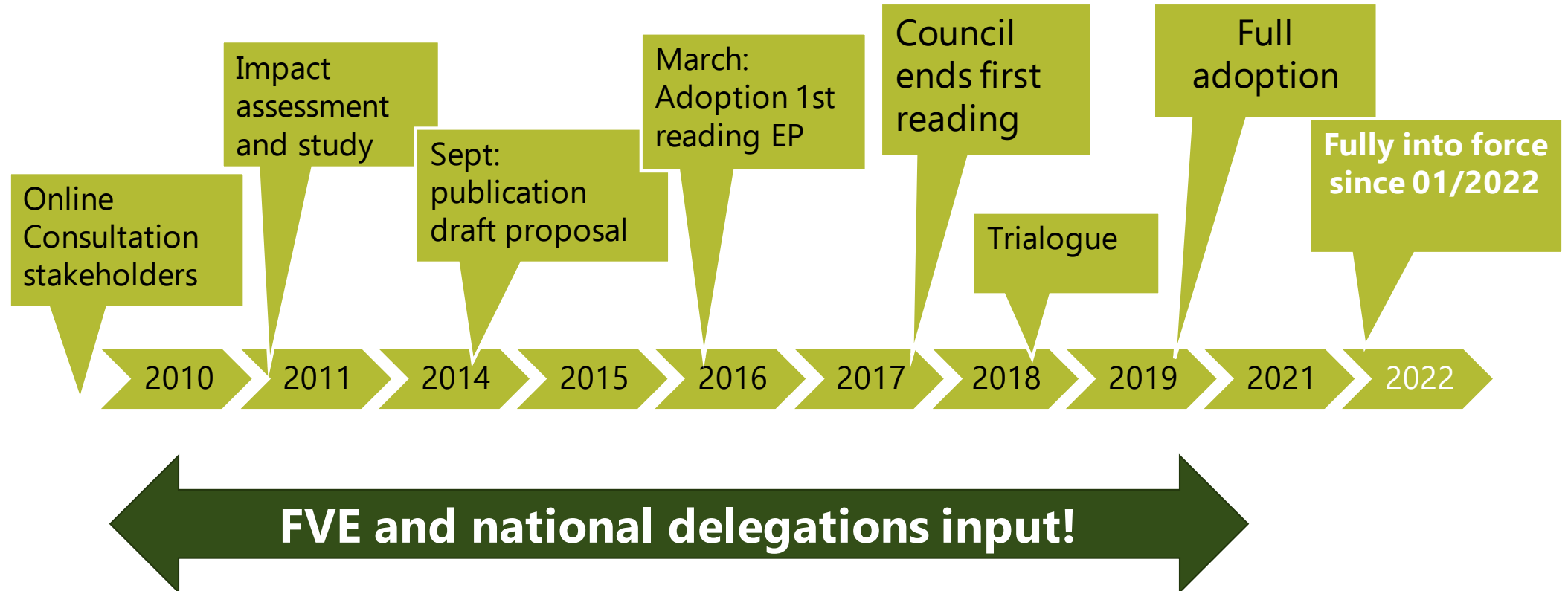
Together with its members, FVE supports veterinarians in delivering their professional responsibilities to the best possible standards and ensures that veterinary expertise is recognised and valued by society.

FVE Affiliations & Liaison





Timeline EU Medicines legislation revision: 2019/6



All FVE position papers on 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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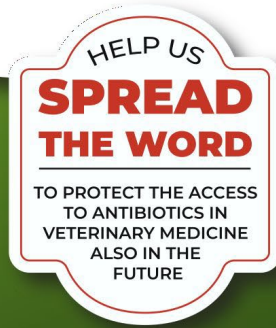
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New Reg provides excellent tools to fight AMR

- 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**



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FECAVA
Federation of European Companion
Animal Veterinary Associations



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

Year	Animals (mg/kg)	Humans (mg/kg)
2014	155	125
2015	140	127
2016	125	132
2017	108	128
2018	105	132

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

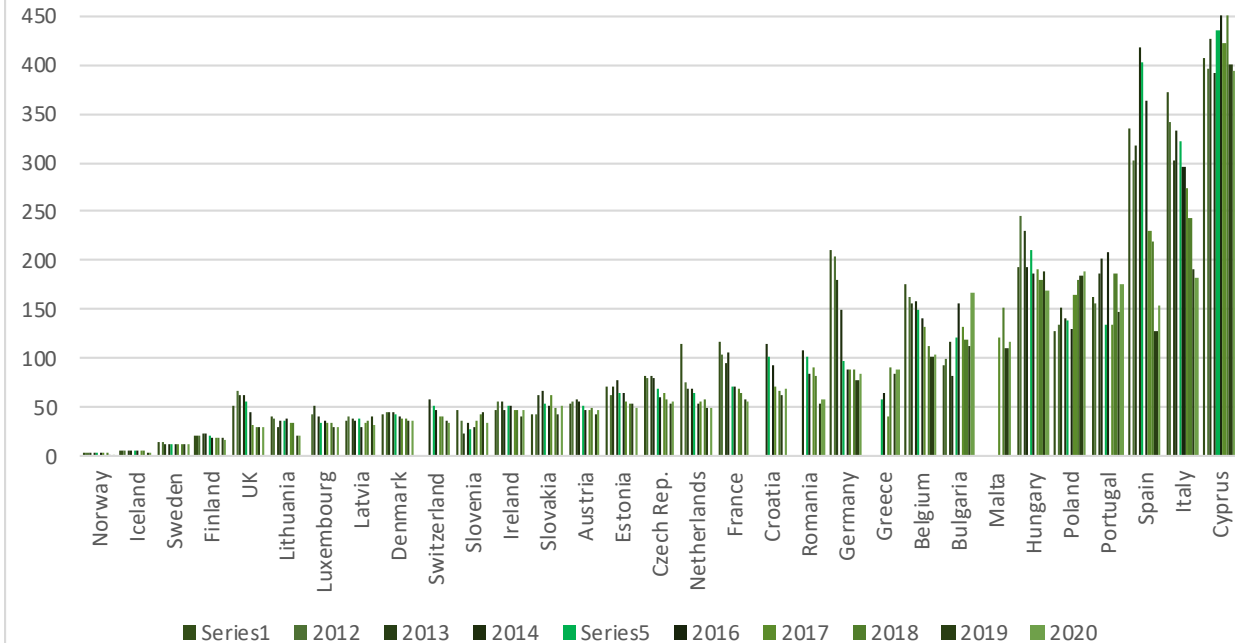
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- F2F goal: EU sales of antimicrobials for animals minus 50% by 2030
- Reduce gap between MSs
- Enhance 'One Health Approach'



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/>



EUROPEAN
MEDICINES
AGENCY



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4TH 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

FVE infographic: explaining the new Regulation



European law on veterinary medicines: what's new?



The EU has officially adopted new legislation on veterinary medicines*. It will be applicable in all EU countries from 28 January 2022.

FVE has actively contributed to the drafting of the Regulations, allowing the new legislation to strengthen the position of the veterinarian.

The rules are more transparent and easier to implement, helping the profession in safeguarding animal health, animal welfare and public health, including combating antimicrobial resistance.

What will change in veterinary practice?



Veterinary prescriptions can only be issued by veterinary surgeons (exceptions apply). The prescription will be valid throughout the EU. The quantity prescribed should be limited to the treatment.

Reg. 2019/6 Ac. 108



To combat **antimicrobial resistance**, use of certain **important antibiotics** can be restricted or prohibited in animals. The European Commission is expected to draw up a list. Preventive antibiotic use is only permitted in exceptional circumstances. Restrictions also apply to metaphylactic use.

Reg. 2019/6 Ac. 10, 107



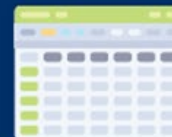
The **prescription cascade** will become more flexible. Importing veterinary medicines from another EU country will become easier. Third country medicines can also be used under certain conditions. Restrictions may apply to antibiotics.

Reg. 2019/6 Ac. 110-115



On-farm monitoring systems of antibiotic use and national surveillance of antibiotic use become mandatory. **Advertising** veterinary prescription medicines in the lay press will be forbidden, although Member States can allow vaccine adverts for farmers.

Reg. 2019/6 Ac. 12, 128



A central **EU database** of all authorised veterinary medicines will be set up, easily accessible by all veterinarians. **Pharmacovigilance** data, recording adverse events, will become accessible to all veterinarians. The reporting will become more user-friendly.

Reg. 2019/6 Ac. 105, 106, 111



Medicated feeds require a veterinary prescription, can only be prescribed for two weeks and cannot contain more than one antimicrobial substance. Preventive antibiotic use is not allowed, metaphylactic use only under certain conditions.

Reg. 2019/6 Ac. 106, 109 Reg. 2019/6 Ac. 15



Online sales are only allowed for medicines not requiring a veterinary prescription. Individual Member States can overrule this, but only on their own territory. Legal online pharmacies must be monitored and certified with a common EU logo.

Reg. 2019/6 Ac. 106



Imported animals and animal products from outside the EU need to conform to the ban on growth-promoting antimicrobials and the ban on antibiotics reserved for human use.

Reg. 2019/6 Ac. 118

* Regulation (EU) 2019/6 on veterinary medicinal products, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019R0006>; Regulation (EU) 2019/6 on medicinal products for animals, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019R0006>; Directive 2010/63/EU on the protection of animals used for scientific purposes, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32010D0063>.

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

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WHERE WE ARE

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