



# General on Animal Health Law



Better Training for Safer Food: New legislation on Animal Health

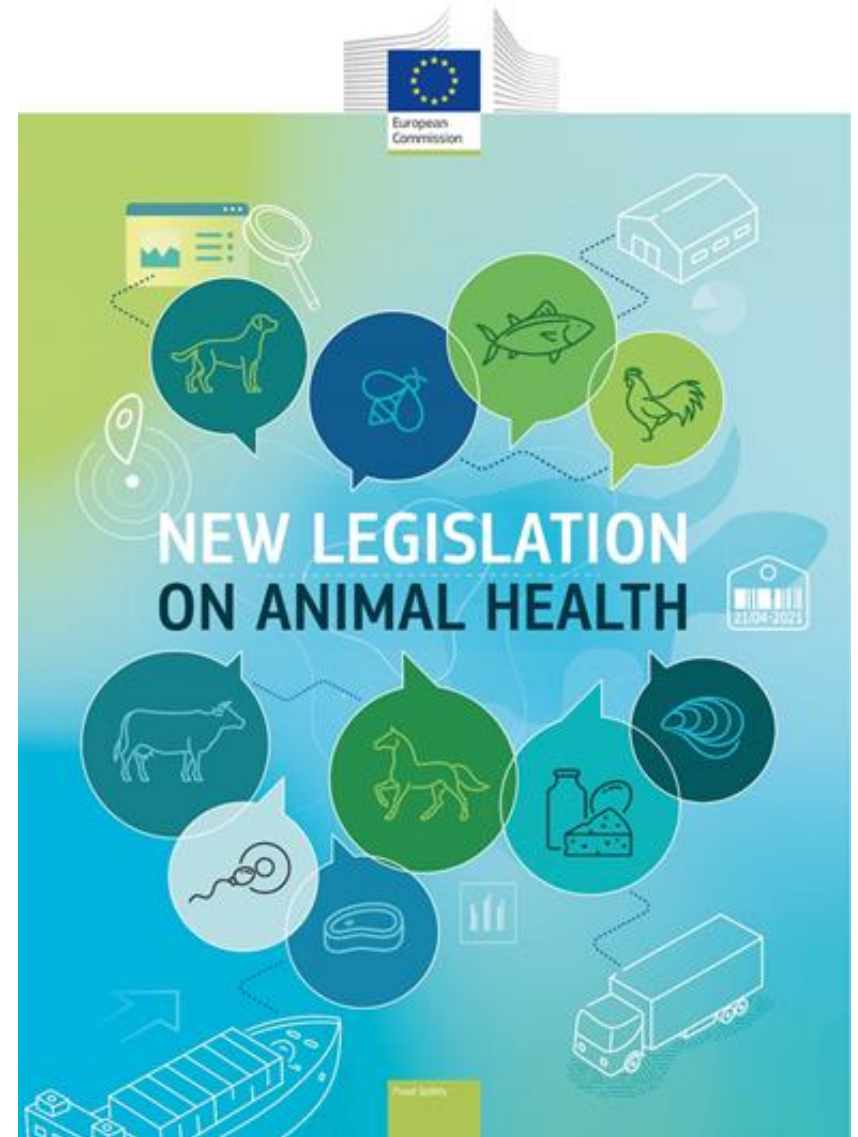
Brussels, 2021

*DG SANTE*

*Unit G2 – Animal Health*

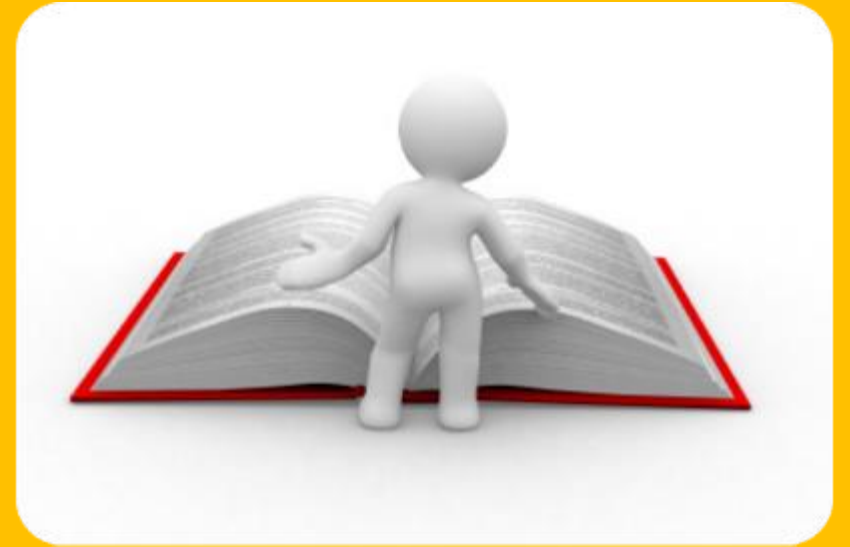
# Outline of the presentation

- Introduction – AHL and the process
- What is the AHL about?
- AHL structure and contents
- Information on supplementing acts



# Introduction Animal Health Law and the process

Why a new law and what is it all about?



# Introduction – Animal Health Law

- Regulation (EU) 2016/429 on transmissible animal diseases ('Animal Health Law') (AHL)
  - adopted by the European Parliament and the Council in March 2016
  - applies from 21 April 2021
  - is/will be complemented by additional rules



# Based on:

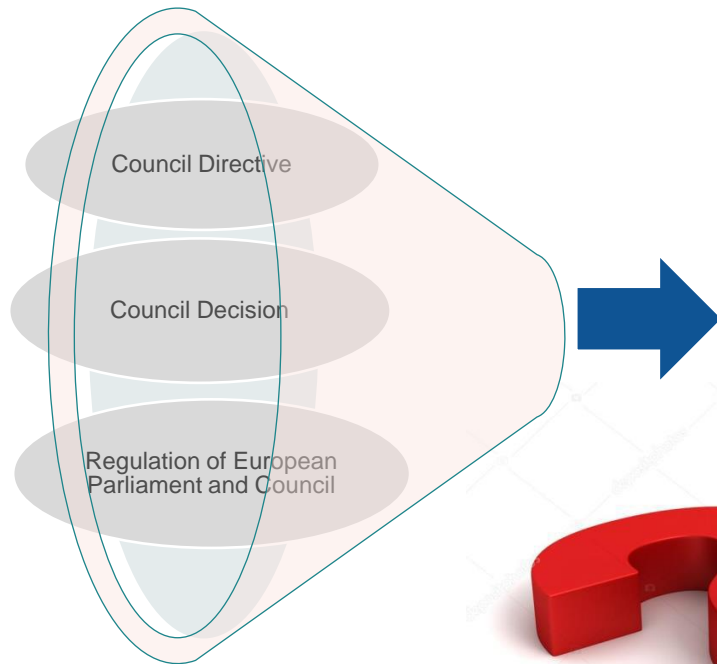
- Evaluation of the EU Animal Health policy 1995-2004 (2006)
- AH Strategy **“Prevention is better than cure”** (2007)
- AHS Action Plan (2008)
- Impact Assessments (Strategy and AHL)



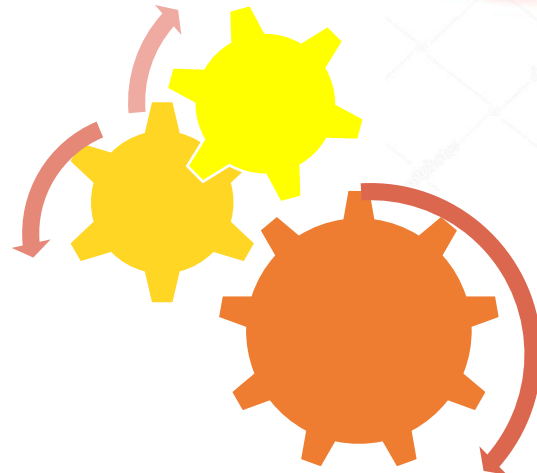
# AHL: Reasoning



# AHL process



## Regulation (EU) on transmissible animal diseases (AHL)



# AHL: important new elements

- ✓ **Responsibilities** of keepers, operators, veterinarians, competent authorities, etc.
- ✓ More **risk based approach** including prioritisation and categorisation of animal diseases for EU intervention
- ✓ More **prevention**
  - ✓ biosecurity
  - ✓ surveillance
  - ✓ knowledge on animal health
  - ✓ use of vaccines
  - ✓ emerging diseases
  - ✓ AMR
- ✓ **Easy and safe** trade
- ✓ **IMPORTANT:**
  - ✓ some rules (e.g. responsibilities) apply to all animals, species, regardless of diseases
  - ✓ some disease specific rules apply only to listed diseases





# Legally speaking

- AHL is a Regulation = directly applicable in all Member States (MS)

**But!**

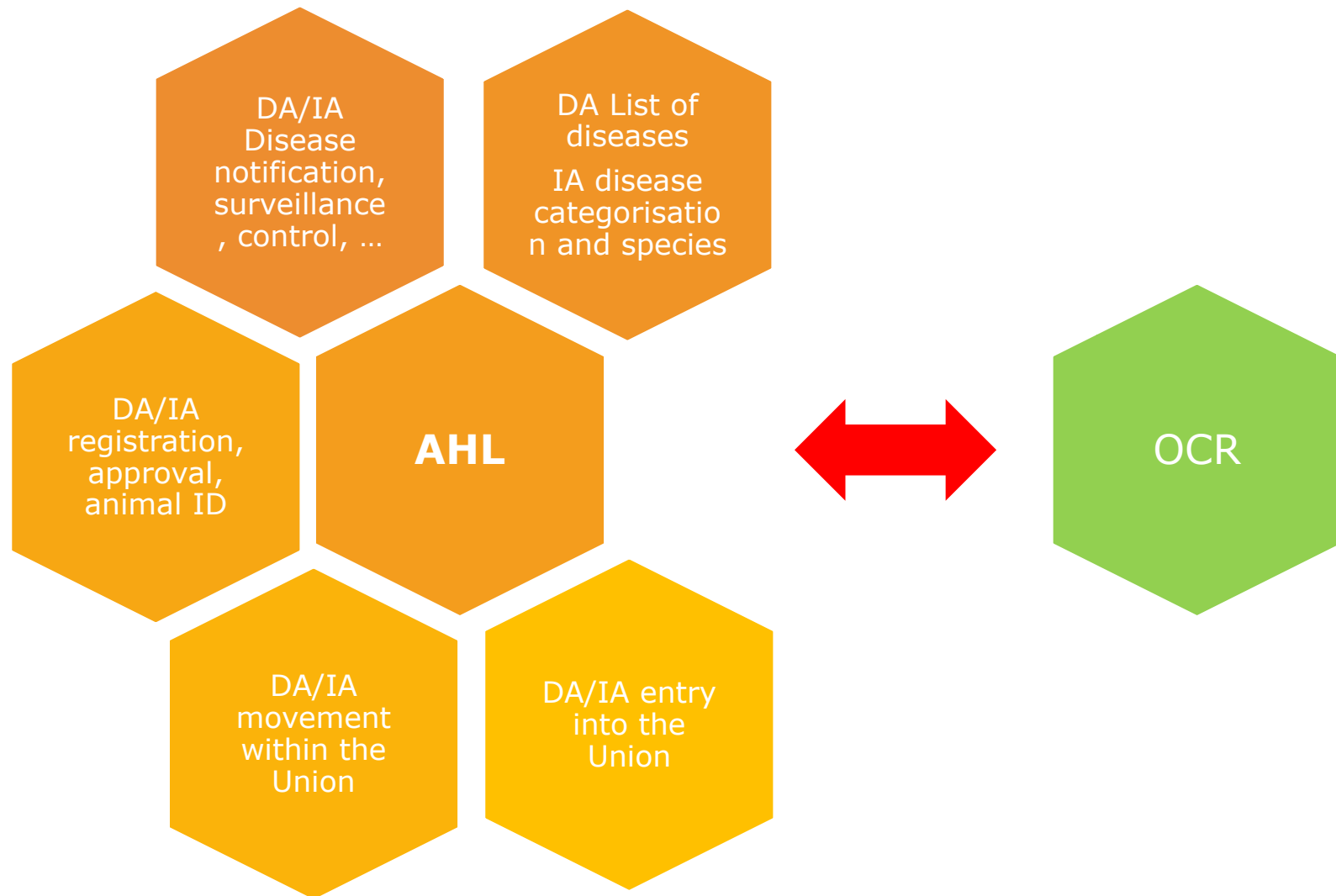
- a number of provisions to be laid down by MSs (designation of authorities for the application, national measures, stricter measures, penalties, etc.)
- AHL is complemented by various Delegated acts (DA) and Implementing acts (IA), which make it operational

# Delegated & Implementing acts (in short!)

Provided for under the **Lisbon Treaty**

- Basic Act (in this case the AHL), provides **'empowerments'** for the Commission to bring forward Delegated Acts and Implementing Acts
- DAs have general application and **supplement or amend certain non-essential elements** of the basic act ..... **'what do we do'**? Parliament & Council have a say
- IAs are more technical in nature..... **'how do we do it'**? Objective is to **ensure uniform application** of the Basic Act or the DA - agreed via Comitology process (Standing Committee on Plants, Animals, Food and Feed where all 27 MSs are represented)

# AHL and OCR (Official controls regulation)

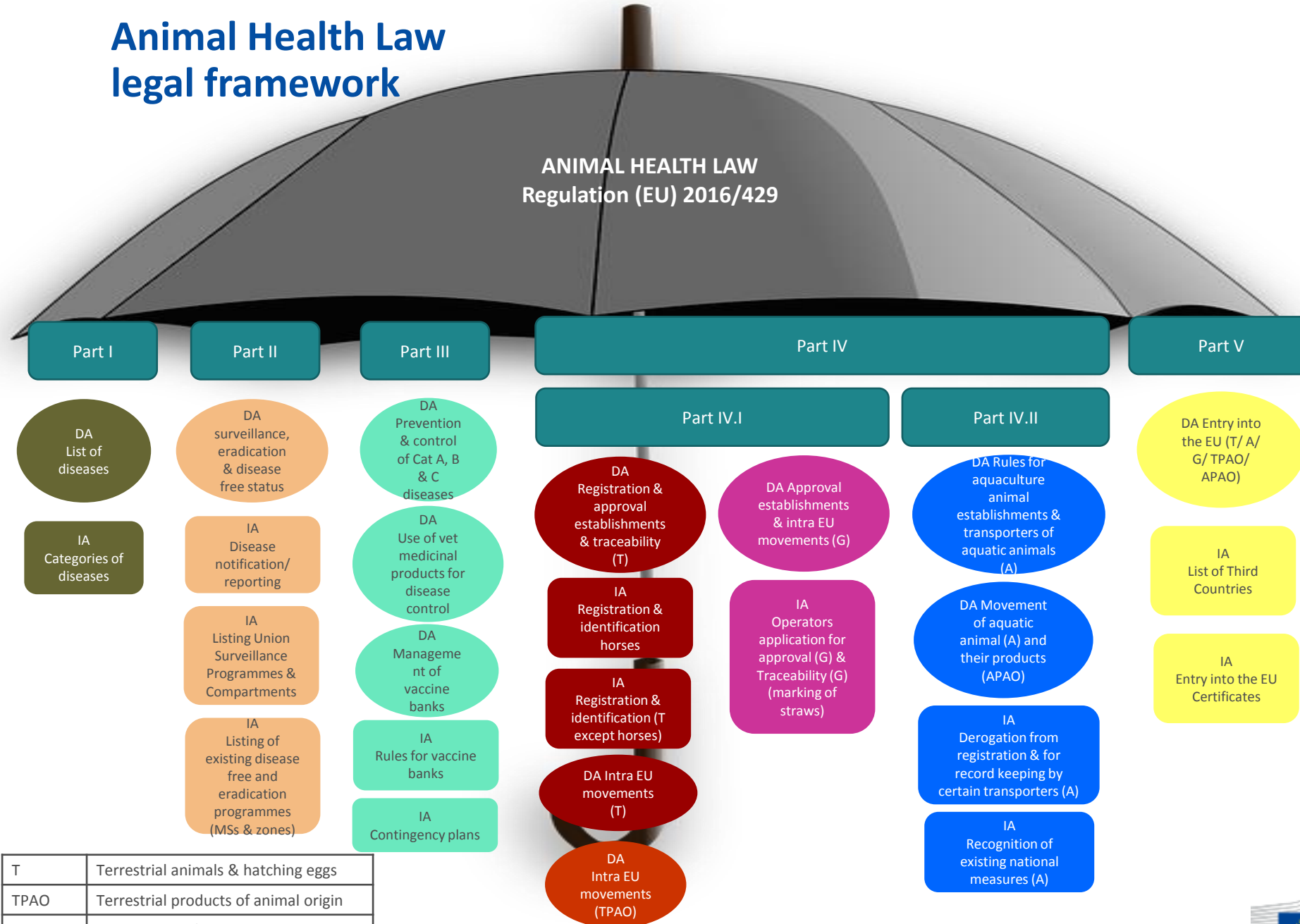


- Delegation of tasks to natural and legal persons
- Veterinary checks intra EU and borders
- Laboratories (including EURLs and NRLs)
- Sampling and diagnostic methods (“cascade”)
- IMSOC
- Etc...

# AHL structure and contents



# Animal Health Law legal framework



|      |                                       |   |                       |
|------|---------------------------------------|---|-----------------------|
| T    | Terrestrial animals & hatching eggs   |   |                       |
| TPAO | Terrestrial products of animal origin |   |                       |
| A    | Aquatic animals                       |   |                       |
| APAO | Aquatic products of animal origin     | ○ | Delegated Act (DA)    |
| G    | Germinal products                     | □ | Implementing Act (IA) |

IA intra EU animal health Certificates (T/ A/ G/ TPAO/ APAO)

# Structure of the AHL

Part I – General rules

Part II – disease notification, reporting, surveillance, eradication programmes,  
disease freedom

Part III – Disease awareness, preparedness, control

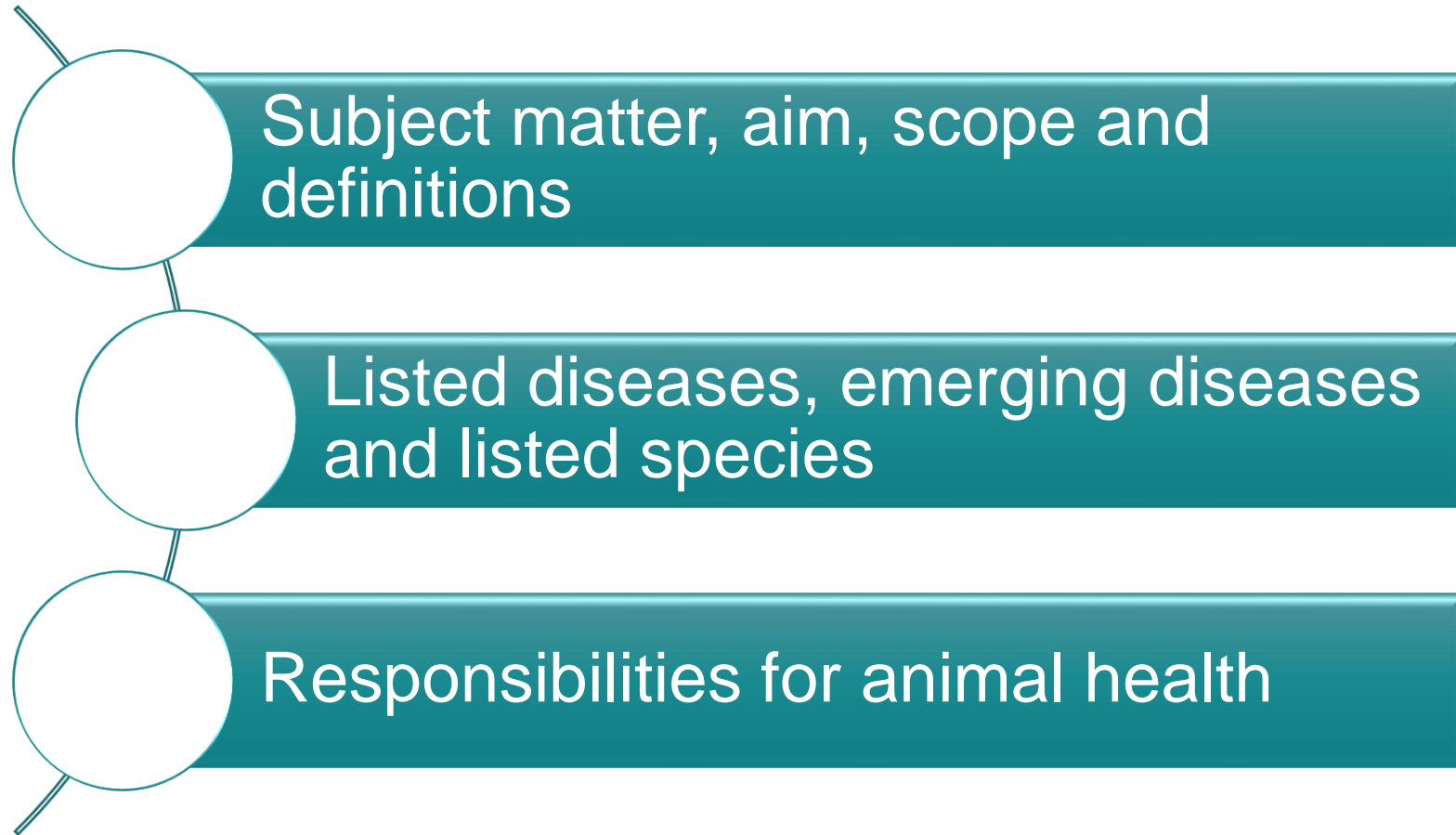
Part IV

Title 1 – registration , approval, traceability and movements  
(terrestrial)  
Title 2 – registration , approval, traceability and movements (aquatic)  
Title 3 – other animals and their products

Part V Entry into EU

Part VI – non-commercial pets  
Part VII – Emergency measures  
Parts VIII/IX – Common and transitional provisions

# Part 1 – General rules



# AHL- Subject matter



## About?

- ✓ General principles for **transmissible animal diseases** in:
  - ✓ Kept and wild animals and their products
  - ✓ **Terrestrial, Aquatic** and **Other** animals (e.g. reptiles)
- ✓ Animal health rules for:
  - ✓ **Disease prevention**
  - ✓ **Disease surveillance, control and eradication**
  - ✓ **Intra-EU movements and entry into the EU of animals and products**
  - ✓ **Emergency measures**

## Not about?

- ✓ **Not in scope:**
  - ✓ **Animal welfare**
  - ✓ **EU veterinary expenditure** (incl. compensations)
  - ✓ **Feed, medicated feed**
  - ✓ **Veterinary medicines (VMP)**
  - ✓ **Veterinary education**
  - ✓ **Official controls**

- ✓ **Specific rules remain in place for:**
  - ✓ **Animal by-products**
  - ✓ **TSE rules**
  - ✓ **Certain zoonoses**





# Definitions

- 56 definitions / terms that are used in that Regulation

- **Some key definitions:**

- Kept vs. wild animals, pet animals
- Terrestrial, aquatic and other animals
- Operators, establishments, etc.

- **Annex I** is a part of definition (11) "pet animal"

- **Annex III** is a part of definition (45) "ungulates"

- **Remember that:**

- DAs and IAs adopted on its basis have additional definitions, and that
- AHL definitions automatically apply for all DAs and IAs on its basis



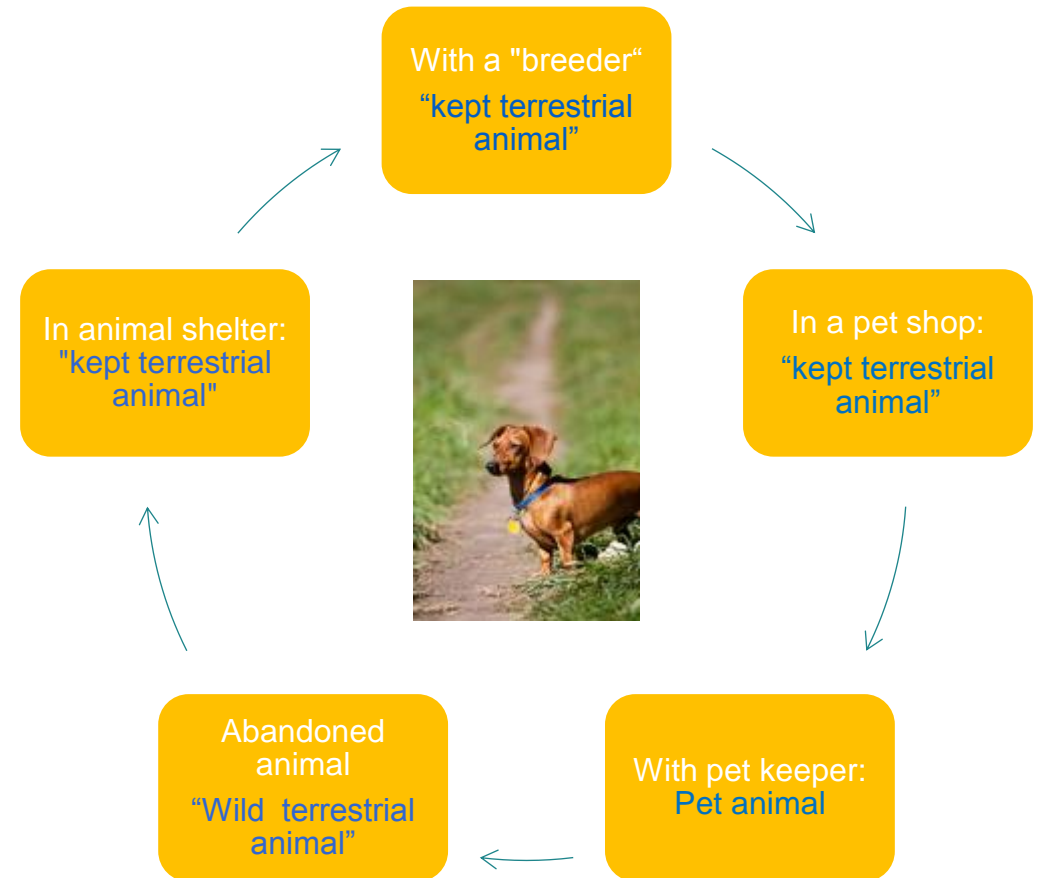
# Different situations in respect of “kept” and “wild” animals



Note that in the context of AHL:

“kept” and “wild” animals depend on the fact if they are kept by humans or not:

- a camel or a giraffe are not necessarily wild animals (if in zoo, they are kept animals)
- domestication of species doesn't play a role



# Animal diseases under the AHL

- ✓ EU limits its intervention with regard to certain measures to certain “listed” diseases
  - ✓ List of diseases for the EU intervention 
  - ✓ Categorise diseases by assigning measures to them for 
    - ✓ disease preparedness, awareness and disease control measures
    - ✓ disease eradication and disease freedom
    - ✓ animal health requirements for movements and trade
    - ✓ disease notification and reporting, surveillance
  - ✓ Lists animal species and assigns them to listed diseases 
- ✓ EU intervention possible for emerging diseases 
  - ✓ Defines what is considered as emerging disease
  - ✓ Sets the EU reaction on them

# Responsibilities for animal health (operators, veterinarians)

- Operators:
  - health of their animals, biosecurity, etc.
  - knowledge on animal health
    - Animal diseases, biosecurity, interaction with animal welfare, good husbandry practices and antimicrobial resistance
  - more preventive behaviour, better biosecurity
    - Contribute to better overall husbandry
    - Result with healthier animals and possible lower use of veterinary medicines
- Veterinarians to play a more active role in:
  - raising animal health awareness,
  - awareness on interaction between animal health, animal welfare and human health and on resistance to treatments
- Roles of veterinarians apply equally to aquatic animal health professionals, **if recognised by national rules!**



# MS responsibilities for animal health and delegation of tasks

- Member States to ensure resources, personnel, laboratories, etc.
- Public information, e.g. passengers information
- Delegation by a competent authority of official tasks to veterinarians other than official veterinarians in relation to



- Practical application of eradication programmes
- Support to the CA on surveillance activities
- Activities related to disease awareness, preparedness and control (e.g outbreaks of category A diseases)
- Registration, approval, I&R



- **Remember:** rules for delegation of tasks according to **OCR Regulation** apply!

# Laboratories: what is in the AHL?



- Biosecurity, biosafety and bio-containment obligation of all laboratories, facilities and other handling disease agents, vaccines etc.
- Requirements for movements of disease agents
  - Completing, but not overlapping, with the rules set out in Regulation (EU) No 1069/2009 (ABP regulation), which deals with the “matrix”

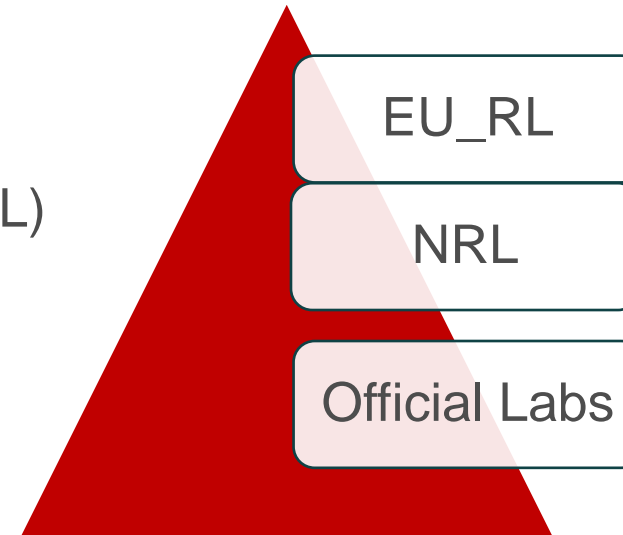


# EU animal health laboratory network

Article 17

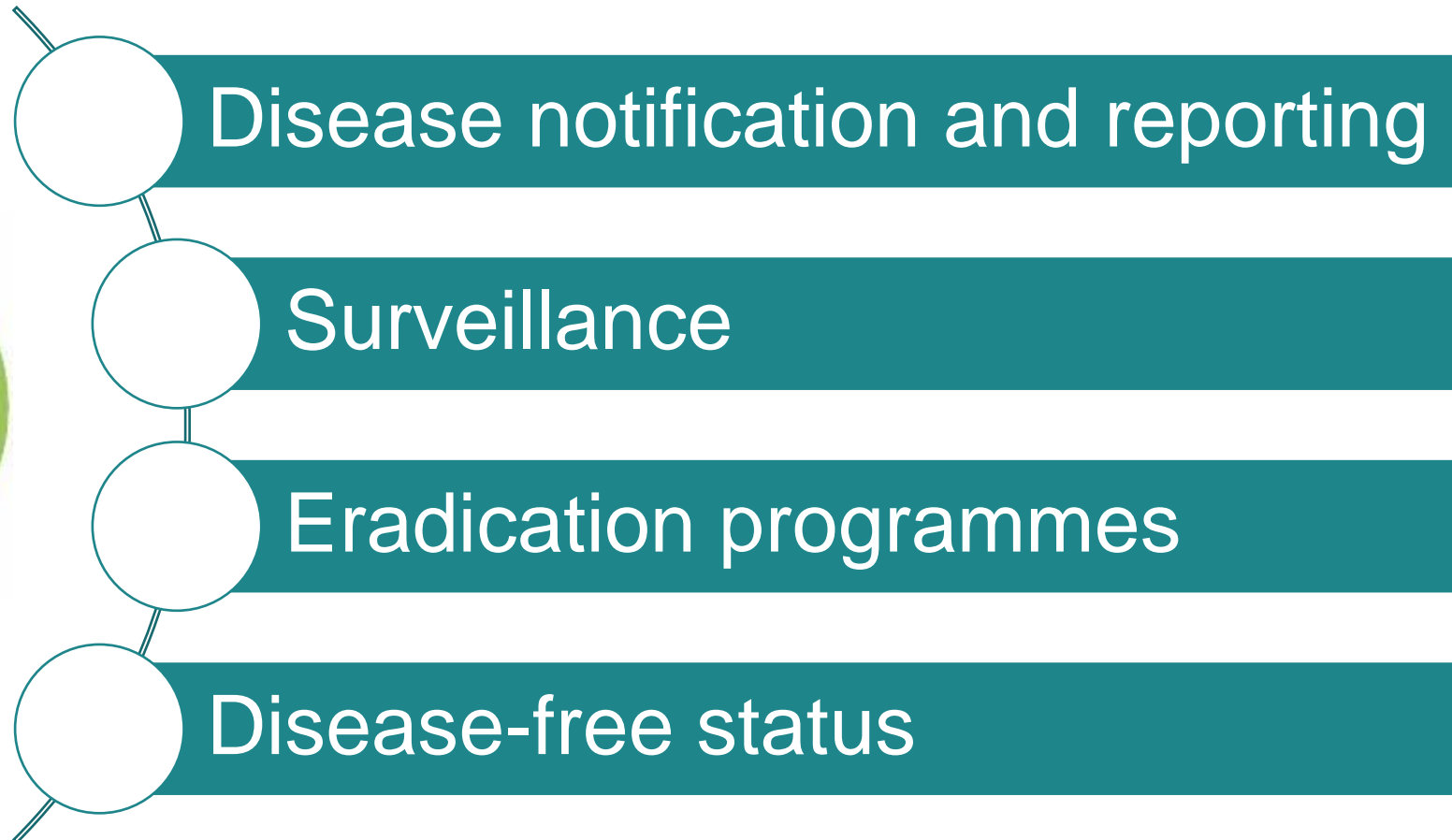
Network of official laboratories in animal health consists of:

- Reference laboratories:
  - European Union Reference Laboratories (EU-RL)
  - National Reference Laboratories (NRL)
- Official laboratories in Member States



- **Remember:** designation and obligations of official laboratories, including reference laboratories is set out in the OCR

# Part 2 – Disease notification and reporting, surveillance, eradication programmes and disease freedom





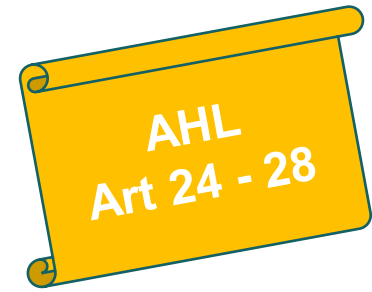
# Disease notification and reporting



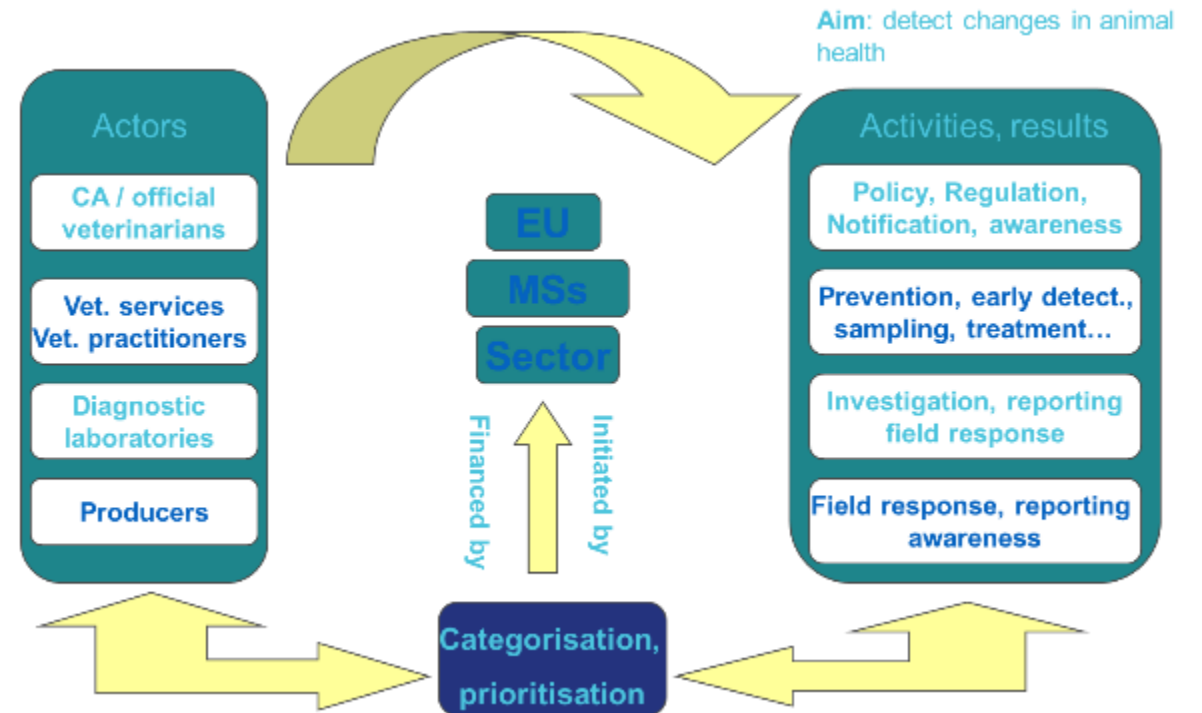
- Rules for notification of animal diseases (in MSs)
  - Notification of natural and legal persons to veterinarians and the CA Union notification and reporting
- Computerised information system (ADIS)



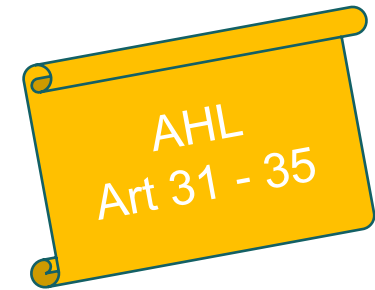
# Surveillance in the AHL



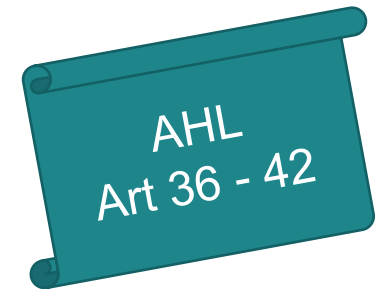
- Surveillance (responsibilities):
  - Obligation of operators for surveillance (incl. Animal Health Visits)
  - Obligations of competent authorities
  - Union surveillance programmes



# Eradication programmes and disease free status



- Compulsory and optional eradication programmes
  - Compulsory for Category B diseases
  - Optional for Category C diseases
- Measures under programmes and contents
- Disease free status

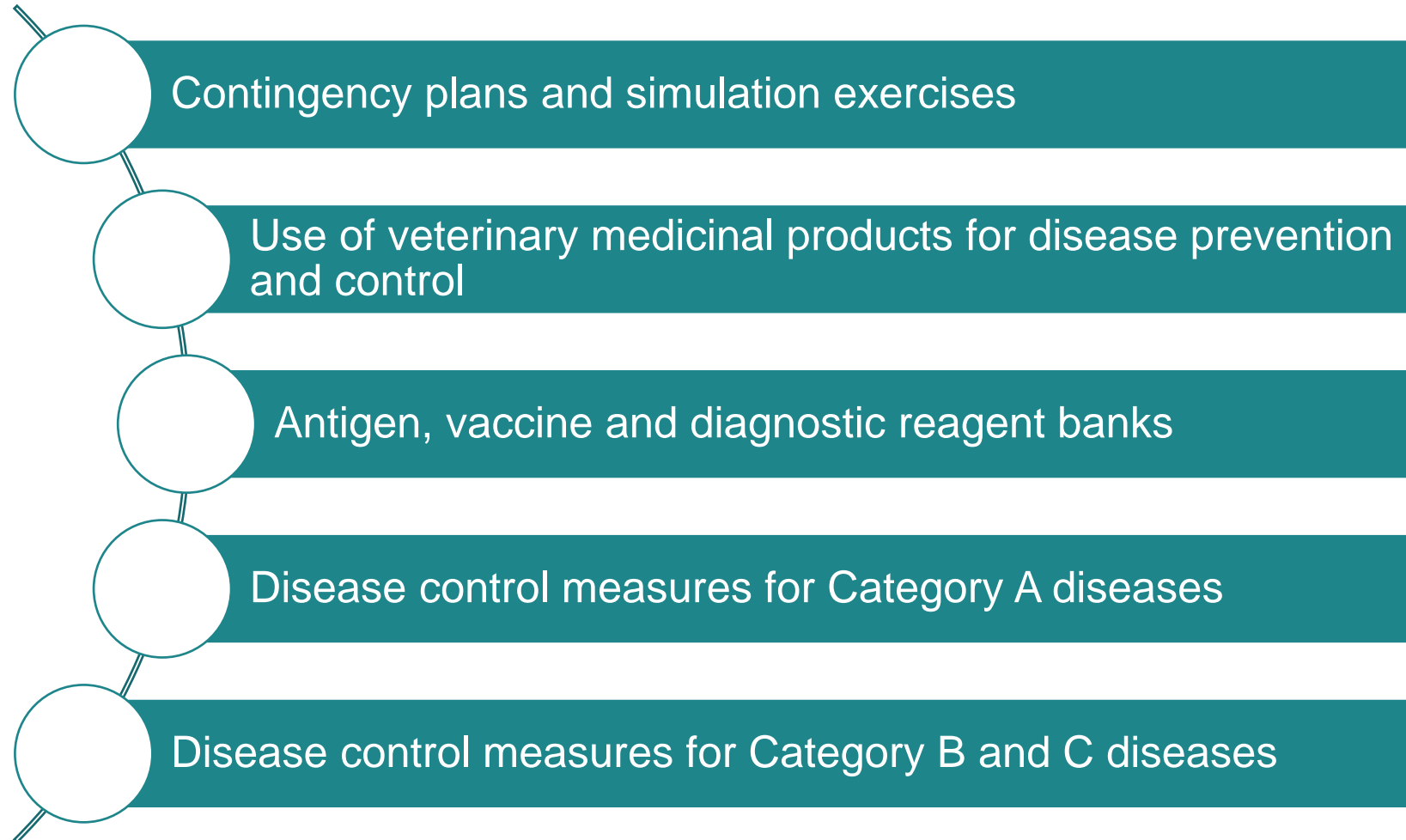


- Countries
- Zones
- Compartments (n.b. only rules for aquatic compartments developed)
- Maintenance, suspension, withdrawal and restoration

# Surveillance, eradication programmes, disease freedom



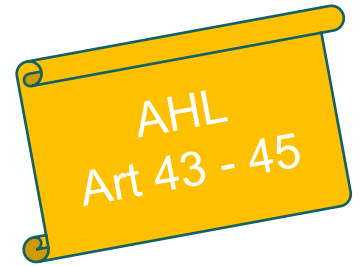
# Part 3 – disease awareness, preparedness and control



# Disease awareness, preparedness and control



- Contingency plans and simulation exercises
- The use of VMPs for disease prevention and control
- Union antigen, vaccine and diagnostic reagent banks for cat A diseases
  - Establishment of the banks
  - Access to the banks
  - Confidentiality
- National antigen, vaccine and diagnostic reagent banks for cat A diseases
- Disease control measures for Cat A, B and C diseases



# Disease awareness, preparedness and control



For terrestrial and aquatic animals

# Part IV: Registration, approval, traceability and movements

## P IV: registration, approval, traceability, movements

Terrestrial animals, GP and POA

Aquatic animals and POA from aquatic animals

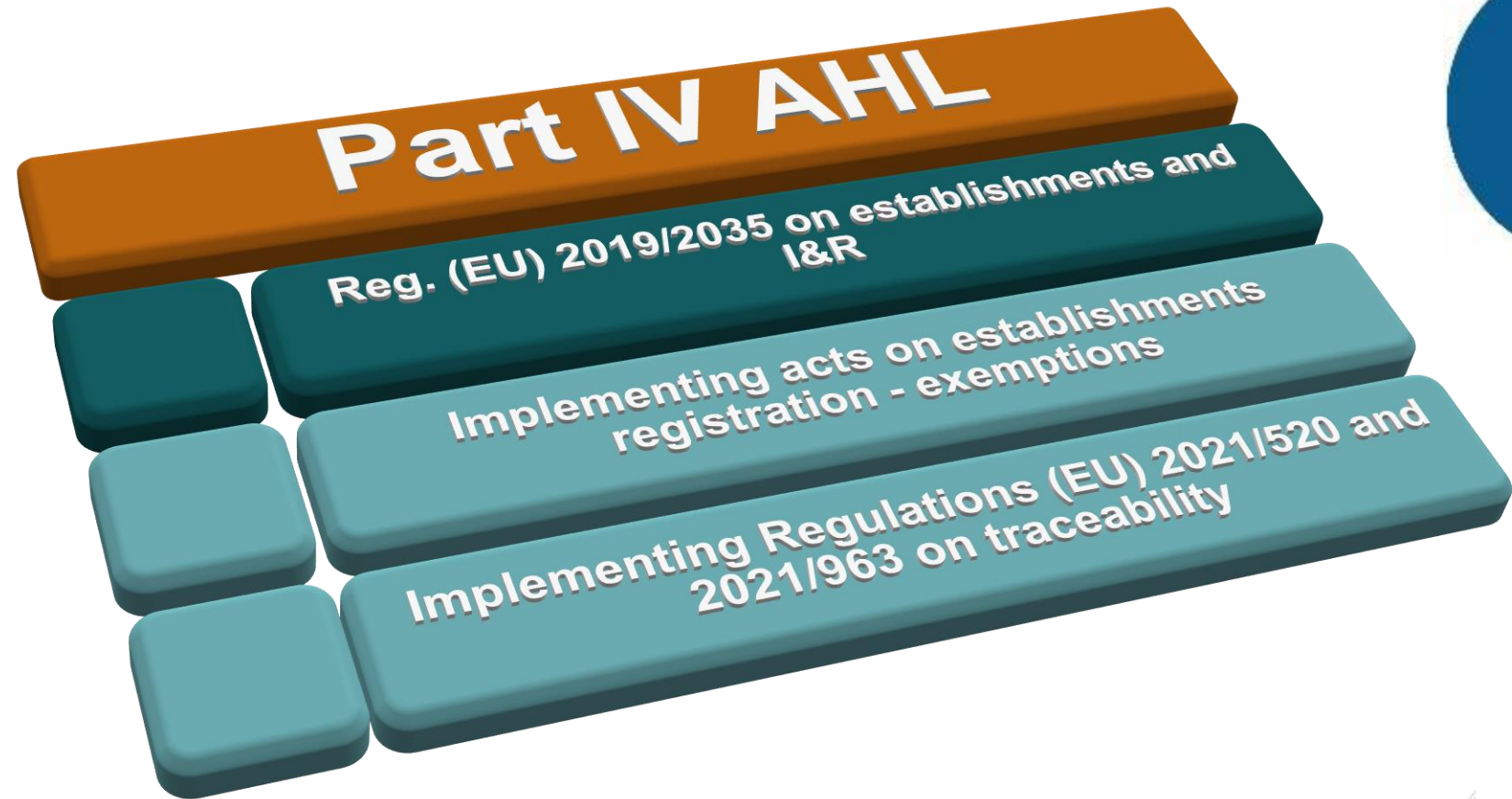
Other animals, GP and POA



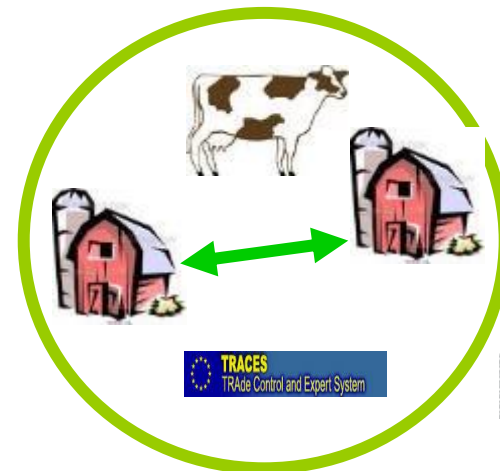
# Terrestrial animals, germinal products and products of animal origin



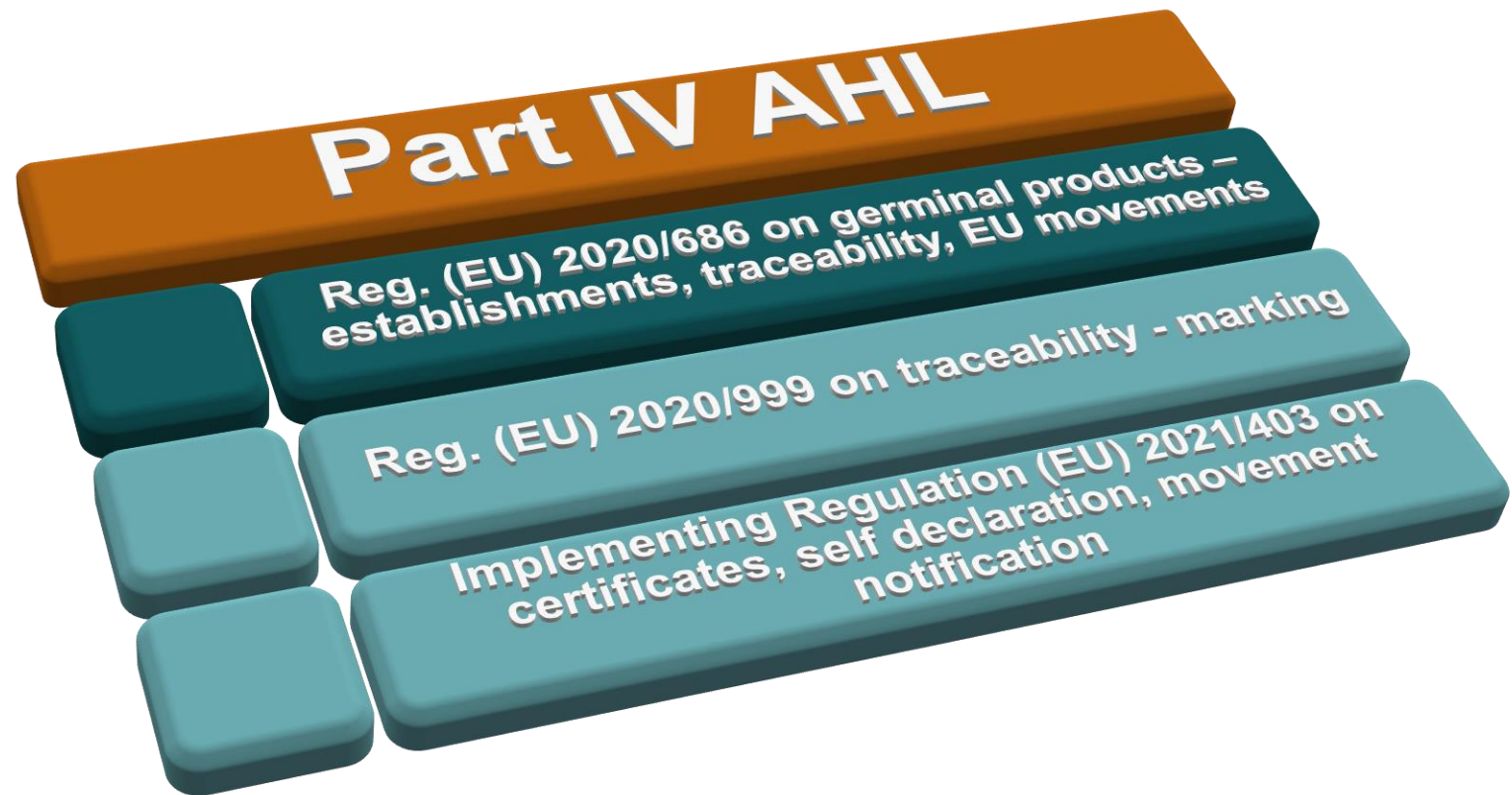
# Terrestrial animals: Establishments, identification & registration, traceability



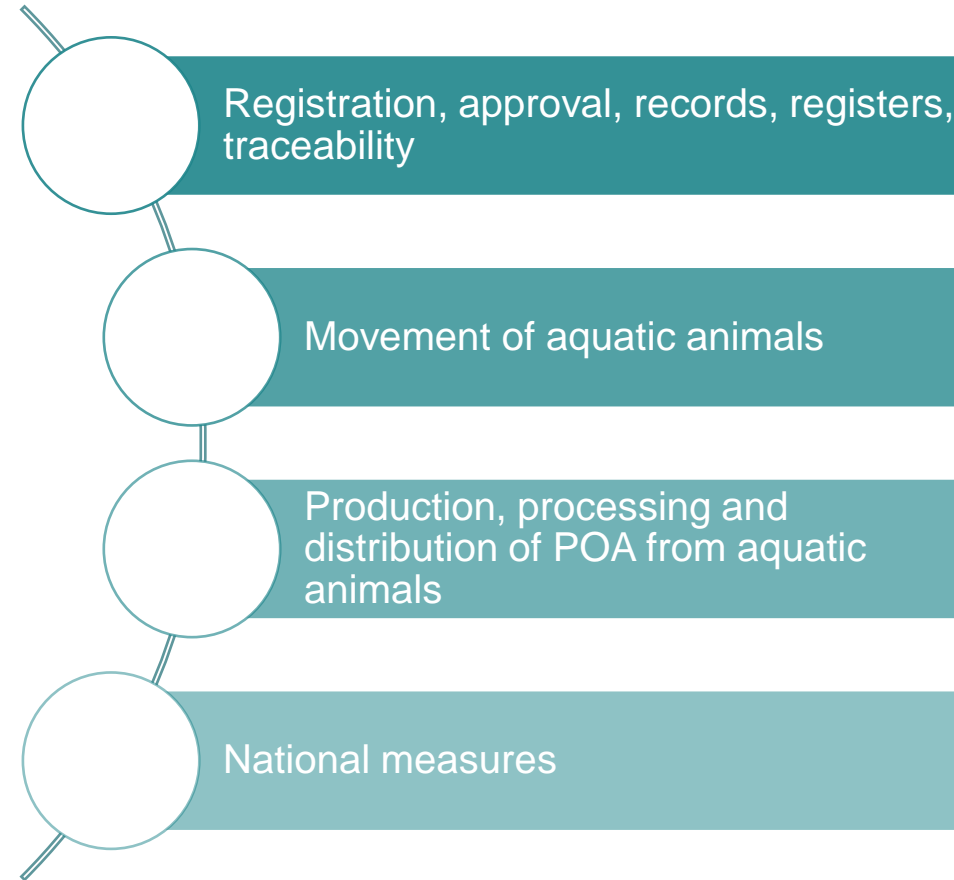
# Animal health requirements for movements of terrestrial animals



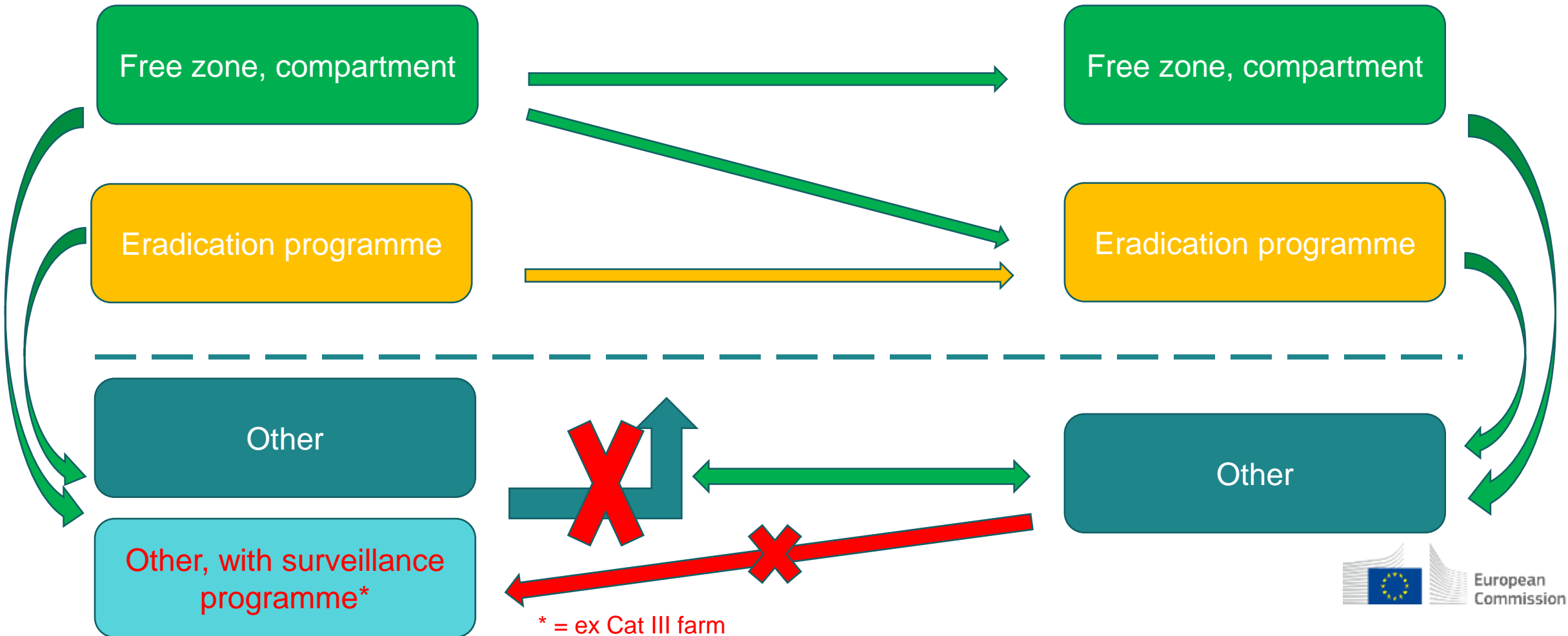
# Animal health requirements for germinal products



# Aquatic animals and products of animal origin from aquatic origin



# Movements of aquatic animals within the Union – specific requirements – the approach



# Animal health requirements for aquatic animals



# Other animals



- Basic animal health requirements for other animals, if they are of listed species for one of the listed diseases
- In such case:
  - Requirements for registration, approval and traceability would apply, rules for movements and animal health certificates
  - A delegated and an implementing act will develop such rules



# Part V – Entry into EU



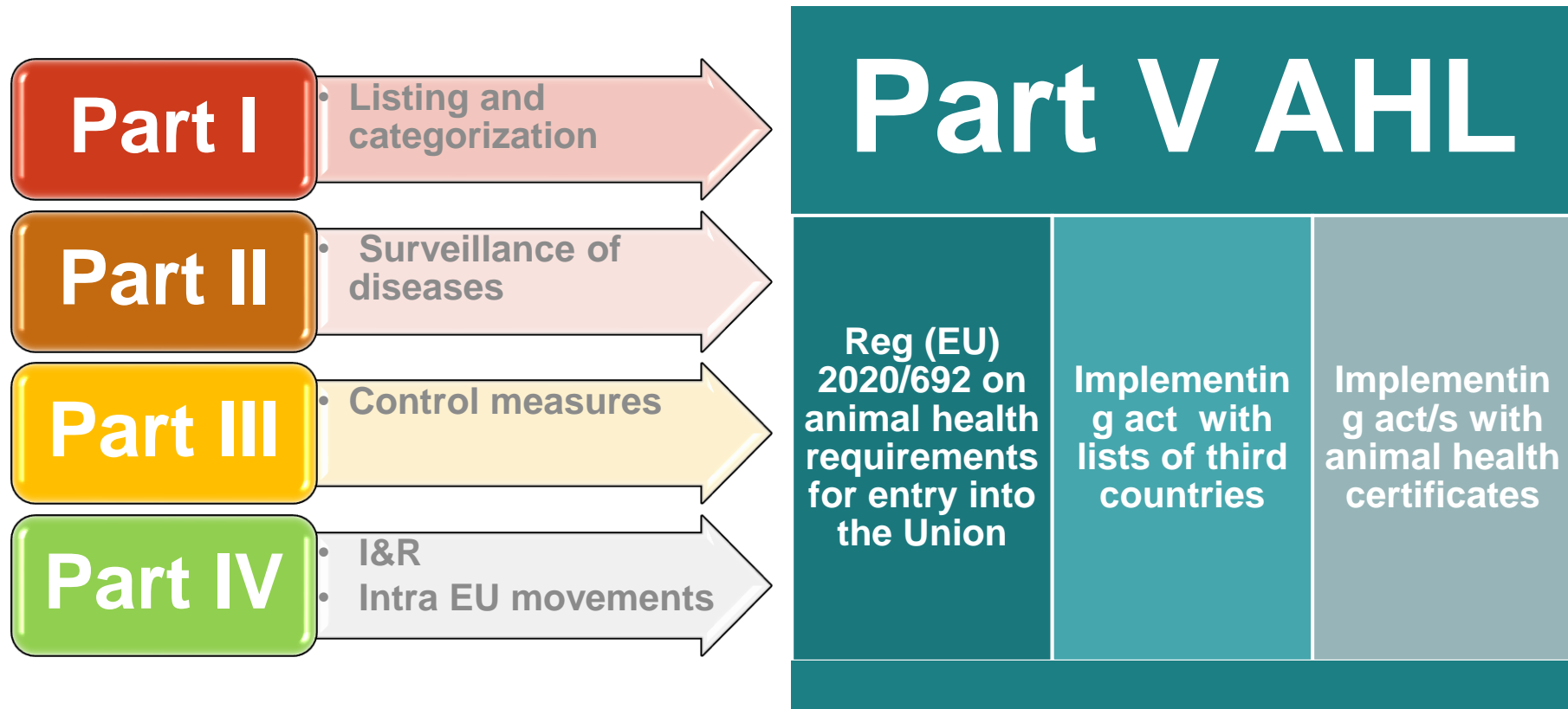
# Entry into EU of animals, germinal products and products of animal origin



- Requirements for entry into Union
- List of third countries and territories
- Approval and listing of establishments in third countries and territories
- Animal health requirements for entry into the EU of species and categories of animals, germinal products and products of animal origin
- Animal health certificates, declarations and other documents
- Derogations and special rules

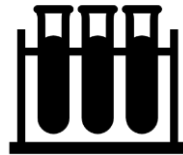


# Requirements for entry into the Union: interlinked acts



# Entry into EU of certain other goods and export from Union

- Entry of other goods:



- Disease agents
- Plant material
- Option provided for rules, if necessary
- Means of transport, equipment, packaging material, transport water and fodder



- Export from the Union

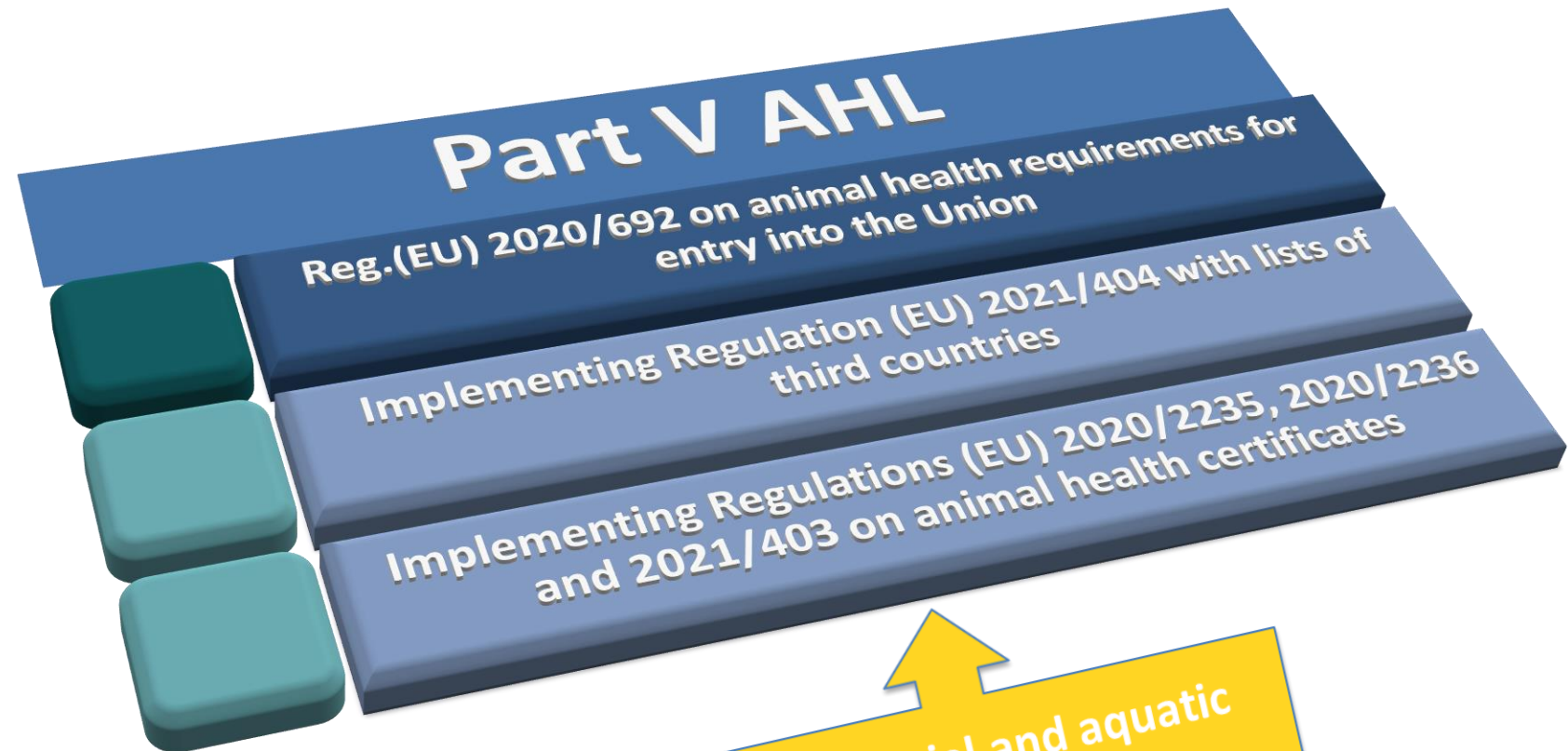


- Main objective: the export should not hamper animal health in third countries and territories, and their health statuses

Articles  
240 - 241

Article 243

# Entry into the Union



For terrestrial and aquatic animals

# Part VI: Non-commercial movements of pet animals



- Part VI of the AHL




- *Will apply after 21 April 2026*
- Until that date: Regulation (EU) No 576/2013 applies



# Part VII – Emergency measures



- Emergency measures in EU
  - By MSs and by the Commission
- Emergency measures on consignments from third countries and territories
  - By MSs and by the Commission
- **Remember:** 
  - these are “old” safeguard measures from Dir 90/425, 89/662, 97/78 and 91/496
  - emergency measures also exist in Reg (EU) No 178/2002 and Reg (EU) 2017/625

# Member States' national (stricter) measures

- Additional and more stringent measures by MSs in areas (Article 269):
  - Responsibilities on animal health (Articles 10-17)
  - Surveillance (Articles 24-30)
  - Registration, approval, record keeping and registers (Articles 84-107 and Articles 172-190)
  - Traceability (Articles 108-123)
- National disease control and movements measures in terrestrial animals
  - for Category D and E diseases (Article 170) and to limit the impact of diseases other than listed diseases in terrestrial animals (Article 171)
- National measures to limit the impact of diseases other than listed diseases in aquaculture animals (Article 226)
  - Currently under Decision (EC) 2010/221



# Common and Final Provisions

- “Grandfathers” rights
  - Existing operators and establishments (including I&R)
  - Existing disease free MSs, zones and compartments and existing MSs eradication and surveillance programmes
- Transitional provisions
  - Transitional measures for rules on identification and registration – **will not be used!**
  - Transitional measures for disease control rules (Category A diseases) – **will not be used!**
  - Transitional measures for rules on non commercial movements of pets
- Amendments to Regulation (EC) 1760/2000 – removing rules for “bovine animals”



# Annexes

- Annex I – species of pet animals (n.b. part of a definition)
- Annex II – list of diseases
- Annex III – species of ungulates (n.b. part of a definition)
- Annex IV – criteria for the application of the disease prevention and control rules referred to in Article 9(1) to diseases listed in accordance with Article 5
- Annex V – correlation tables

# Thank you for your attention



© European Union 2020

[https://ec.europa.eu/food/animals/health/regulation\\_en](https://ec.europa.eu/food/animals/health/regulation_en)

