



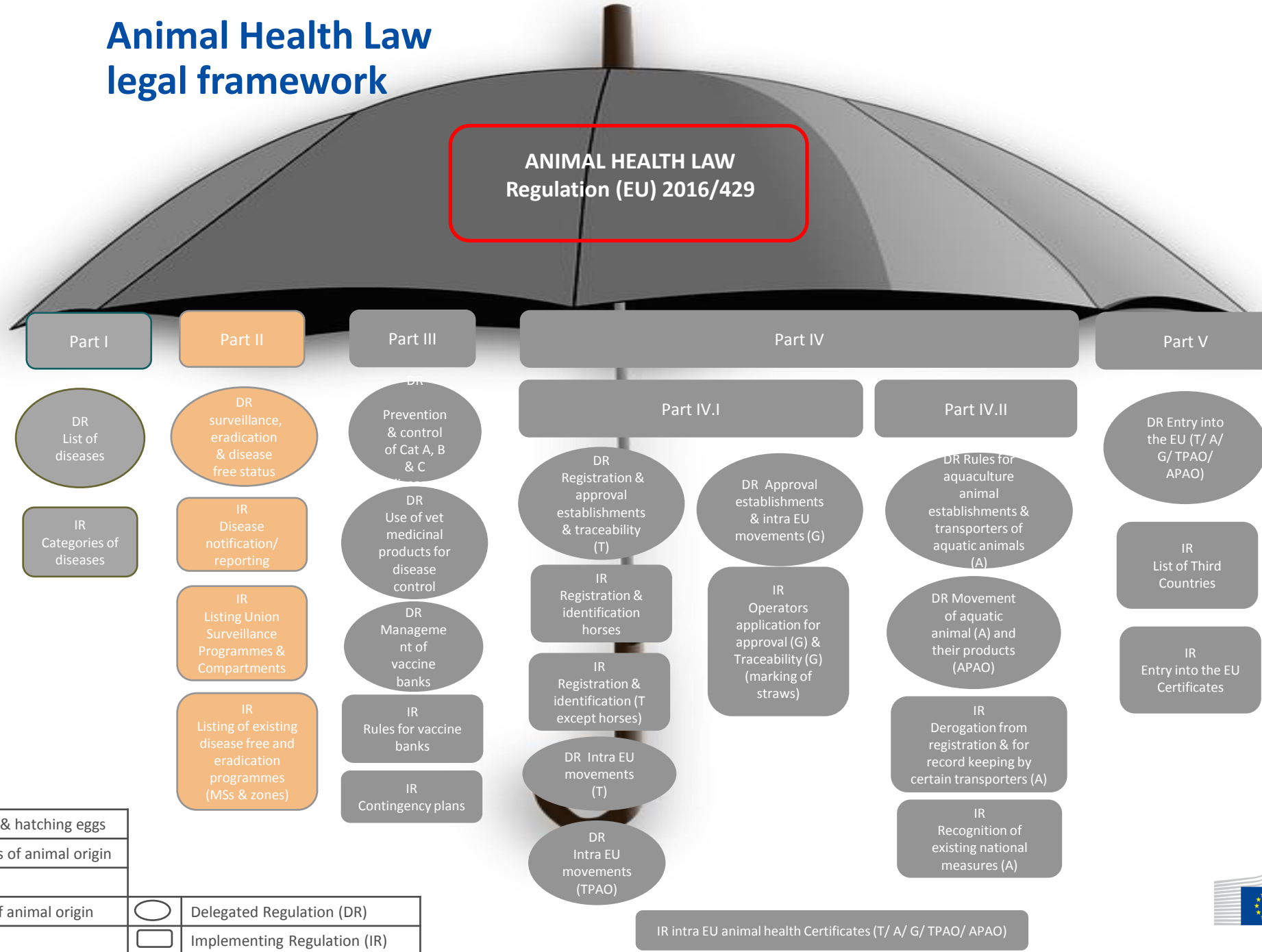
# Surveillance, eradication, disease freedom

Regulation (EU) 2016/429, Part II


Commission Delegated Regulation (EU) 2020/689

*BTSF 2021*

# 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
G	Germinal products

	Delegated Regulation (DR)
	Implementing Regulation (IR)

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

# Regulation (EU) 2020/689 & AHL Articles 18-42

1. Disease notification and reporting
2. Surveillance
3. Eradication programmes
4. Disease free status

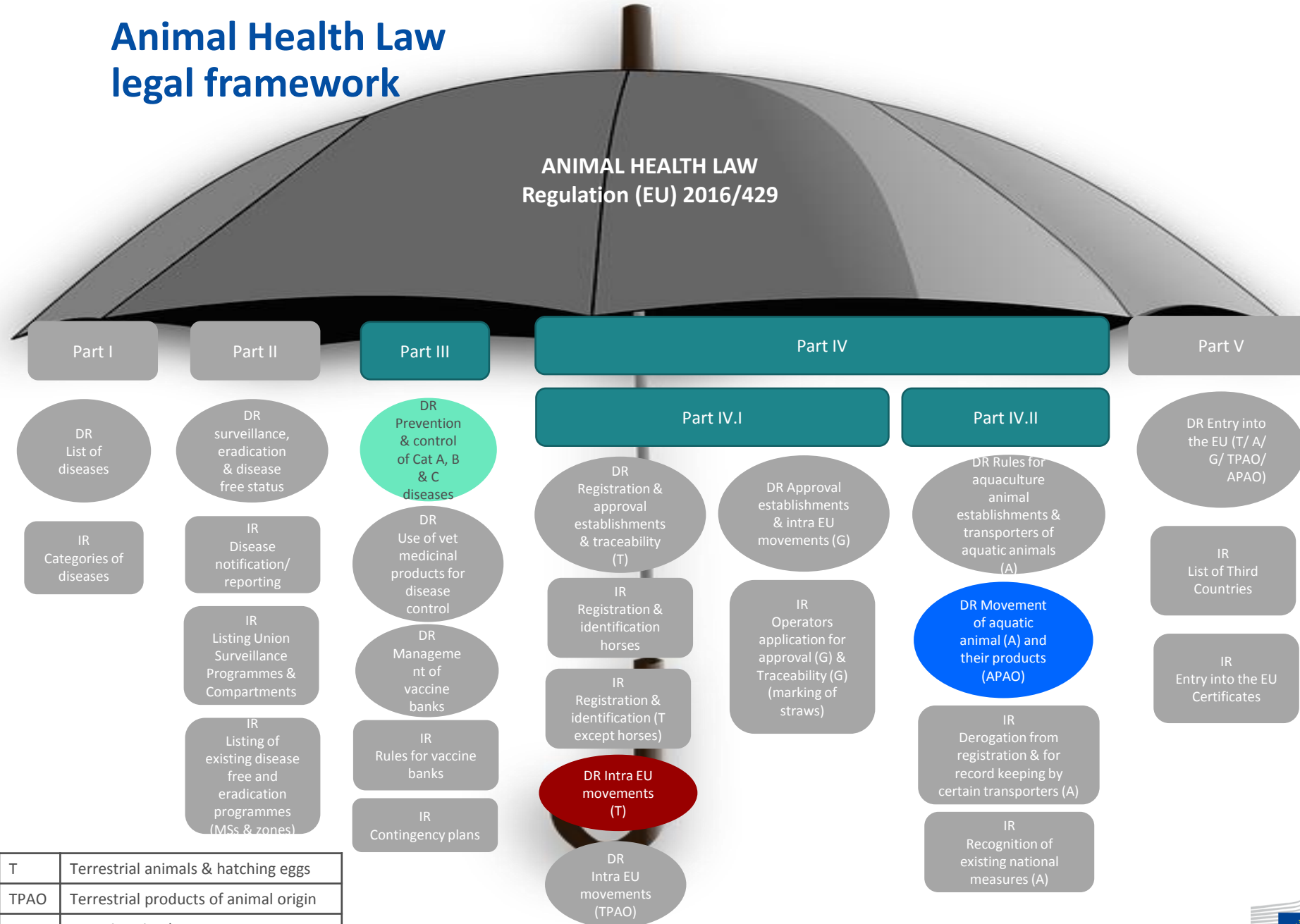
- Operator's obligations

- observe health, changes in the production parameters, abnormal mortalities
- Animal health visits for the purpose of prevention

- CA's obligation

- Presence of listed and emerging diseases

# 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
G	Germinal products

○	Delegated Regulation (DR)
□	Implementing Regulation (IR)

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

# Relations with other delegated acts

## With Part IV: Reg (EU) 2020/688 & Reg (EU) 2020/990

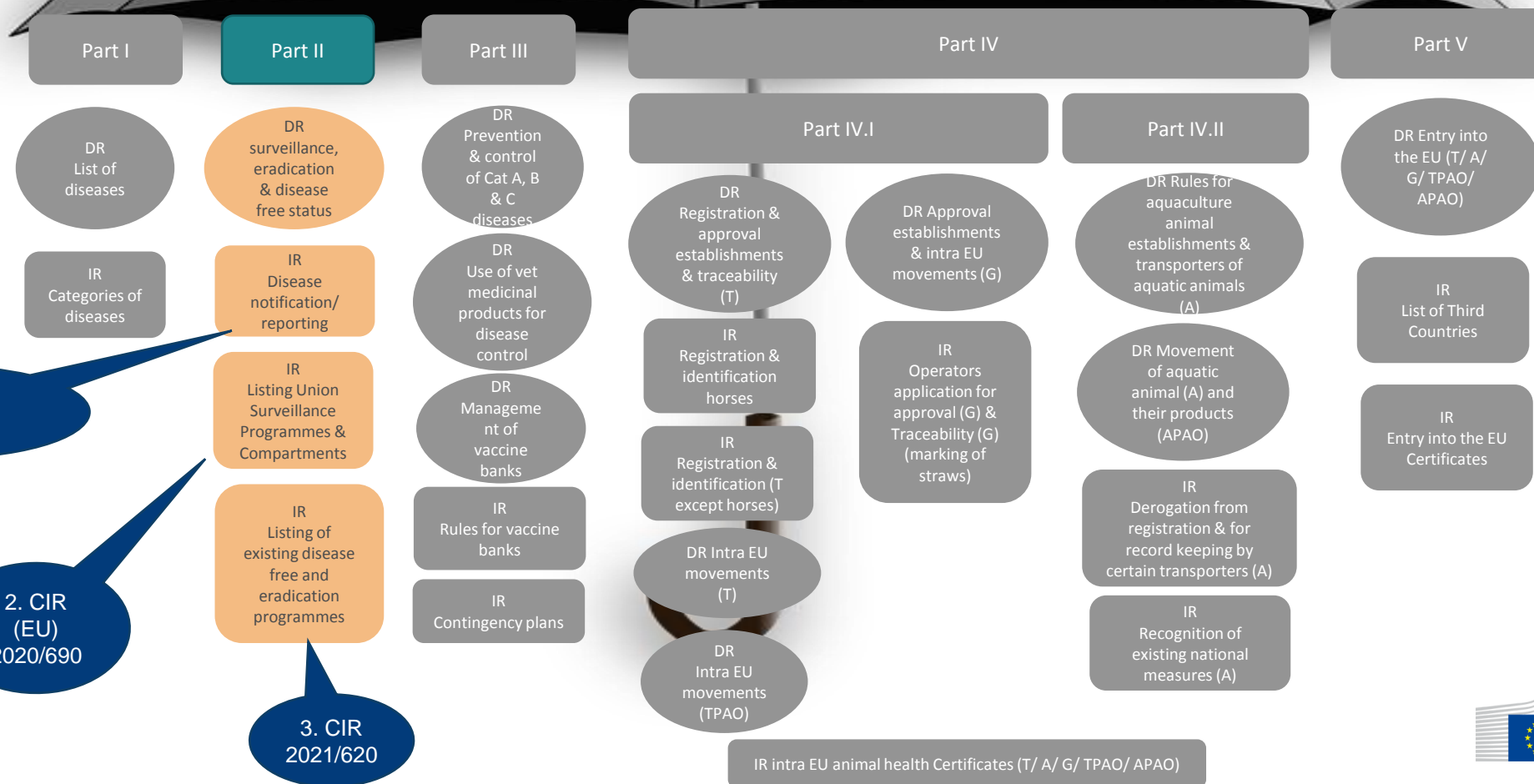
- Movement regime for diseases subject to eradication programmes
- **In this DA:** conditions to move animals into a disease-free area or one under a programme
- **In Part IV:** conditions to certify a movement from a MS to another MS (disease-free, under a programme or without status)

## With Part III: Reg (EU) 2020/687

- Disease control measures
- **In this DA,** those to be implemented in areas under a programme
- **In Part III,** those to be implemented in disease free areas (identical to those laid down in this DA)

# Animal Health Law legal framework

## ANIMAL HEALTH LAW Regulation (EU) 2016/429



# Complementing implementing acts

1. **CIR (EU) 2020/2002** on reporting and notification
  - Disease notification and reporting: diseases, deadlines, notification regions
  - Submission and reporting of eradication programmes, Union surveillance programmes
  - Applications for disease freedom
  - The computerised information system for Union notification and Union reporting of diseases
2. **CIR (EU) 2020/690** laying down rules as regards the listed diseases subject to USP, their geographical scope and the listed diseases for which the disease-free status of compartments may be established
  1. USP: Avian influenza (HPAI and LPAI viruses)
  2. Compartments: diseases of aquatic animals
3. **CIR(EU) 2021/620 listing** disease free areas and areas with an approved programme

# Acts repealed by this DA

## Diagnostic methods

- Decision 2000/428/EC: diagnostic methods SVD
- Decision 2002/106/EC: diagnostic methods SVD
- Decision 2003/422/EC: diagnostic methods SVD
- Decision 2006/437/EC: diagnostic manual AI
- Implementing Decision 2015/1554: diagnostic methods SVD

## Surveillance

- Regulation (EC) No 1266/2007: on surveillance of aquatic animals
- Decision 2008/896/EC: risk based surveillance-aquatic animals

## Acts listing free areas and approved programmes

- Repealed by CIR (EU) 2021/620 listing disease free areas and programme

**AS FROM APRIL 2021**



# Surveillance

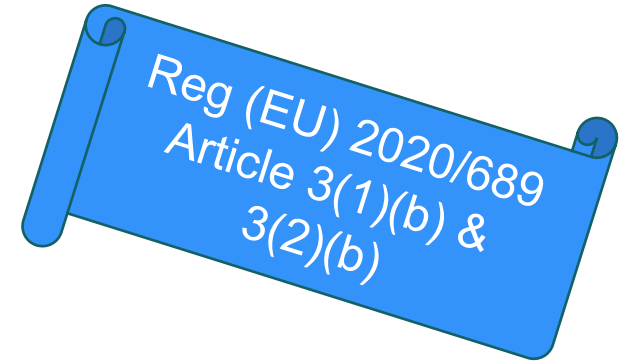


- **Obligation of the CA:** Design the surveillance for listed and emerging diseases
- **General requirements:**
  - Notification
  - Investigation of increased mortalities, decreased production rates, signs, suspicion of Category E diseases or emerging diseases
  - Contribution of official controls-other official activities

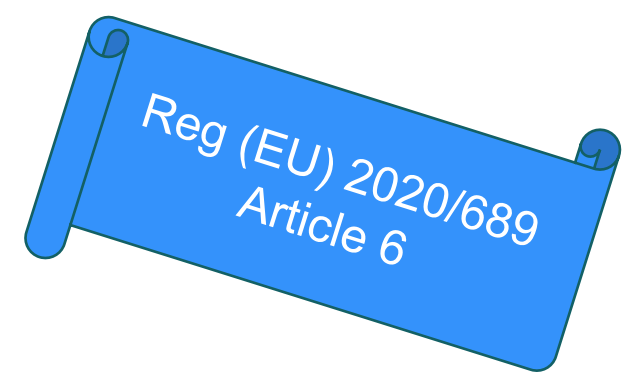
# Surveillance

- Specific surveillance requirements in the following circumstances:

- Union surveillance programmes (terrestrial only)
- Compulsory or optional eradication programmes plus maintenance of disease freedom
- Disease control measures
- Movements (trade-imports)
- Approval of establishments
- Risk-based surveillance (aquatic only)
- Voluntary surveillance programmes for Cat C diseases (aquatic only)



# Diagnostic methods



From a prescriptive approach to a more flexible approach

1. Specific legislation and guidance which will be made available in the websites of the EURL and COM

2. OIE Manuals

3. Art 34 of OCR

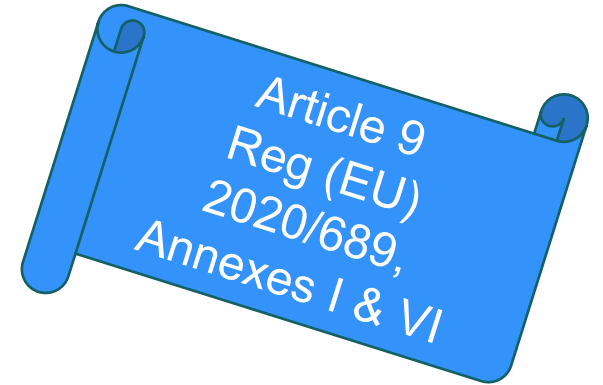


- National rules. In absence of national rules, relevant methods recommended by NRL validated in accordance with international standards or
- relevant methods validated with inter or intra-laboratory methods validation studies
- In case of urgency, NRL (in absence, other designated lab) may use methods which have not been validated



4. Diagnostic methods for granting and maintaining disease freedom are laid down in Annexes III and VI

# Case definition



## General definition

- Suspicion
  - Clinical, post mortem, laboratory examinations or results from a diagnostic method which are indicative of a particular disease
  - Epidemiological link with a confirmed case
- Confirmation
  - Isolation (excluding vaccine strains)
  - Animal with clinical signs or with an epidemiological link with a suspected or confirmed case where:
    - Antigen or nucleic acid (excluding vaccine strains) is identified or
    - Positive to an indirect diagnostic method (excluding vaccinations strains)

**Specific definitions:** HPAI, LPAI, NC in Annex I /Aquatic diseases in Annex VI

# Union surveillance programmes



- **Obligation of the CA** to perform surveillance for diseases that are relevant for the Union (Art 28 of AHL)
- For the time being, only **HPAI** (*and LPAI*)
- **Submitted** to the Commission, but no need for approval (Art 28 of AHL)
- **Content** of the AI Union surveillance programme: Annex II to Regulation (EU) 2020/689
- **Information** for the submission of the programmes and **reporting** obligations (Art 11 of Regulation (EU) 2020/689)
- **Deadlines** are in CIR (EU) 2020/2002 on reporting and notification
  - Submission: 31 May
  - Reporting: 15 March

# AI Union surveillance programmes



- **Early detection** of HPAI in poultry
- Early detection of HPAI in wild birds: targeted populations in EURL web
- Detection of HPAI in poultry species **not showing significant clinical signs**: targeted populations defined
- **Detection of LPAI** that may spread between flocks: targeted populations defined
- Contribution to increase the knowledge of **zoonotic risks**
- Sampling and laboratory testing methods

# Additional surveillance in aquaculture animals

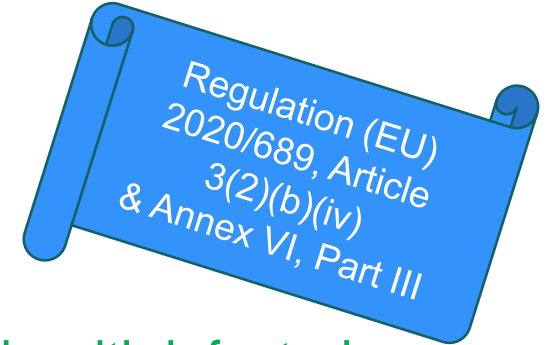
- Risk-based surveillance
  - Applied in certain **approved aquaculture establishments and groups of approved** aquaculture establishments approved in accordance with Regulation (EU) 2020/691
  - Objective is to detect increased mortality, listed diseases, emerging diseases
  - Depends on the risk the establishment poses in relation to contracting and spreading disease => **applies to listed and non-listed diseases**
  - **Ranking of establishments:** High / Medium/ Low
  - Maybe **combined** with health visits and sampling as part of:
    - Eradication programmes
    - Maintenance of freedom
    - Surveillance programmes



# Additional surveillance in aquaculture animals

- Surveillance programmes

- **Establishment** level
- Not participating in an eradication programme but **do not wish to trade with infected establishments**
- **Targeted surveillance** but at a lower level than for an eradication programme
- Details set out in Chapters 1 to 6 of Part III of Annex VI, depending on the disease
- **General requirements** – health visits and sampling
- **Specific requirements** for each Cat C disease to:
  - Demonstrate the implementation of the surveillance programme
  - Re-start a surveillance programme after a disease outbreak





# Eradication programmes

- For category B diseases (compulsory) and category C diseases (optional)
- Territorial scope: Member State, Zone(s) or compartment (aquaculture only)
  - **Zone (terrestrial)**: administrative unit of more than 2000 km<sup>2</sup> including at least one notification and reporting region-possible derogations
  - **Zone (aquatic)**: contiguous hydrological system with a distinct health status with respect to a specific disease or specific diseases that forms an area that is referred to in one of the following:
    - (i) An entire water catchment from source to the estuary or lake
    - (ii) More than one water catchment
    - (iii) Part of a catchment from the source to a barrier that prevents the introduction of disease(s)
    - (iv) Part of a coastal area with a precise geographical delimitation
    - (v) An estuary with a precise geographical delimitation

Reg (EU) 2020/689  
Article 13

AHL, Article 4  
Definition 35(b)

# Eradication programmes (aquatic)

## Compartment:

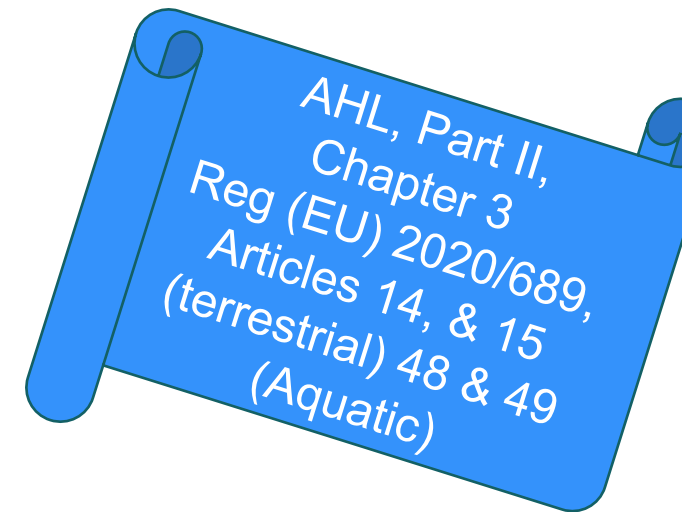
- animal sub-population
- contained in one or more aquaculture establishments
- common biosecurity management system
- distinct health status for specific disease(s)
- subject to appropriate disease control and biosecurity measures



May be independent of surrounding waters or dependent on the health status of surrounding waters

# Eradication programmes

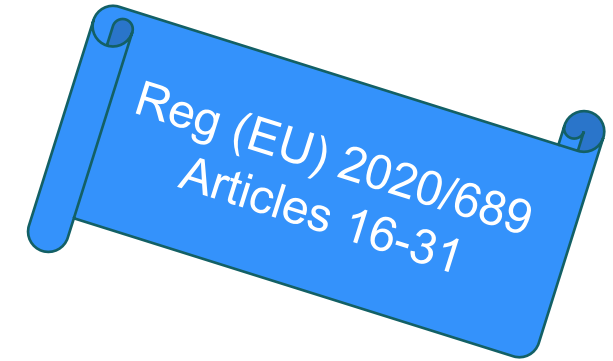
- **Targets:** intermediate and final to show progress towards eradication or its achievement
- **Duration:** for optional programmes maximum of 6 years
- **Deadlines** CIR (EU) 2020/2002 on reporting and notification
  - Submission: 31 May 2021 (compulsory) –any time (optional)
  - Reporting: 30 April
- **Content** of submitted programmes and reports (CIR (EU) 2020/2002)



# Eradication programmes - terrestrial

- Based on granting disease free status at the **level of establishments**
  - Cat B diseases (terrestrial): MTBC, infection with *Brucella abortus*, *B. melitensis* and *B. suis*
  - Cat C diseases (terrestrial): EBL, IBR/IPV, ADV, BVD
- Based on granting the disease free status at **an area level**
  - Cat B diseases: infection with RABV
  - Cat C diseases: infection with BTV

# Eradication programmes- terrestrial Establishment level



- Targeted population + additional animal **populations**
- Obligations of **operators**
  - General: surveillance ordered by the CA, introductions into their establishment, vaccination, disease control measures, any other additional measure
  - Disease specific: detailed rules for each disease in the annexes
- Obligation of **competent authorities**
  - Commence, maintain or withdraw the eradication programme
  - Grant, suspend and withdraw disease free status
  - Specify maximum period of time for a suspension
  - Define epidemiological units (in peace time)

# Eradication programmes- terrestrial. Establishment level

## Disease control measures

- Suspicion and confirmation
- Movement restrictions and derogations
- Suspicion and confirmation in wildlife
- Management of products
- Cleaning and disinfection
- Risk mitigating measures to prevent reinfection
- Testing regime and removal of animals
  - To complete the epidemiological enquiry
  - To restore the free status
  - Any additional testing
  - Slaughter-killing of confirmed cases (suspicion) in a maximum period of time to be determined

# Eradication programmes. Establishment level

## Annex: MTBC

- **Granting the status at establishment level**

- No cases in 12 months+ two tests + introduction from free establishments (if not from free areas pre-movement testing) + free germinal products
- Fast track for new establishments

- **Maintenance of status at establishment level**

- Conditions for granting are kept. Testing regime less frequent and finally risk based

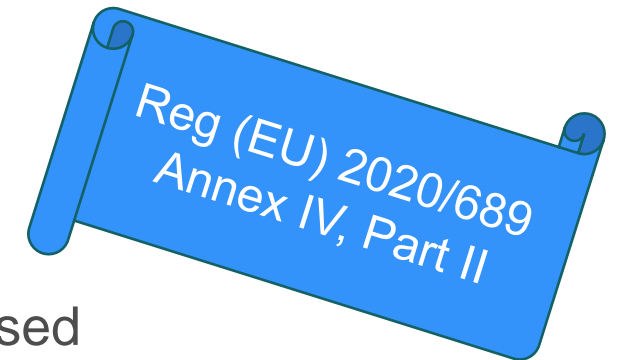
- **Suspension and restoring:**

- Conditions for maintenance are not kept
- Suspicion

- **Withdrawal**

- Suspension period elapsed
- Confirmation or MTBC cannot be ruled out
- Justified to control MTBC

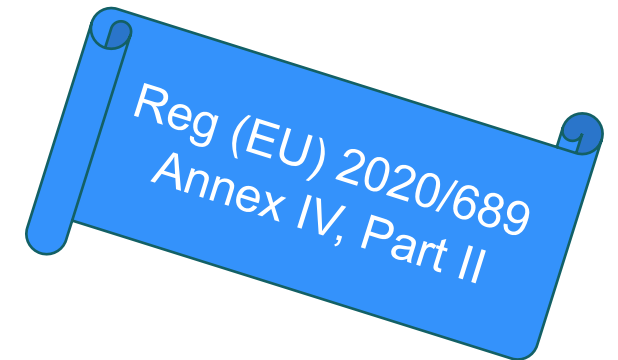
- **Regaining: fast track possible**



# Eradication programmes. Establishment level

## Annex: MTBC

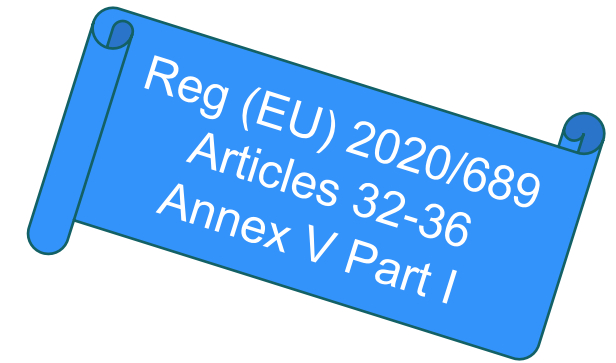
- **Granting of the status at MS or zone level**
  - Last three years 99.8% of establishments keeping 99.9% of population MTBC free
  - Incidence rate during the year not exceed 0.1%
  - Surveillance including at least
    - Ante and post-mortem surveillance
    - Investigation of any lesion
- **Maintenance at MS or zone level**
  - After two years of MTBC freedom, switch to a risk based approach





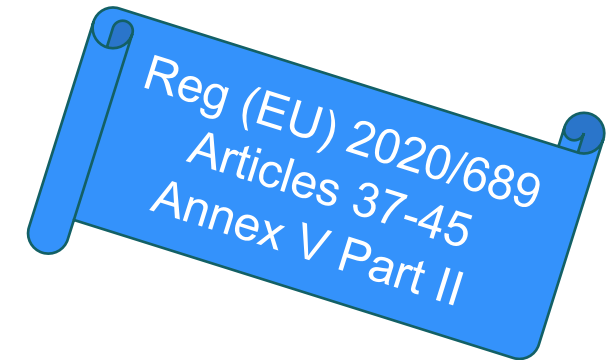
# Eradication programmes. Rabies

- Mostly focused on **foxes**
- **Obligations** of CA
  - Surveillance
  - Disease control measures
  - Vaccination
    - In kept animals
    - In wild animals: regular campaigns, bait distribution, control-GIS, monitoring
- MS or zones **rabies free**
  - General surveillance in the last 24 months and 24 months without cases



# Eradication programmes. BTV

- To eradicate **all serotypes**
- All MS or minimum of 150 km around infected establishment (derogations)
- Based **on vaccination** (unless risk assessment justifies the contrary)
- Disease control measures
- Movement restrictions into areas free or under a programme
  - Movements that always are to be accepted
  - Movements that may be accepted: **no bilateral agreements**
- Annex
  - Surveillance
  - Movement requirements
  - Granting and maintaining the status



# Eradication programmes: Aquatic animals

- **Territorial scope**: MS/ zone/compartment
- **Species** to be included: All establishments keeping relevant listed species
- By way of derogation, **establishments may be excluded** if:
  - they do not pose a significant risk to the success of the programme &
  - are exempted from the requirement for approval
- Establishments **keeping only vector species** may also be excluded from the programme based on a risk assessment
- **Intermediate and final targets** to show progress towards eradication, or its achievement



# Measures in MS/zones/ compartments covered by eradication programmes (aquatic)

- **Obligations of operators**

- General: surveillance ordered by the CA, introductions into their establishment, notification, vaccination (where relevant), disease control measures, any additional measures
- Disease specific: detailed rules for each Cat C disease in Annex VI
- Comply with the above until the programme has been successfully completed or is withdrawn

- **Obligation of competent authorities**

- Commence, maintain or withdraw the eradication programme
- Inform operators on evolution of programme



# Eradication programmes (aquatic)

## Disease control measures

- Suspicion and confirmation of Cat B or relevant Cat C disease (Ref Annex VI)
- Movement restrictions – animals & products
- Certain derogations & risk mitigating measures
- Possible extension of disease control measures
- Removal of animals (slaughter or killing)
- Cleaning, disinfection, following
- Risk mitigating measures to prevent reinfection
- Complete the epidemiological enquiry
- Restore the free status



# Eradication programmes: Aquatic animals

## Annex VI

- Requirements for **health visits and sampling** for all Cat C diseases of aquatic animals
  - Fish: VHS, IHN, infection with HPR-deleted ISAV
  - Molluscs: infection with *Marteilia refringens*, infection with *Bonamia exitiosa*, infection with *Bonamia ostreae*
  - Crustaceans: infection with WSSV
- **Specific requirements** for each disease
  - number of health visits per year
  - number & category of animals to be tested
  - period of time to run the programme
  - Organs and tissue material to be sampled
  - Diagnostic methods to be used



# Eradication programmes: Aquatic animals

## Example: VHS /IHN

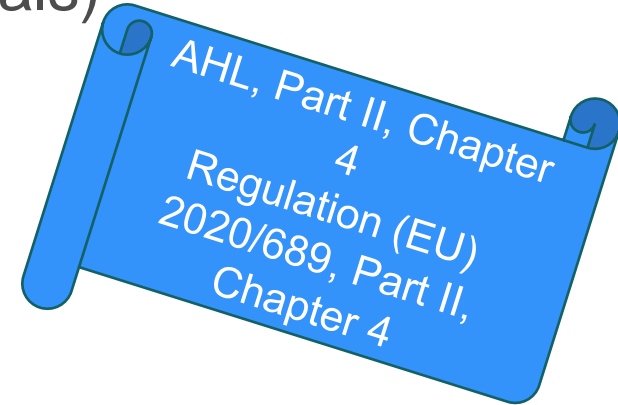
- General requirements for **health visits & sampling** (water temp, intervals between samples, selection of animals to be tested, sampling in the wild where necessary)
- Granting of **disease- free status in MS/zone/compartment with an unknown health status** ( 2 year model or 4 year model, number of health visits/ year, timing of health visits, number of samples per year, categories of animals to be tested, number of animals per sample, number of fish per pool)
- Granting of **disease –free status in MS/zone/compartment known to be infected** (as above plus disease control measures)
- Surveillance required to **maintain disease-free status**
- **Diagnostic methods** to be used



**NOTE:** Similar structural approach is taken to all Cat C diseases as set out in Chapters 1 to 6, Part II, Annex VI

# Disease freedom

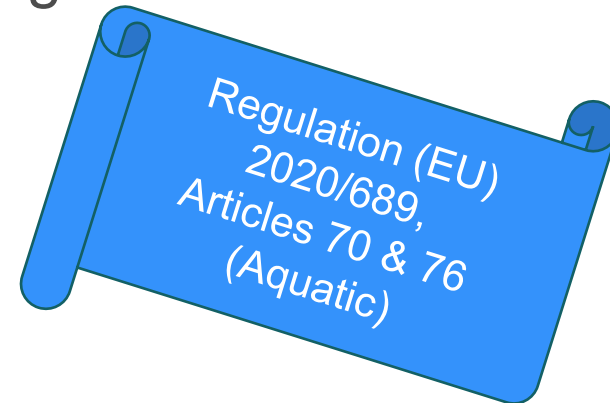
- MS, zone or compartment level (only aquatic animals)
- Several pathways
  - **Absence** of listed species
  - Disease agent's **incapacity to survive**
  - **Incapacity to survive** of listed vectors for listed diseases of terrestrial animals
  - Based on **historical** and surveillance data
  - Based on **eradication** programmes
  - Specific rules for certain aquatic compartments which are independent of surrounding waters
- Details for the submission in CIR (EU) 2020/2002 on reporting and notification





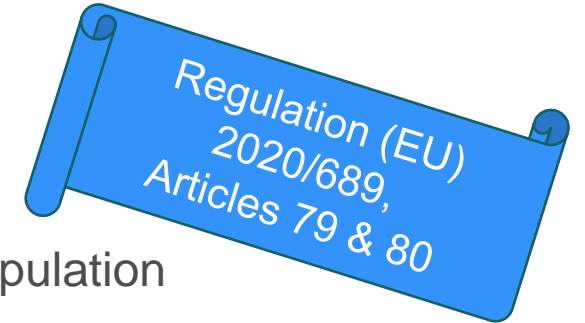
# Disease freedom based on historical and surveillance data

- **Never** reported or was **eradicated** more than 25 years ago
- Reported in the last 25 years and eradicated in accordance with the eradication criteria of this Regulation
- **Only possible** in a new MS or for a newly categorised disease for a period of 2 years
- **Particular cases:**
  - Rabies and infection with BTV
  - Varroa and status free from infections with Newcastle virus without vaccination
  - BVD, infection with *Bonamia exitiosa*, Infection with WSSV



# Disease freedom: specific rules for independent aquatic compartments

- An independent compartment which **commences or re-commences aquaculture activities** after a break is considered to be disease-free when it:
  - Has never had a Cat B or Cat C disease
  - It has been cleaned, disinfected and fallowed if necessary, prior to re-population
  - It is re-stocked with animals from a disease-free MS/zone/compartment
- An independent compartment which **re-commences aquaculture activities after an outbreak** of a Cat B or Cat C disease is considered to be disease-free when:
  - It has been cleaned, disinfected and fallowed prior to re-population
  - It is re-stocked with animals from a disease-free MS/zone/compartment
  - The first cohort is sampled 3-12 months after re-population using a sample size that ensures the detection of the relevant pathogen with a 95% confidence if the targeted prevalence is 2%



# Maintenance and suspension

- Maintenance:

- General principles: surveillance, biosecurity
- Specific disease requirements: reference to the annexes

- Suspension

- Intermediate step before withdrawal
- Can be used as a transitional measure after suspicion or confirmation
- It provides time to manage the situation informing regularly MS and the Commission



# Particular cases

Free from infestation with *Varroa spp.*, and Status free from infection with Newcastle disease without vaccination

- No provisions for eradication programmes
- Requirements in Annex V to grant the status

*Echinococcus multilocularis*

Provisions for freedom based on Regulation 576/2013 are valid until 2026

# Transitional provisions

- Existing disease free areas

- They are considered as free areas under the provisions of this Delegated Regulation
- They are listed in CIR 2021/620
- MS must ensure that the conditions of maintenance conform with the provisions of this Delegated Regulation

- Existing eradication or surveillance programmes

- They are considered as approved under the provisions of this Delegated Regulation for 6 years
- They are listed in CIR 2021/620
- MS must ensure that the measures conform with the provisions of this Delegated Regulation



# Thank you



© European Union 2020

Unless otherwise noted the reuse of this presentation is authorised under the [CC BY 4.0](https://creativecommons.org/licenses/by/4.0/) license. For any use or reproduction of elements that are not owned by the EU, permission may need to be sought directly from the respective right holders.

Slide xx: **element concerned**, source: e.g. [Fotolia.com](https://www.fotolia.com/); Slide xx: **element concerned**, source: e.g. [iStock.com](https://www.istock.com/)