



Disease prevention and control measures

NEW LEGISLATION ON ANIMAL HEALTH

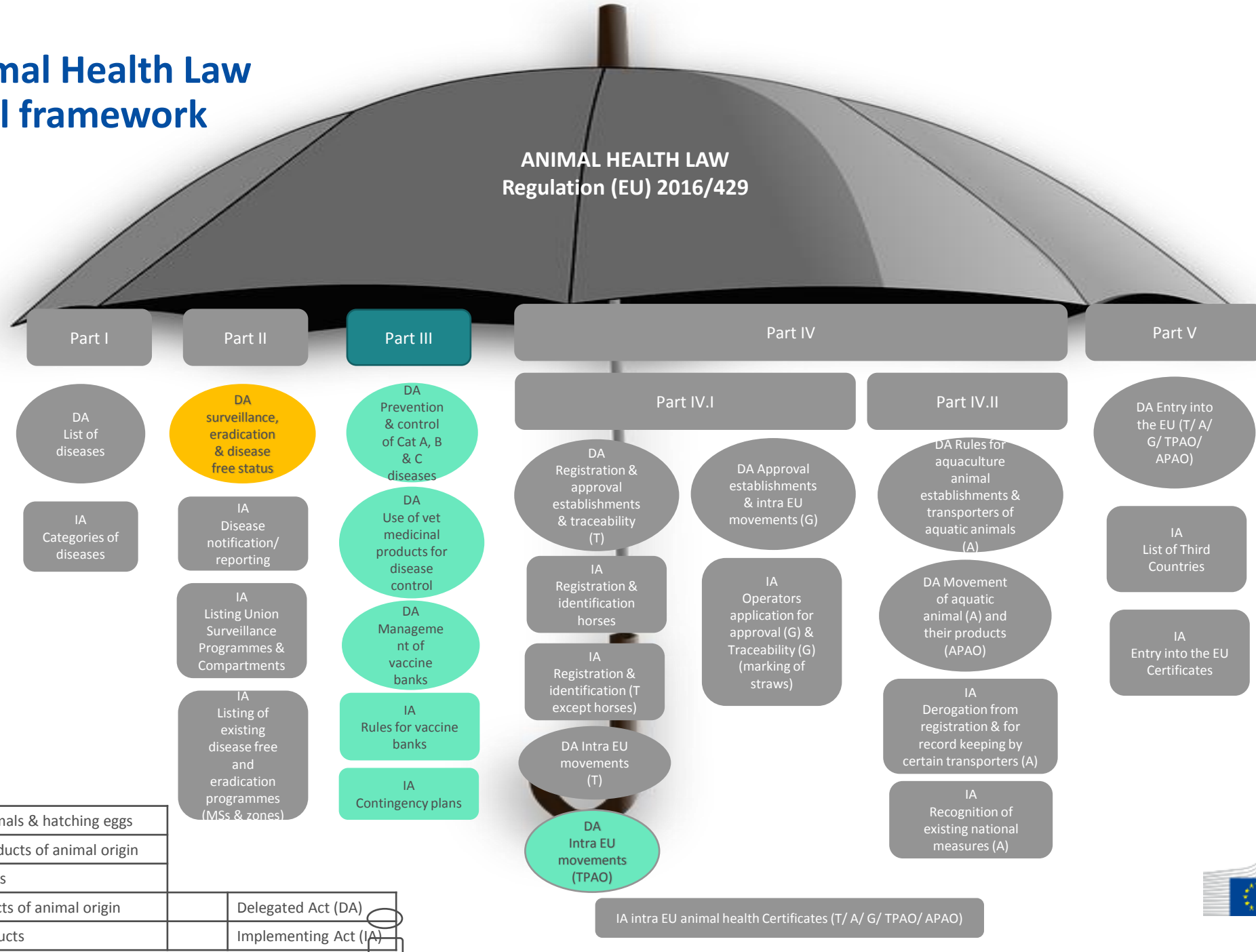
BRUSSELS, BELGIUM 2020-2021

European Commission

The infographic features a central title "NEW LEGISLATION ON ANIMAL HEALTH" surrounded by various icons representing different aspects of animal health and disease control. These include a dog, a cow, a horse, a fish, a chicken, a pig, a sheep, a microscope, a location pin, a computer screen with a magnifying glass, a barcode with the date "21/04-2021", a factory, a truck, and a ship. The background is a light blue and green gradient with a faint map of Europe.

DG SANTE Unit G2 – Animal Health

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 Act (DA)
	Implementing Act (IA)

Legal acts involved

- ✓ **Commission Delegated Regulation (EU) 2020/687** as regards rules for the prevention and control of certain listed diseases
- ✓ **Commission Delegated Regulation (EU) 2021/... [SANTE/7144/2020]** on the use of veterinary medicinal products for prevention and control of certain listed diseases
- ✓ **Commission Delegated Regulation (EU) 2020/689** as regards rules on surveillance, eradication programmes and disease-free status
- ✓ **Commission Delegated Regulation (EU) 2020/2154** as regards animal health certification and notification requirements for movements within the Union of products of animal origin from terrestrial animals
- ✓ **Commission Delegated Regulation (EU)** on the management of the EU vaccine banks
- ✓ **Commission Implementing Regulation (EU)** on the rules for the EU vaccine banks
- ✓ **Commission Implementing Regulation (EU)** on contingency plans

Commission Delegated Regulation (EU) 2020/687 as regards rules for the prevention and control of certain listed diseases

Supplementing Articles 53 to 69 of the AHL



Process



Rules replaced by this DA from 21 April 2021

- ✓ Directive 92/35/EEC on African horse sickness
- ✓ Directive 92/66/EEC on Newcastle disease
- ✓ Directive 92/119/EEC on various diseases (LSD, etc.)
- ✓ **Directive 2000/75/EC** on Bluetongue
- ✓ Directive 2001/89/EC on classical swine fever
- ✓ **Directive 2002/60/EC** on African swine fever
- ✓ Directive 2003/85/EC on foot and mouth disease
- ✓ Directive 2005/94/EC on avian influenza
- ✓ Directive 2006/88/EC on aquaculture animals
- ✓ Implementing acts (e.g. on diagnostic manuals 2003/422/EC, 2002/106/EC and 2014/709/EU on ASF)

Approach: following R(EU) 2016/429

R (EU) 2016/429

- Part III

- Title II

- Chapter 1

- Chapter 2

Suspicion

Epidemiological enquiry

Disease confirmation

Measures in the affected establishment and epidemiologically linked establishments

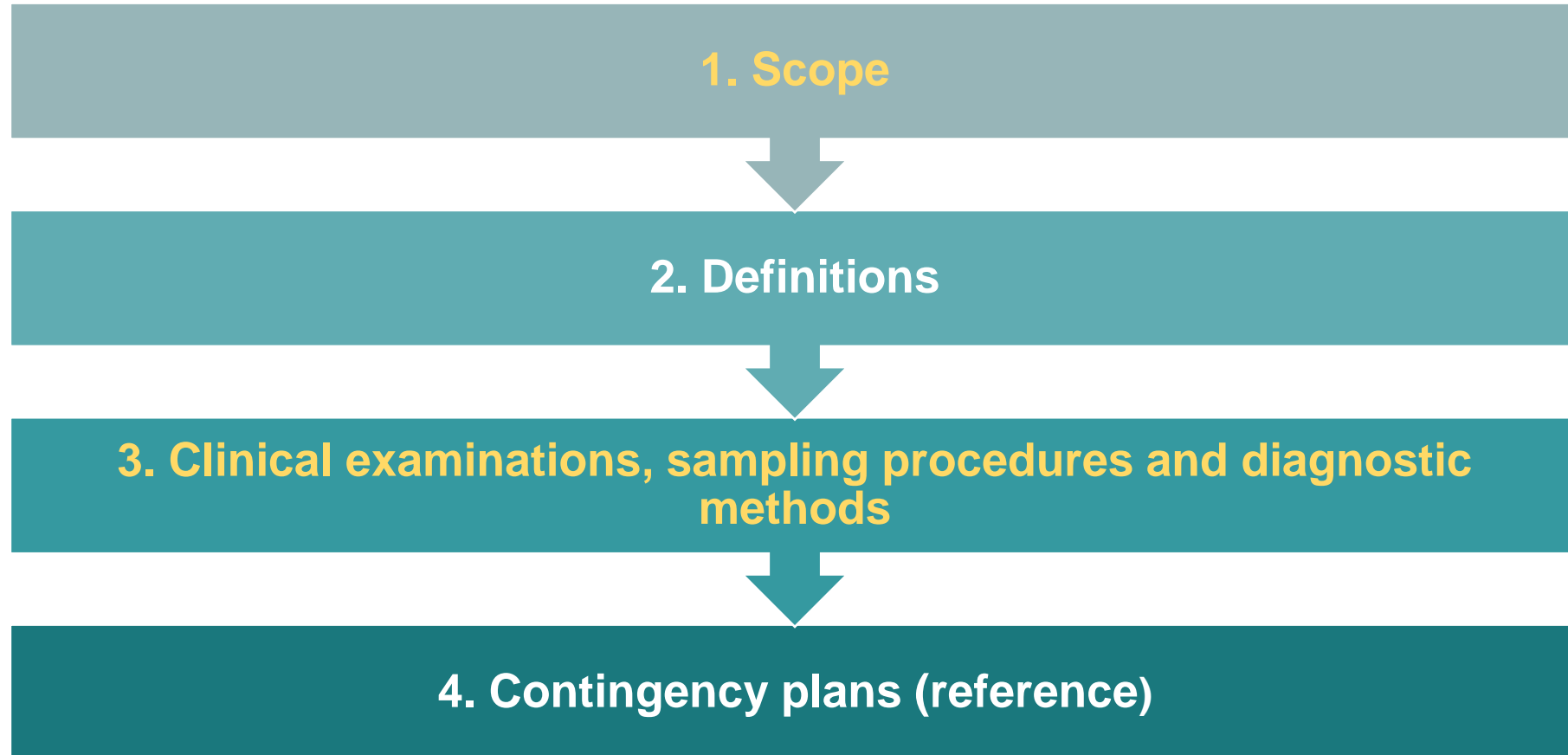
Establishment of restricted zones

Disease control measures in the restricted zones

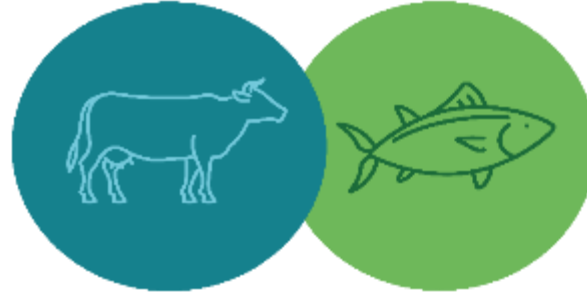
Wild animals

Part I – General provisions

General articles



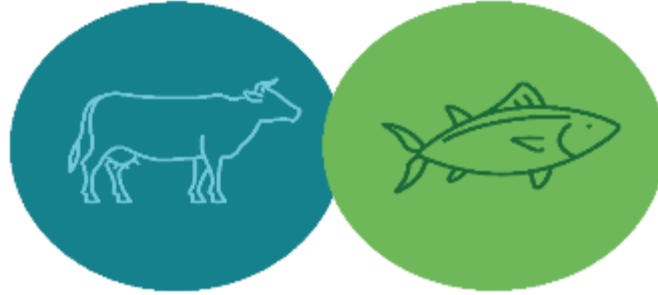
Scope 1



**Category A
diseases**



Scope 2

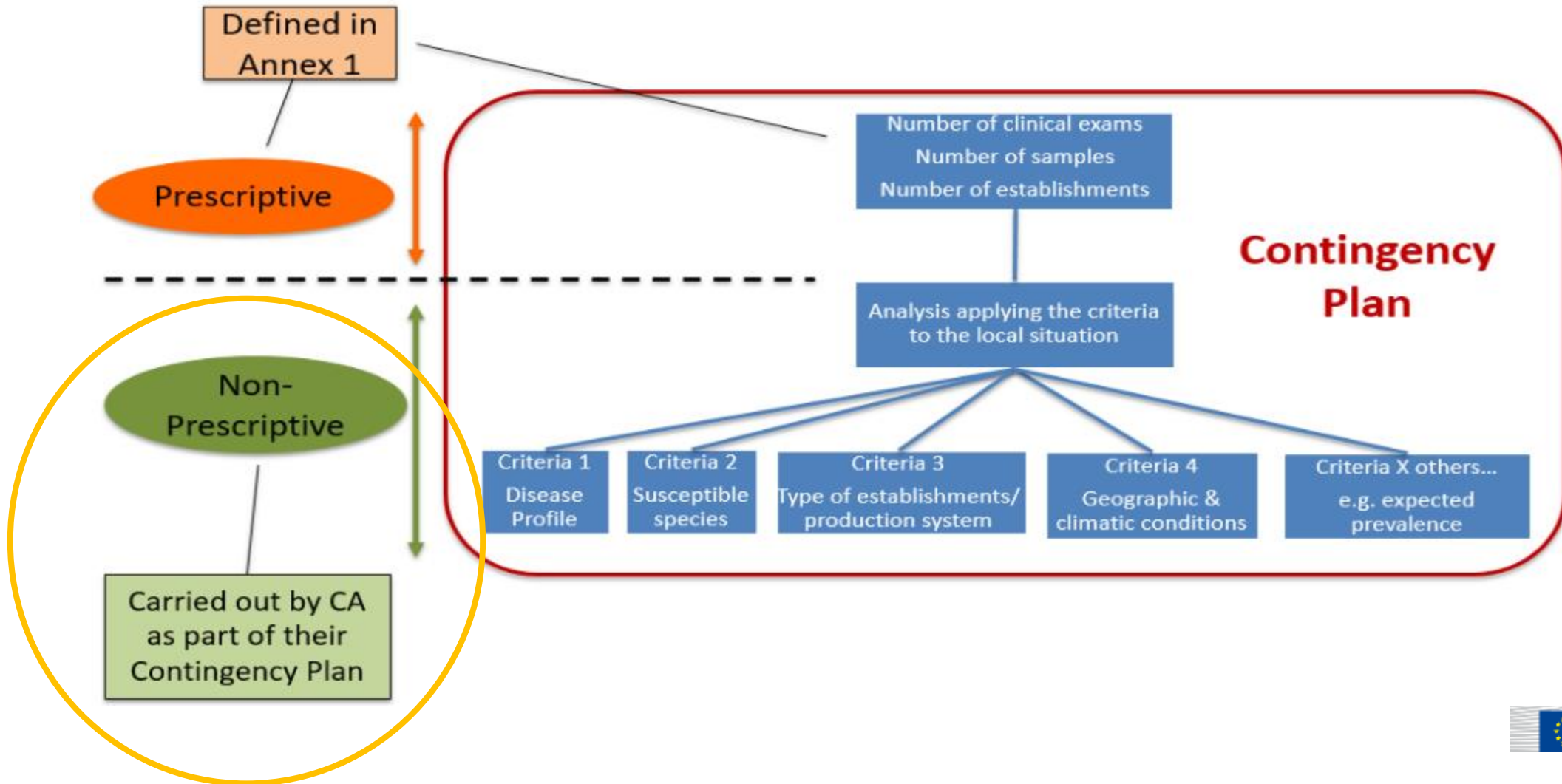


**Category B
and C
diseases**



Reference to **Commission Delegated Regulation (EU) 2020/689** as regards rules on surveillance, eradication programmes and disease-free status

Sampling procedures



Diagnostic methods

- ✓ Reference to Commission Delegated Regulation (EU) 2020/689 for the techniques, validation and interpretation of the diagnostic methods:
 - ✓ Article 6(1) for **terrestrial animals**: reference to **OIE**
 - ✓ Annex VI for **aquatic animals (C diseases)**: **disease specific**



Part II – Terrestrial animals



Suspicion of a category A disease



5. Obligations on operators in the event of a suspicion in an establishment



6. Investigation by the CA in the event of a suspicion in an establishment



7. Preliminary restriction and biosecurity measures



8. Inventory and record analysis



9. Temporary restricted zones



10. Measures to applied in case of suspicion in food and feed businesses, etc.

Obligations on operators



- ✓ Isolate all animals suspected of being infected with the category A disease;
- ✓ Keep the manure, including litter and used bedding, and any product, material or substance likely to be contaminated with and to transmit category A diseases isolated and protected from insects and rodents, kept animals of non-listed species and wild animals to the extent technically and practically feasible;
- ✓ Implement the appropriate additional biosecurity measures to avoid any risk of spread of the category A disease;
- ✓ Cease all movements of kept animals of listed species from or to the establishment;
- ✓ Prevent non-essential movements of animals of non-listed species, products, materials, substances, persons and means of transport from or to the establishment;
- ✓ Ensure that production, health and traceability records of the establishment are updated;
- ✓ Provide the competent authority, on its request, with any relevant information regarding the category A disease; and
- ✓ Follow any instructions given by the competent authority regarding the control of the category A disease, in accordance with Regulation (EU) 2016/429 and this Regulation.

Inventory and record analysis



MONITORING PERIOD

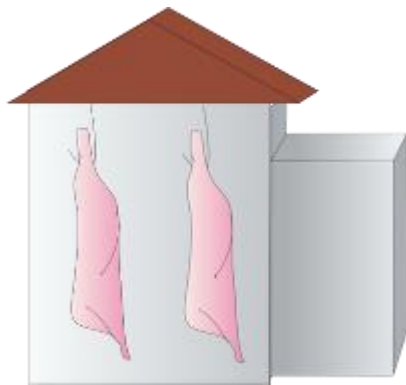


- ✓ A time frame of reference (related to the incubation period, but not equivalent) set out for each category A disease of **terrestrial animals** (Annex II) to specify the period of time:
 - ✓ that must elapse for the competent authority to apply, order, authorise or lift certain disease control measures;
 - ✓ that must be covered by the competent authority in certain investigations and record analysis;
 - ✓ before which certain commodities originating in the restricted zone may be considered as not posing a risk of spreading of disease.

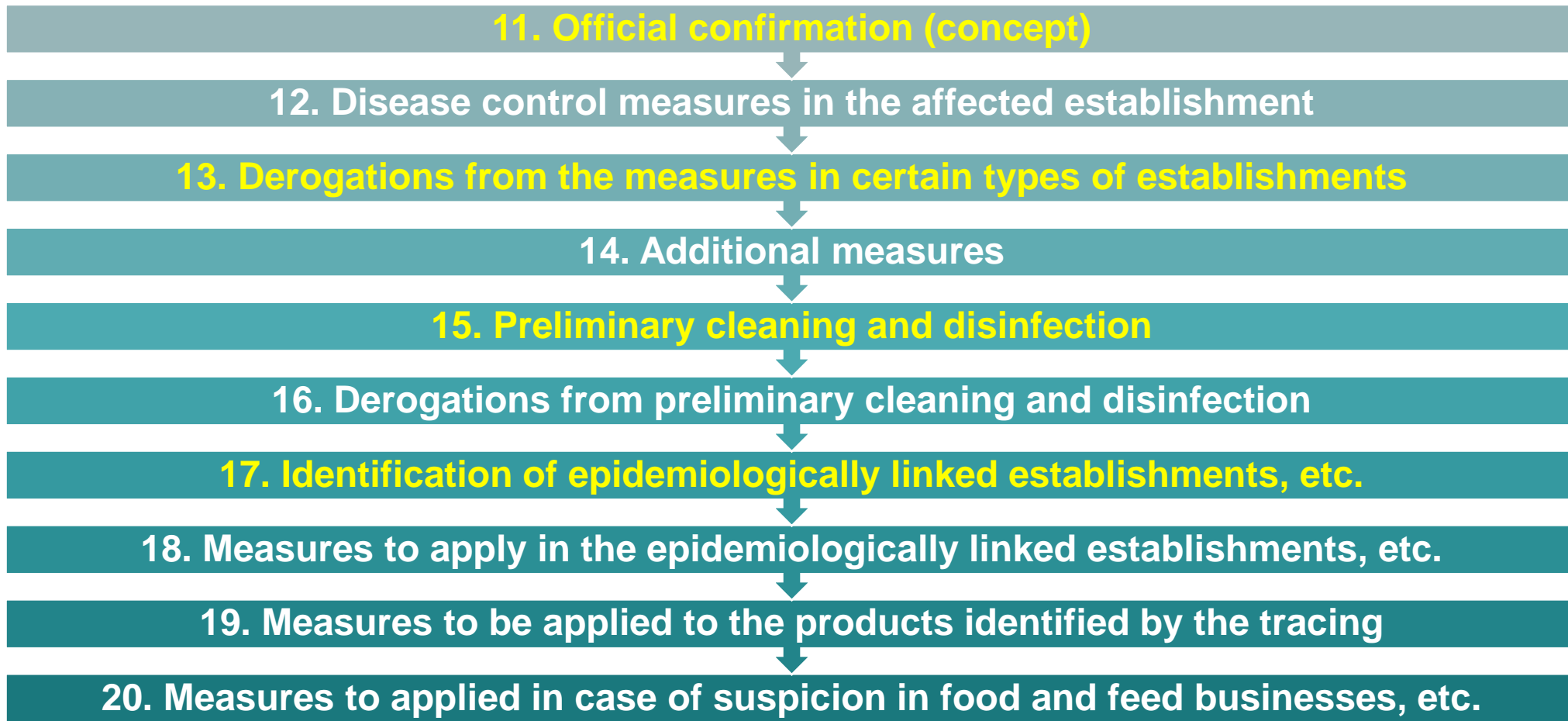


Measures to be applied in food and feed businesses, border control posts, animal by-products establishments or any other location of relevance, including means of transport

- ✓ The DA contains specific rules for these type of establishments and locations in each Section/Chapter, providing to the competent authority with the possibility to adapt the rules to the specific situation and, in certain cases, providing for specific rules and derogations.



Confirmation of a category A disease





Official confirmation (concept)

The competent authority shall officially confirm an outbreak of a category A disease in kept terrestrial animals when a case is confirmed in accordance with **Article 9(2), (3) and (4) of Delegated Regulation (EU) 2020/689**:

- ✓ The competent authority shall classify an animal or a group of animals, as a confirmed case of a listed disease or of an emerging disease when:
 - (a) **the disease agent**, excluding vaccine strains, **has been isolated** in a sample from an animal or from a group of animals;
 - (b) **an antigen or nucleic acid specific to the disease agent that is not a consequence of vaccination has been identified** in a sample from an animal or from a group of animals showing clinical signs consistent with the disease or an epidemiological link with a suspected or confirmed case; or
 - (c) **a positive result from an indirect diagnostic method** that is not a consequence of vaccination has been obtained in a sample from an animal or **from a group of animals showing clinical signs consistent with the disease or an epidemiological link with a suspected or confirmed case.**

Derogations from killing



The DA provides for the possibility for the CA to grant derogations from killing, after a risk assessment has been carried out and subject to specific biosecurity measures. The scope of such derogations is wider than in the current legislation. They cover:

- ✓ animals kept in a confined establishment;
- ✓ animals kept for scientific purposes or purposes related to conservation of protected or endangered species;
- ✓ animals officially registered in advance as rare breeds;
- ✓ animals with a **duly justified high genetic, cultural or educational value**;
- ✓ equine animals (AHS and Glanders).

Preliminary cleaning and disinfection



The DA maintains the concept of **'preliminary cleaning and disinfection'** as the starting point to countdown the period during which measures are in place in the restricted zone.

The concept of **'final cleaning and disinfection'** is also maintained as the starting point to countdown the waiting period before repopulating the affected establishments.



Identification of epidemiologically linked establishments and other locations of relevance, including means of transport



- ✓ 'In the frame of the **epidemiological enquiry**': supplementing **Article 57 of the AHL** (no duplication of rules)
- ✓ **Safe commodities** may be excluded (detailed in Annex VII based in the OIE terrestrial code)
 - ✓ Casings for LSD
 - ✓ Milk for CBPP and CCPP
- ✓ The CA must impose **measures** in such establishments and locations depending on the type of epidemiological link with the affected establishment



Restricted zone



21. Establishment of a restricted zone



22. Measures to be applied in the restricted zone



23. Derogations from measures to be applied in the restricted zone



Requirements for the means of transport of kept animals of listed species and products

Establishment of a restricted zone



- ✓ **Restricted zone = protection zone + surveillance zone + further restricted zones(optional)**
- ✓ **Size: specified in Annex V for each category A disease**
- ✓ **Derogations from the establishment of the restricted zone: the CA may decide not to establish the restricted zone when the outbreak is confirmed in:**
 - a) establishments keeping animals referred to **Article 13(2)**;
 - (b) **hatcheries**;
 - (c) food and feed businesses, border control posts, animal by-products establishments;
 - (d) means of transport;
 - (e) locations where **assembly operations or temporal exhibition or veterinary assistance of animals take place**; and
 - (f) any other location which is **not an establishment**.

Measures to be applied in the restricted zone



Inventory of establishments

Possibility of preventive killing or slaughtering

Rules for the movement of ABP, including certification requirements

Conditions for transit through the RZ

Derogations to the measures to be applied in the restricted zone



The competent authority may grant derogations from **ALL** the measures to be applied in restricted zones, to the extent necessary and after carrying out a risk assessment:

- ✓ in the **further restricted zones** referred to in Article 21(1)(c);
- ✓ in the case that the competent authority decides to establish a restricted zone when an outbreak of a category A disease occurs in **establishments and locations referred to in Article 21(3)**;
- ✓ in the case that the outbreak occurs in an **establishment keeping up to 50 captive birds**; or
- ✓ in **establishments and locations referred to in Article 21(3)** located in a restricted zone.

Summary: levels of flexibility



Article 13: situations in which the **killing of animals** kept in affected establishments is optional

Article 21: situations in which the **establishment of a restricted zone** is optional

Article 23: situations in which, after establishing a restricted zone, **the measures to be applied** are optional

Protection zone



25. Measures to be applied in establishments in the PZ

26. Visits by OV in the establishments in the PZ

27. Prohibitions in the PZ

28. General conditions to grant derogations from prohibitions

29 to 37. Specific conditions to authorise certain movements

38. Measures to apply in food and feed businesses, ABP establishments, BCP, etc

39. Duration of the measures in the PZ

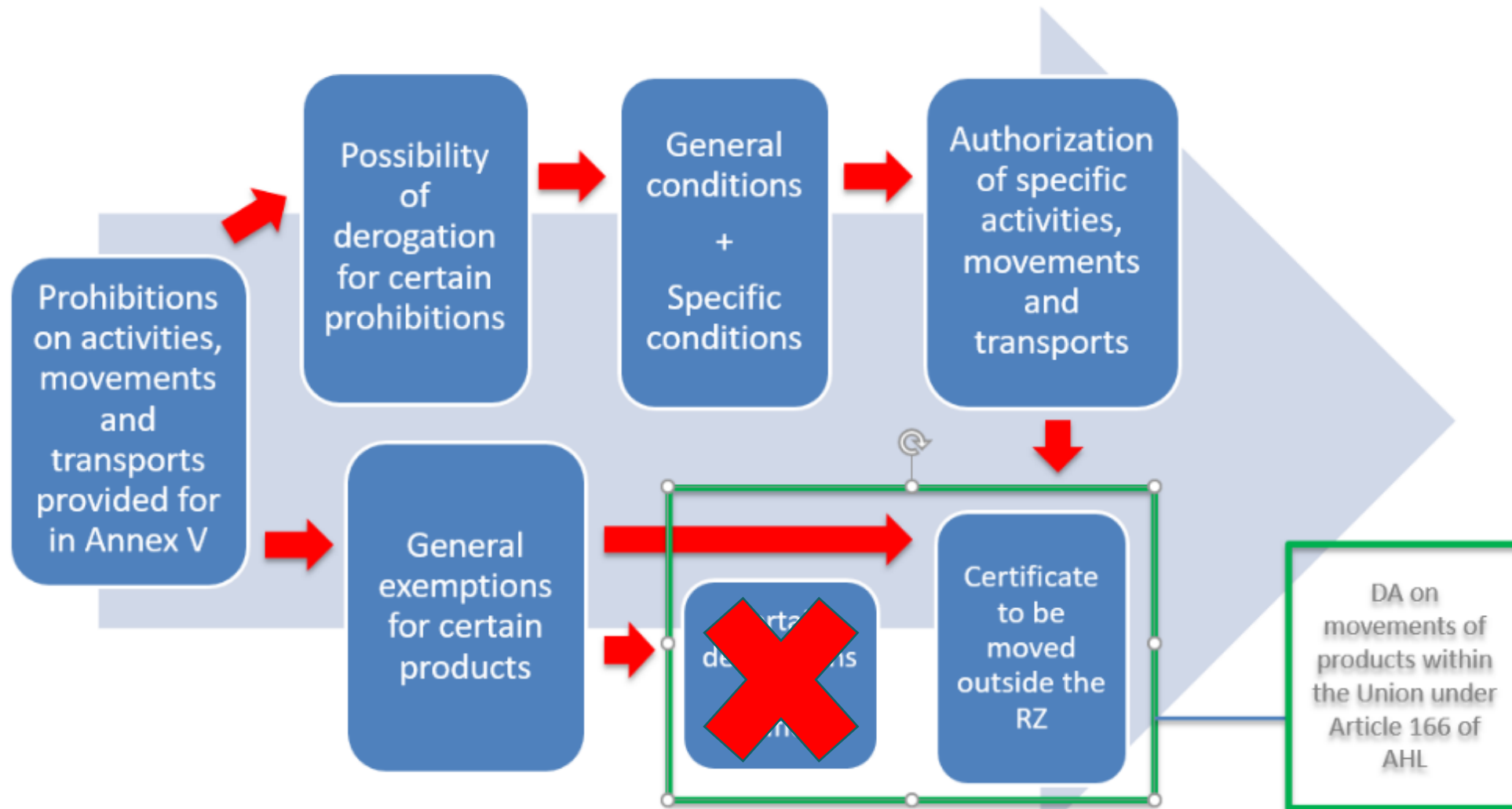


Visits by OV in the establishments in the PZ

- ✓ **All establishments located in the PZ** keeping animals of listed species shall be visited by an official veterinarian
- ✓ When the radius of the protection zone is larger than 3 km (RVF, LSD, AHS), the competent authority may decide to require not the visit to all the establishments but the visit of a representative number of those establishments in accordance



Prohibitions in the PZ



Prohibitions in the PZ



Conditions to be fulfilled to authorise movements of animals kept inside the PZ to a slaughterhouse

General conditions (Art 25)

- Risk assessment
- Clinical examination & sampling
- Designated route
- Designated establishment of destination

Conditions for the means of transport and transport operations (Article 26)

- Constructed and maintained to avoid any leakage
- C&D before and after
- Control of insects and rodents, if relevant
- Biosecurity measures during all transport operations

Specific conditions (Article 28.1 and 28.2)

- Location of the slaughterhouse
- Sealing of the means of transport
- Obligations of the CA in the slaughterhouse

Prohibitions in the PZ



Conditions to be fulfilled to authorise movements of fresh meat obtained from ungulates kept in the PZ

General conditions (Art 25)

- Risk assessment
- Visit by OV in the establishment of origin
- No suspicion
- Designated route
- Designated establishment of destination
- **Separated during the production process, storage and transport from products not eligible to be moved outside the PZ**
- **Marked according to the HP as eligible to be moved outside the PZ**

Conditions for the means of transport and transport operations (Article 26)

- Constructed and maintained to avoid any leakage
- C&D before and after
- Control of insects and rodents, if relevant
- Biosecurity measures during all transport operations

Specific conditions (Article 32)

- The destination must be a processing establishment where it will undergo a treatment (Article 33.1.a)
- Marked according point 2 of Annex VIII (Article 33.2.a)
- Transport carried out in sealed containers
- Situation of the processing establishment
- Supervision of the processing establishment

Surveillance zone



40. Measures to be applied in establishments in the SZ



41. Visits by OV in the establishments in the SZ



42. Prohibitions in the SZ



43. General conditions to grant derogations from prohibitions



44 to 53 . Specific conditions to authorize certain movements



54. Measures to apply in food and feed businesses, ABP establishments, BCP, etc



55. Duration of the measures in the SZ



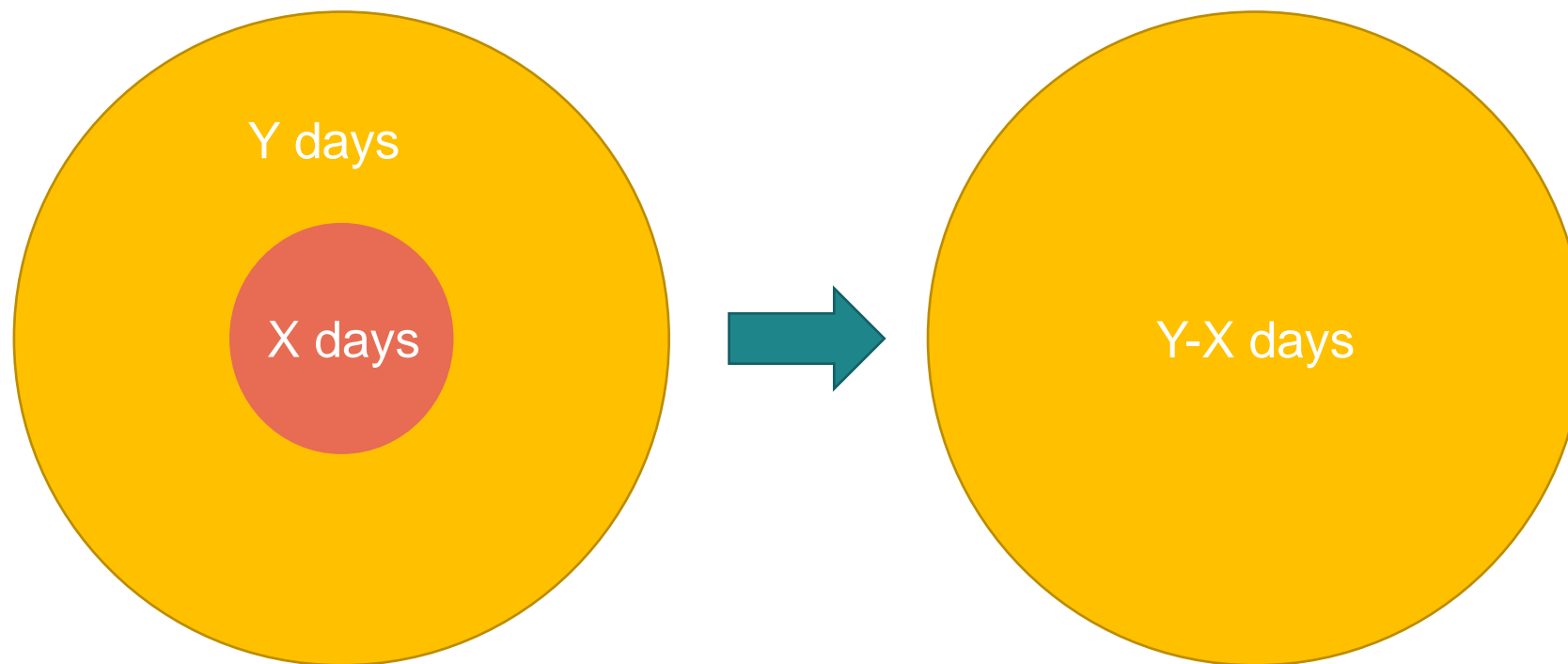
55. Derogations from prohibitions of movements within the restricted zone

Specific conditions to authorise certain movements in/from the surveillance zone



- ✓ The competent authority is given more flexibility to grant derogations and the requirements are less strict for the movement of animals and products from the SZ.
- ✓ Article 45(2) provides for a new possibility:
 - ✓ The competent authority may, after carrying out a risk assessment, authorise the movement of kept animals of listed species of ungulates to an establishment belonging to the same **supply chain**, located in or outside the surveillance zone, to complete the production cycle before slaughter. If the establishment of destination is located outside the surveillance zone, the competent authority shall apply in that establishment the measures provided for in Articles 40, Article 41 and Article 42 as long as the disease control measures in the surveillance zone of origin are maintained as provided for in Article 55.

Duration of the measures in the protection and surveillance zones



Repopulation of establishments in the restricted zones



57. Conditions to authorise the repopulation



58. Derogation from requirement related to time for food businesses, assembly centres, BCP, etc.



59. Requirements for the repopulation of establishments with kept listed diseases

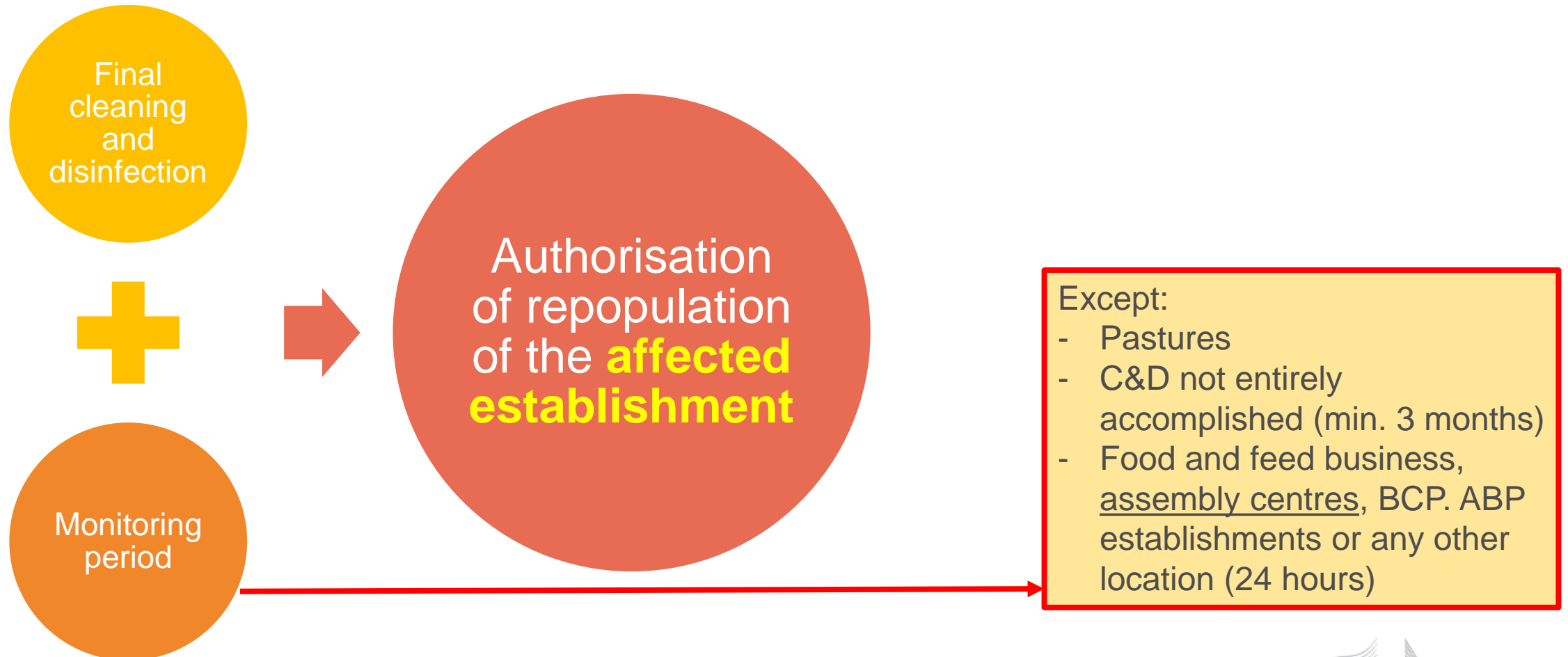


60. Additional requirements for repopulation



61. End of the repopulation and end of the restriction measures in the affected establishment

Conditions to authorize repopulation of establishments in restricted zones



Disease control measures in wild animals



62. Measures in the event of suspicion in wild animals of listed species



63. Measures in the event of confirmation of a category A disease in wild animals of listed species



64. Measures to be applied in the infected zone



65. Additional measures to apply in the infected zone



66. Operational expert group



67. Duration of measures in the infected zone

Disease control measures in wild animals



Suspicion

Investigation (post-mortem examinations of dead and shot animals)

Confirmation

The CA **MAY** establish an **infected zone** where:

- Reinforced biosecurity measures are implemented
- Movements of wild animals and PAO thereof are prohibited
- ABP are disposed or processed in accordance with R 1069/2009
- Additional measures (optional): regulation of movements of kept animals, hunting activities, restrictions to feeding of animals, eradication plan

Operational expert group

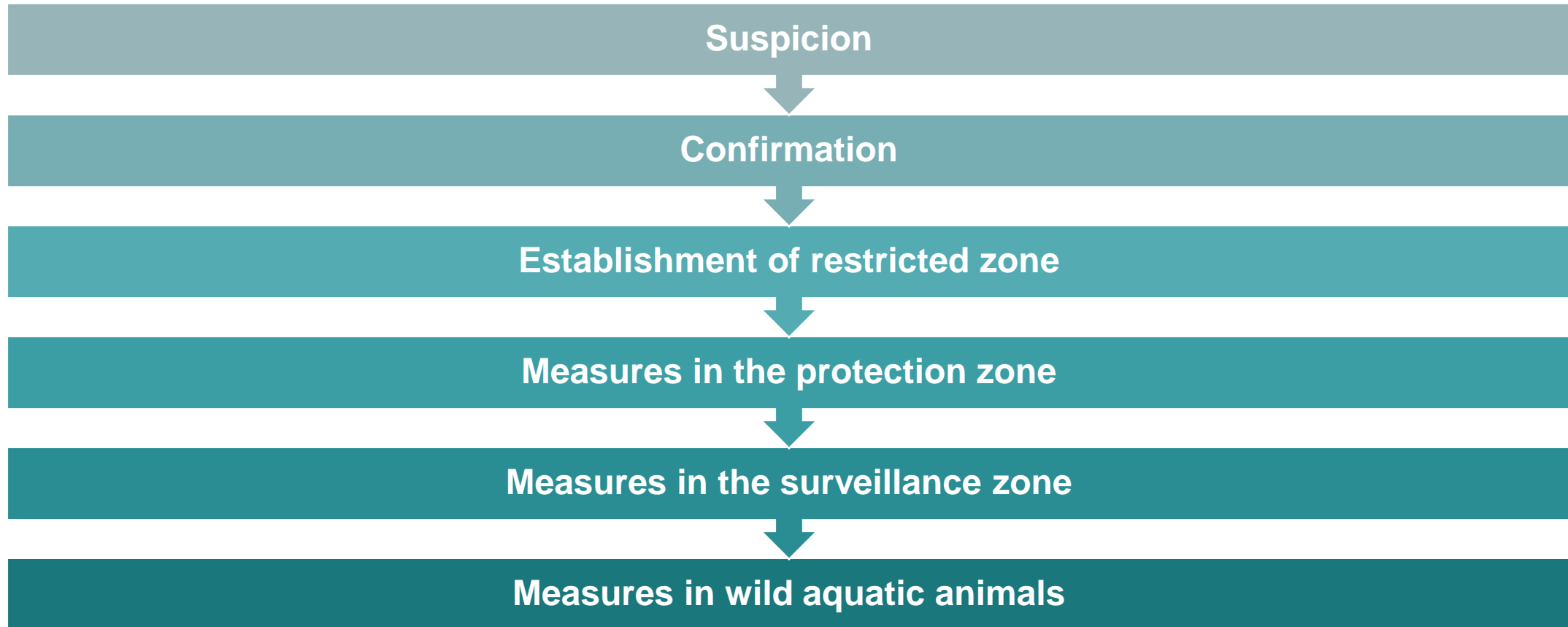


Duration of the measures depending on the evolution of the epidemiological situation

Part III – Aquatic animals

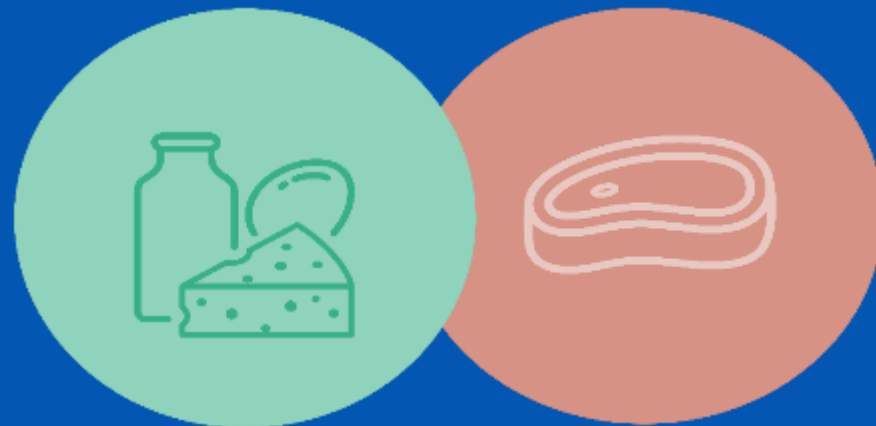


Similar approach



Commission Delegated Regulation (EU) 2020/2154 as regards animal health, certification and notification requirements for movements within the Union of products of animal origin from terrestrial animals

Supplementing Articles 166, 168 and 169 of the AHL



Subject matter and scope

- ✓ **Obligations on operators for movements within the Union of consignments of products of animal origin from terrestrial animals produced or processed in establishments, food businesses or zones subject to emergency measures or movement restrictions as referred to in Article 166(2) of Regulation (EU) 2016/429;**
- ✓ Information requirements for the animal health certificate provided for in Article 167(1) of Regulation (EU) 2016/429 (animal health certification);
- ✓ Information requirements for the advance notification of movements of those consignments to other Member States, provided for in Article 169(1) of Regulation (EU) 2016/429 (advance notification);
- ✓ Emergency procedures for the advance notification of movements of those consignments, provided for in Article 169(1) of Regulation (EU) 2016/429, in the event of power cuts and other disturbances of Traces

Obligations on operators for movements of PAO within the Union

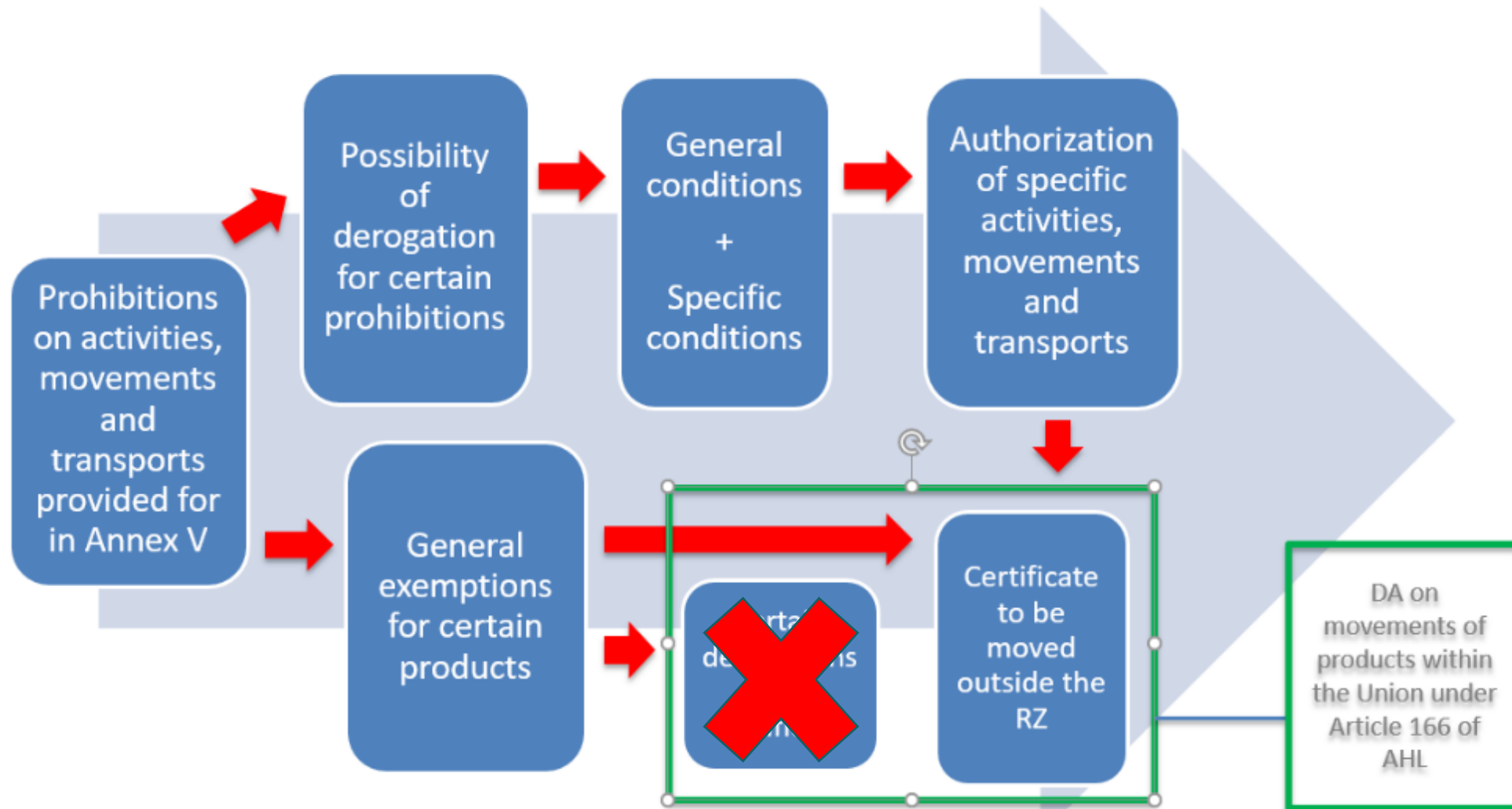
Peace times

- No animal health obligations under the AHL:
- **Please remember that Directive 2002/99 is repealed!!!**

Emergency measures or movement restrictions as referred to in Article 166(2) of Regulation (EU) 2016/429 in place

- Movements of PAO are **authorized by the CA** of the place of origin
- The consignments of PAO comply with the **conditions** for the authorization
- They are **always accompanied by an animal health certificate** (model laid down in the IA laying down models of certificates for FOOD)

Prohibitions in the PZ



Commission Delegated Regulation (EU) 2020/... [SANTE/2020/7144] as regards the use of veterinary medicinal products for prevention and control of listed diseases

Supplementing Article 47(1) of the AHL



Approach

Rules on the use of VMP for prevention and control of listed diseases (Part I)

Circumstances under which VMPs can be used

Who is the responsible to decide when to use VMPs

Which VMPs can be used

Rules on the use of vaccines for prevention and control of category A diseases (Part II)

Preconditions

Strategies

Disease specific rules (Part III)

Implementation

Measures (prohibitions) in the vaccination zone

Recovery of the previous animal health status

Subject matter and scope



Yes, but only covered by the general rules of Part I (no details in Annex I)



Category D diseases

Yes, but only where restrictions are needed





The Union antigen, vaccine and diagnostic reagent banks

Legal acts involved

- ✓ **Animal Health Law (Regulation (EU) 2016/429) as regards rules for the prevention and control of certain listed diseases: Part III, Articles 48-52**
- ✓ **Commission Delegated Regulation (EU) on the management of the EU vaccine banks – document SANTE/7210/2020**
 - Legal base - Article 48(3) of the AHL
- ✓ **Commission Implementing Regulation (EU) on the rules for the EU vaccine banks – document SANTE/7212/2020**
 - Legal base - Article 50(1) of the AHL

Scope

- category A diseases of which vaccination is not prohibited
- management, storage and replacement of stocks of antigens, vaccines and diagnostic reagents in the Union banks (including types/strains and quantities of those biological products)
- biosecurity, biosafety and bio–containment requirements for the operation of the Union antigen, vaccine and diagnostic reagent banks
- access to the Union antigen, vaccine and diagnostic reagent banks
- national antigen, vaccine and diagnostic reagent banks

Thank you



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