

Entry into the Union



DG SANTE Unit G2 – Animal Health

Rules on imports replaced from 21 April 2021

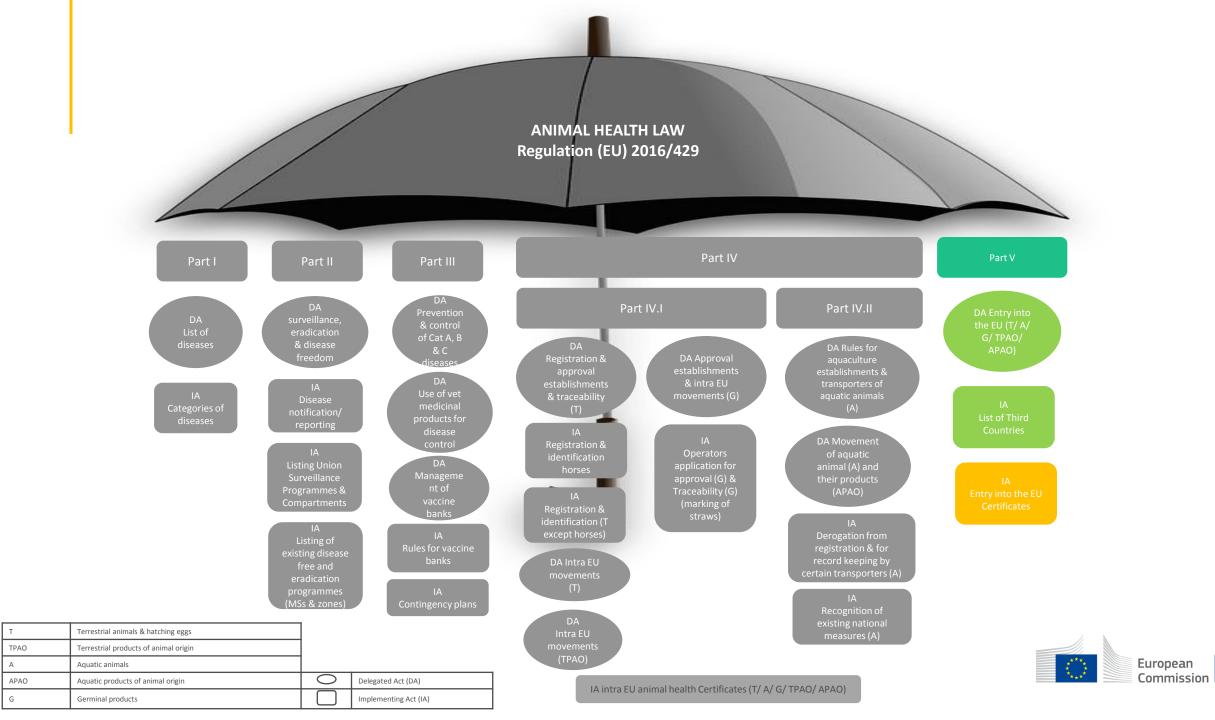
- ✓ Directive 88/407/EEC
- ✓ Directive 89/556/EEC
- ✓ Directive 90/429/EEC
- ✓ Directive 92/65/EEC
- ✓ Directive 92/118/EEC
- ✓ Directive 2002/99/EC
- ✓ Directive 2004/68/EC

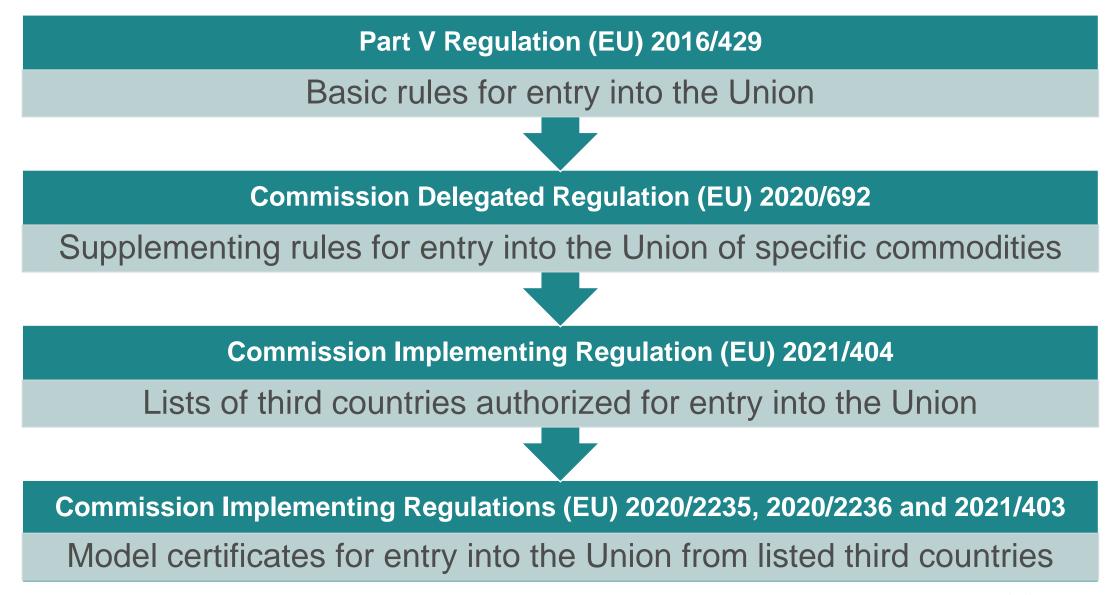
✓ Decision 2003/779

- ✓ Directive 2006/88/EC
- ✓ Decision 2007/777/EC
- ✓ *Regulation (EU)* 798/2008
- ✓ Regulation (EC) No 1251/2008
- ✓ Directive 2009/58/EEC
- ✓ Regulation (EU) 119/2009
- ✓ Regulation (EU) 206/2009

- ✓ Regulation (EU) 206/2010
- ✓ Regulation (EU) 28/2012
- ✓ *Regulation (EU)* 2016/759
- ✓ Regulation (EU) 2019/628









Basic rules for the entry into the Union in the AHL

Articles 229 to 239 of Regulation (EU) 2016/429

Listing of TCs - criteria

 Compliance with animal health requirements – at least as stringent as the requirements applied in the EU

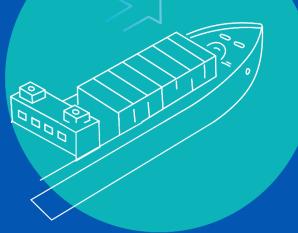
Consignments accompanied by a certificate, or declaration where relevant

Possibilities for derogations

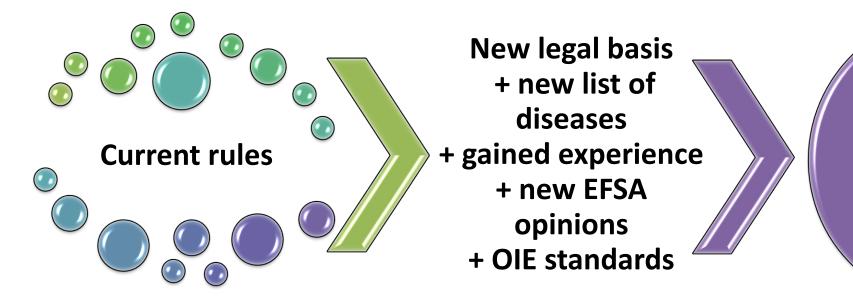




Commission Delegated Regulation (EU) 2020/692 as regards entry into the Union, and the movement and handling after the entry of animals, germinal products and products of animal origin



Process

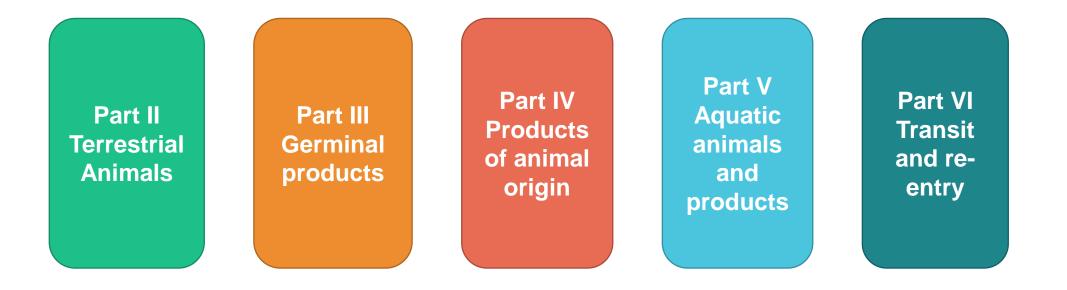


New harmonized framework for T, A, G and PAO in one legal act



Structure







Part I General rules







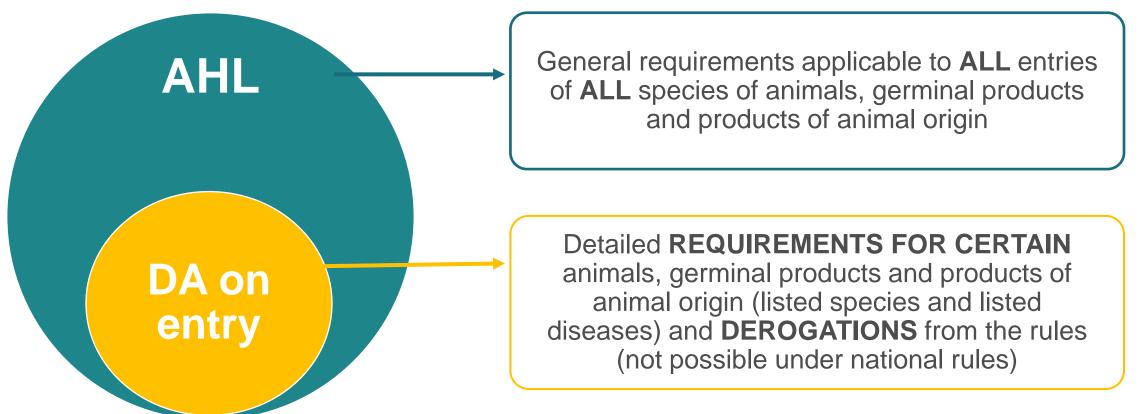
These general rules apply to all species and commodities included in the scope of the DA









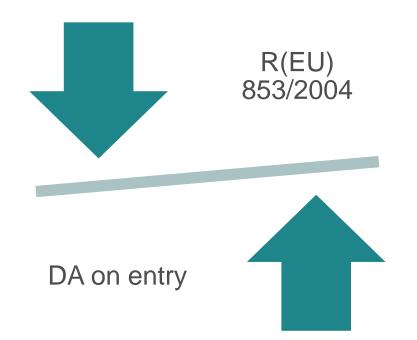


AHL – DA on entry = National rules



Definitions





- Fresh meat: includes minced meat and meat preparations
- ✓ Carcass of an ungulate
- ✓ Offal
- Meat products: includes treated stomachs, bladders, intestines, rendered animal fats and meat extracts



Obligations



CA in the Union	Operator responsible for entry	Operator responsible for movement after entry	
Listed third country , territory or zone for the imported commodity (or listed compartment, only in the case of A and APAO)		Consignment permitted to enter the Union by the CA	
Compliance with ALL requirements applicable to the imported commodity		Compliance with the requirements for movement and handling after the entry	
Accompanying documentat case) and declarations and required)	· · · · · · · · · · · · · · · · · · ·	No diverting of the consignment for uses other than those for which the consignment was certified	



National legislation and animal health systems in the TC of origin

Notification and reporting of listed diseases (relevant for the imported commodity)—Annex I

Live animals: all listed diseases (listed for the species)

Products: limited list of diseases depending on the product

Systems to detect emerging diseases

✓ Systems to ensure that **swill feeding** is not a source of listed diseases



General requirements as regards the establishment of origin of the A, G and PAO

Registration by the CA of the TC (unique registration number)

- Approved in the cases that is required in the Regulation (unique approval number)
- Under the control of the CA of the TC
- Record keeping requirements
- Regular animal health visits at frequencies proportionate to the risk

Alignment with requirements applicable to establishments in the Union





Sampling, laboratory tests and other tests

Today	As from April 21
Specific procedures and references (example: Part 6 of Annex I to R(EU) 206/2010, Annex III to R(EU) 798/2008, Directive 90/429/EEC, Directive 88/407/EEC, etc.)	 Reference to procedures described in: DA on surveillance and eradication programmes DA on movements between MS DA on entry DA on approval of establishments, traceability and movements (G)



Disease freedom of the place of origin and specific conditions



- ✓ Disease freedom ≠ disease-free status: the EU does not grant disease-free status to TC, therefore, where freedom from a disease is required to be listed, they have to demonstrate this freedom in accordance with:
 - ✓ the disease-specific rules laid down in that DA on surveillance and eradication programmes (category B and C diseases)
 - ✓in accordance with a disease surveillance programme that must be assessed by the COM, following the general rules laid down in the DA on surveillance and eradication programmes (category A diseases)



Part II.1 Kept terrestrial animals (common requirements)





Articles 11 to 19: Common requirements

- Residency period (including derogations for horses)
- Inspection prior to dispatch
- Rules for dispatch to the Union(including derogations in case of transhipment)
- Means of transport and containers
- Movement and handling after the entry

(specificities depending on commodity)



Moving and handling after entry of terrestrial animals

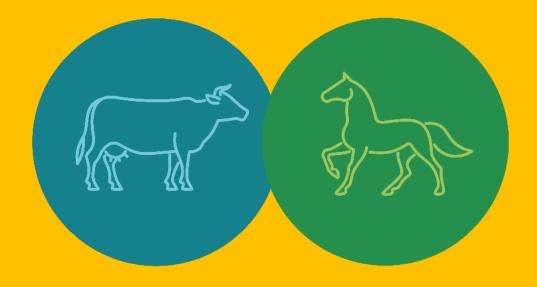




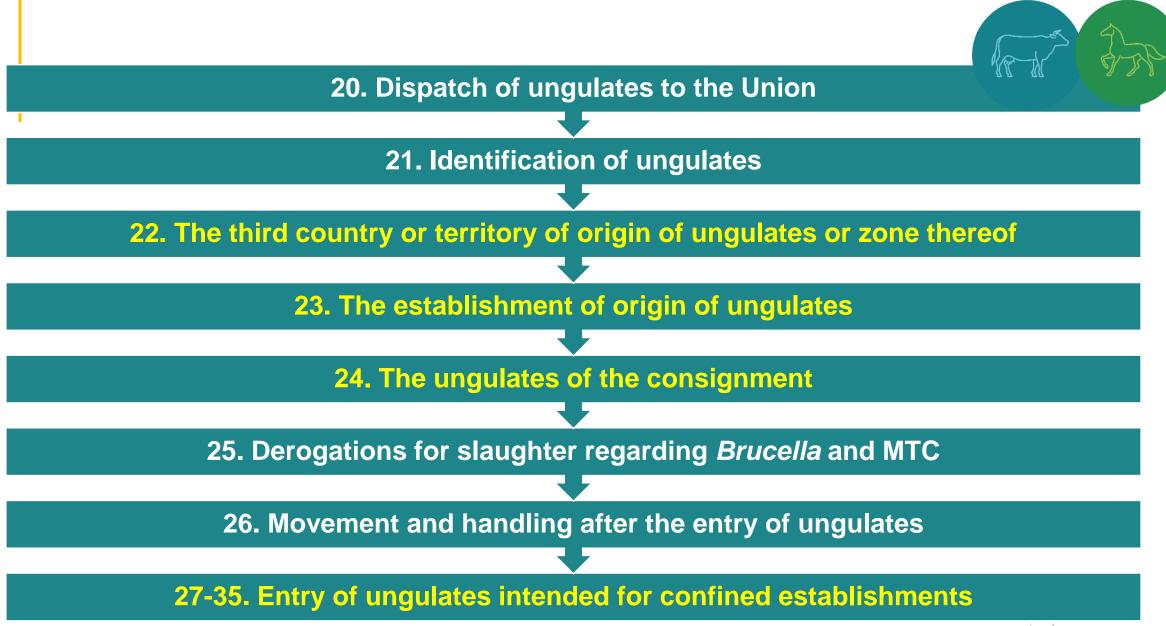
Monitoring in accordance with Article 2 and 3 of R (EU) 2019/1666, which does not cover animals but the reference is to the **procedure**



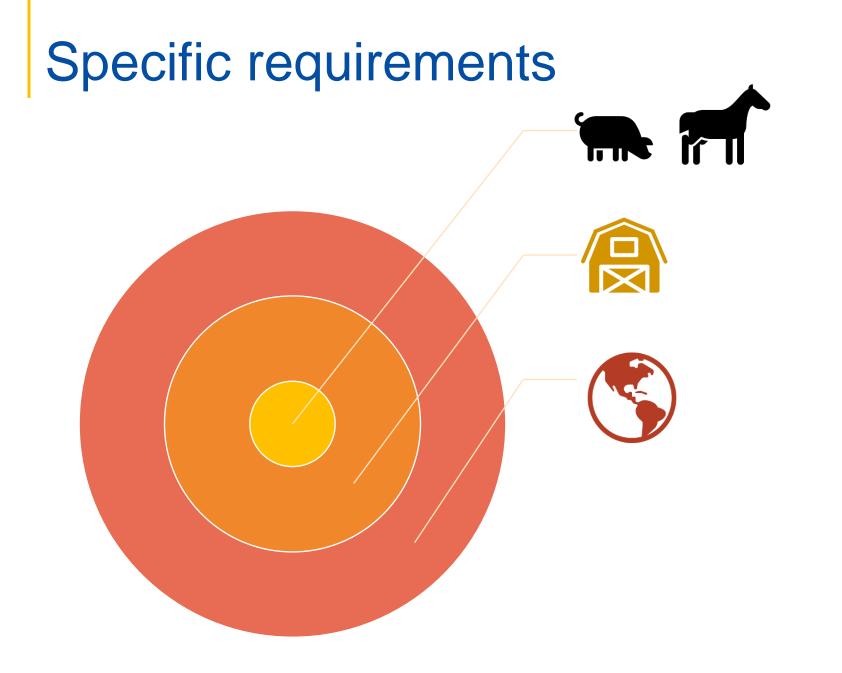
Part II.2 Ungulates











IDENTIFICATION, VACCINATION STATUS

CATEGORY A, B, C AND D DISEASES

CATEGORY A, B AND C DISEASES



The TC, territory or zone of origin of ungulates



Requirements regarding:

- Freedom from category A diseases —
- Absence of vaccination against category A diseases
- Freedom from B diseases (with alternatives)
- Freedom from BTV and EBL (with alternatives)
- Freedom from other C diseases

 (or compliance with specific conditions)
 where the consignment is intended for a MS with an approved eradication
 programme or disease-free status

		Bovine	Ovine	Species X
→	Disease 1	12 m	12 m	NA
	Disease 2	NA	NA	12 m
	Disease 3	12 m	12 m	12 m

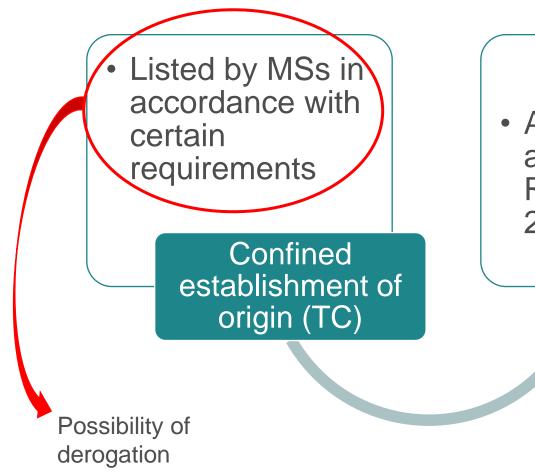
All listed diseases (Annex I)

"freedom" and "specific conditions" must be specifically assigned to the TC in the list of TCs



Ungulates intended for confined establishments





Confined establishment of destination (MS)

 Approved in accordance with R (EU) 2019/2035



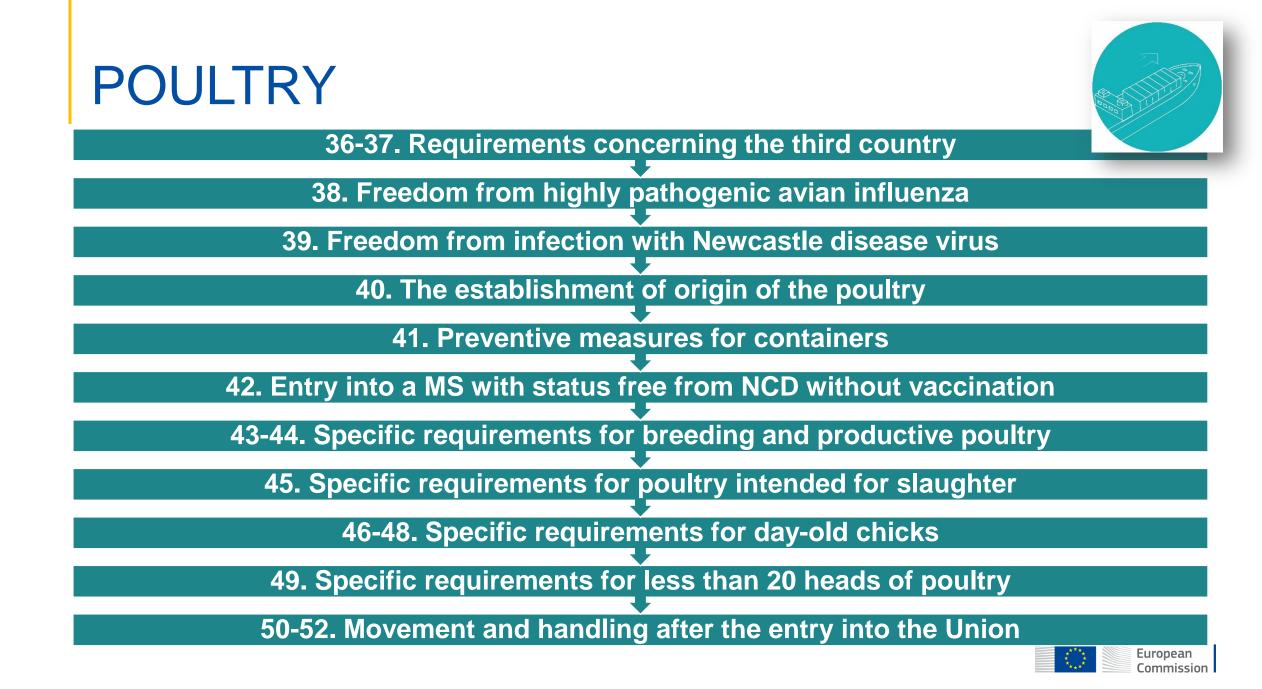
Each consignment must be authorised by the CA of MS of destination following a risk-assessment (and MS of passage)

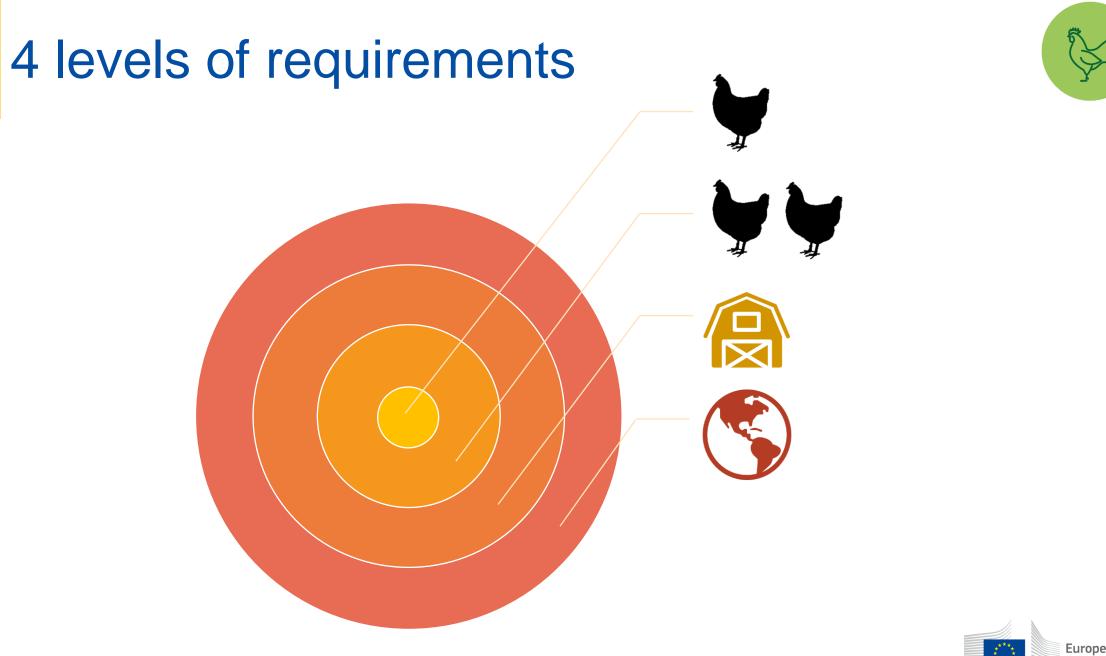


Part II.3 Poultry and Captive birds









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The TC, the establishment, the flock and the poultry

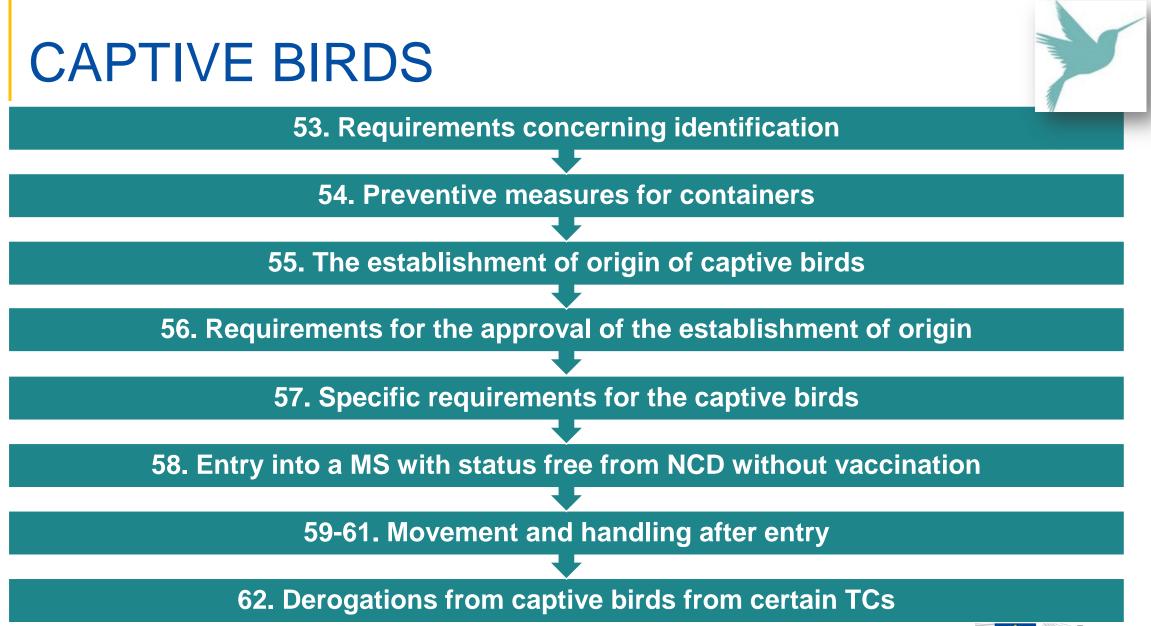


Requirements regarding:

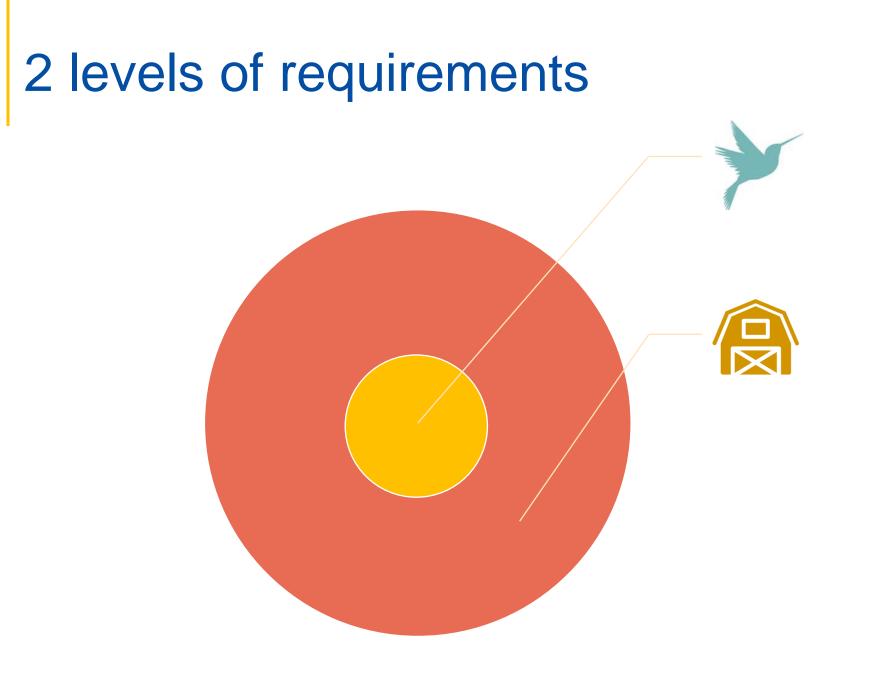
- "Triangulation" only between listed TCs
- ✓ Freedom from category A diseases
- Rules on vaccination against HPAI and NCD
- Specific rules for entry in MSs with status free from NCD without vaccination
- Establishment of origin:
 - ✓ Approved or registered
- ✓ Rules for D diseases
 - ✓ LPAI at the level of establishment
 - Salmonella, Mycoplasma at the level of establishment and flock

		Poultry other than ratites	Ratites		
	HPAI	\checkmark	\checkmark		
	NCD	\checkmark	Freedom or AH guarantees		
	AH guarantees on HPAI vaccination,				
NCD vaccination and NCD free (ratites) must be specifically assign the TC in the IA on listing of TCs					





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The establishment and the captive birds

Requirements regarding:

- Establishment of origin:
 - ✓ Approved
- ✓ Rules for category A diseases
- Rules for category D diseases
 - Avian chlamydiosis (psittacidae)
- Specific rules for entry in MSs with status free from NCD without vaccination (galliformes)
- ✓ After entry
 - Directly to a quarantine establishment
 - ✓ Release by OV

Name and approval number on the list published by CION

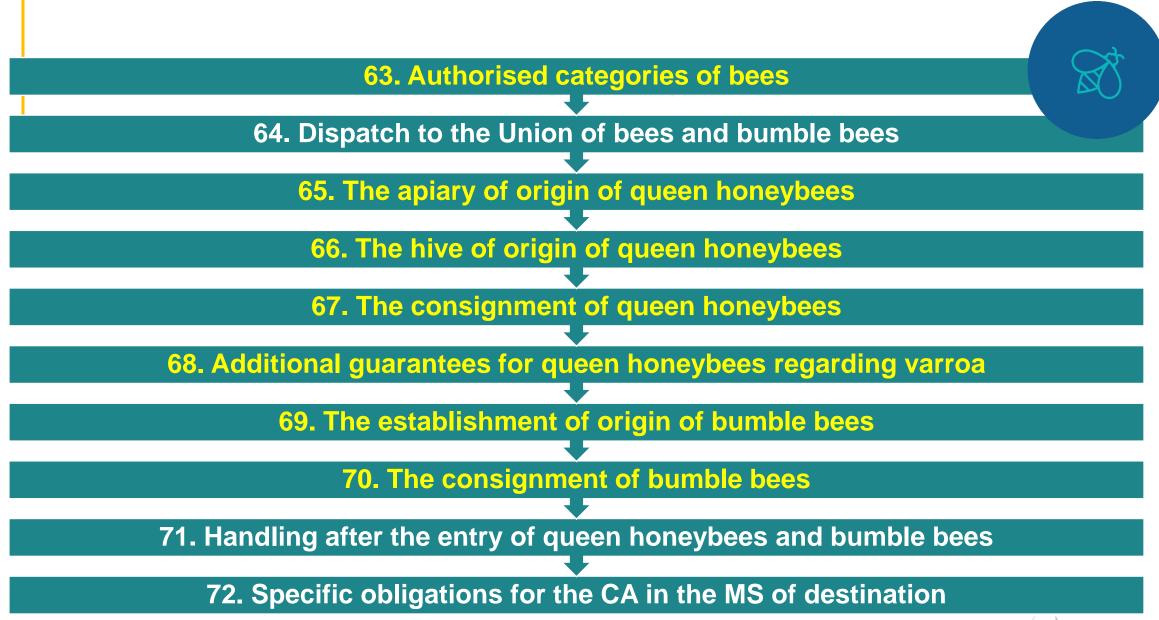
Establishment		Birds	
HPAI	No outbreaks in previous 30	No vaccination	Testing prior
NCD	days	Rules on vaccines	entry



Part II.4 Bees and bumble bees



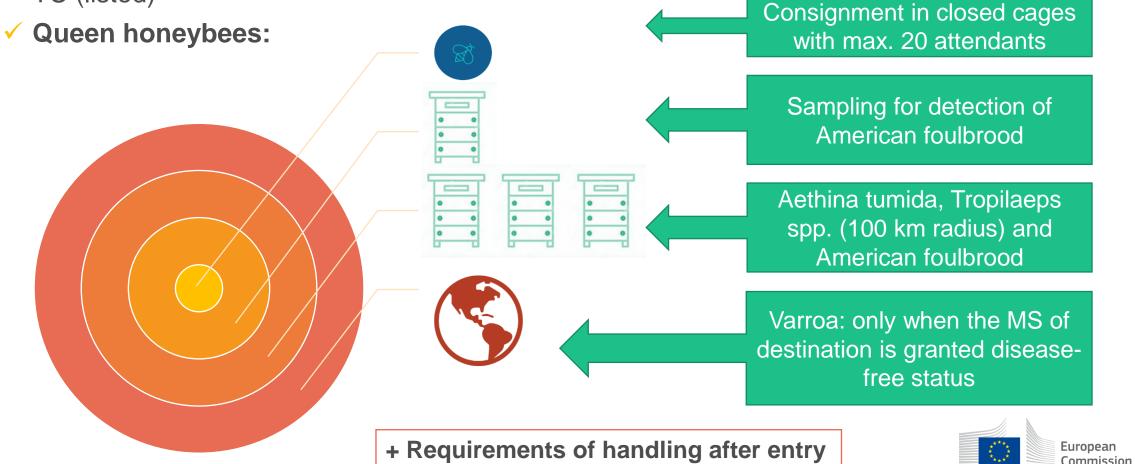






Bees and bumble bees

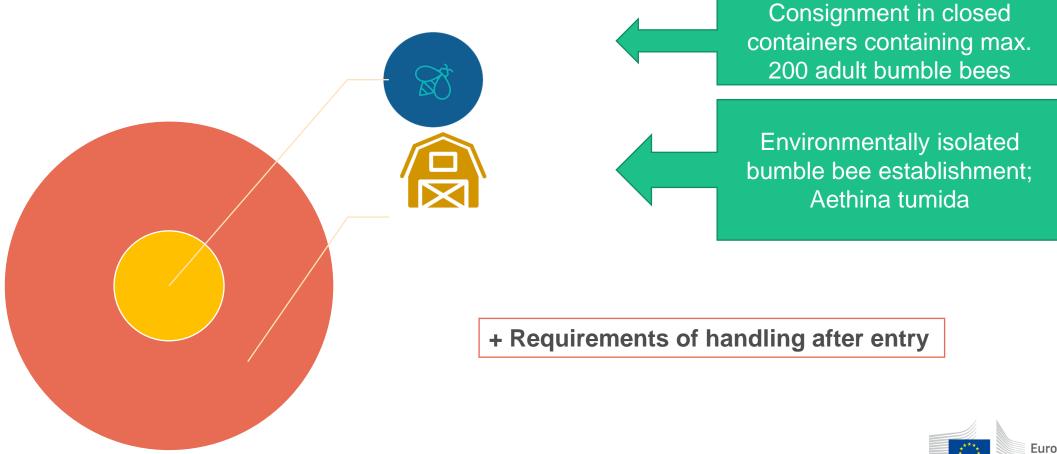
- SS -
- Only queen honeybees and bumble bees are permitted for entry into the Union from TC (listed)



Bees and bumble bees

SS -

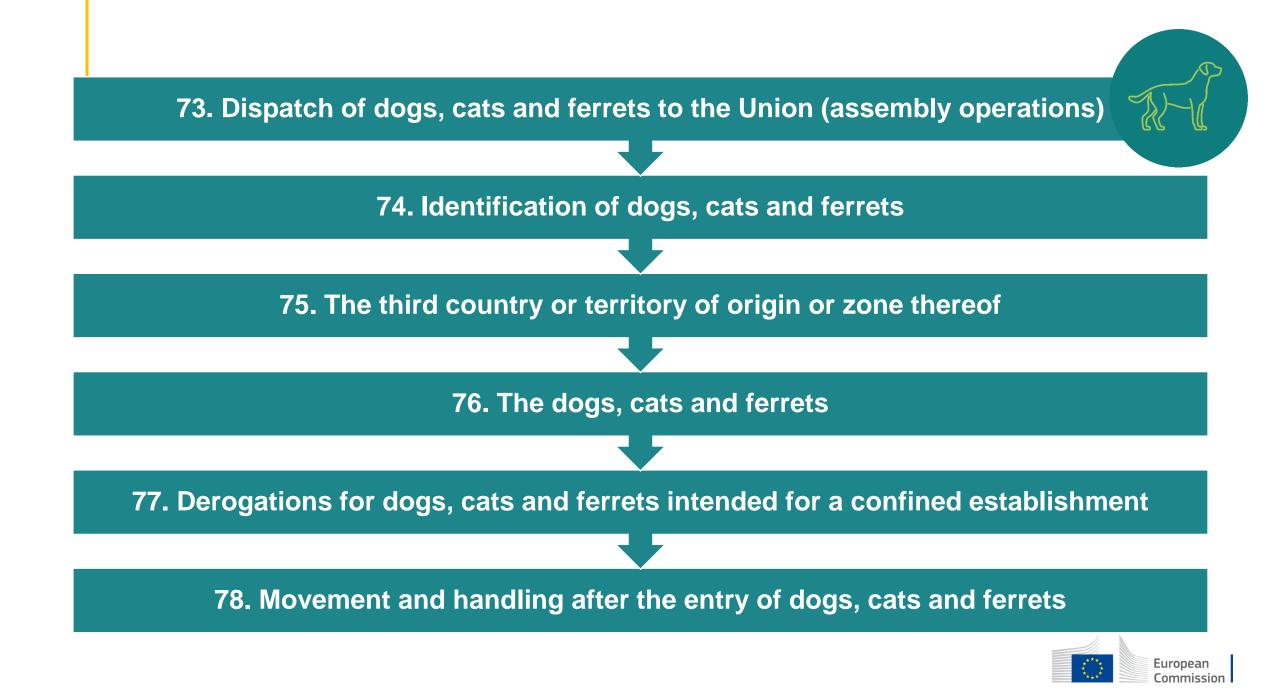
✓ Bumble bees:

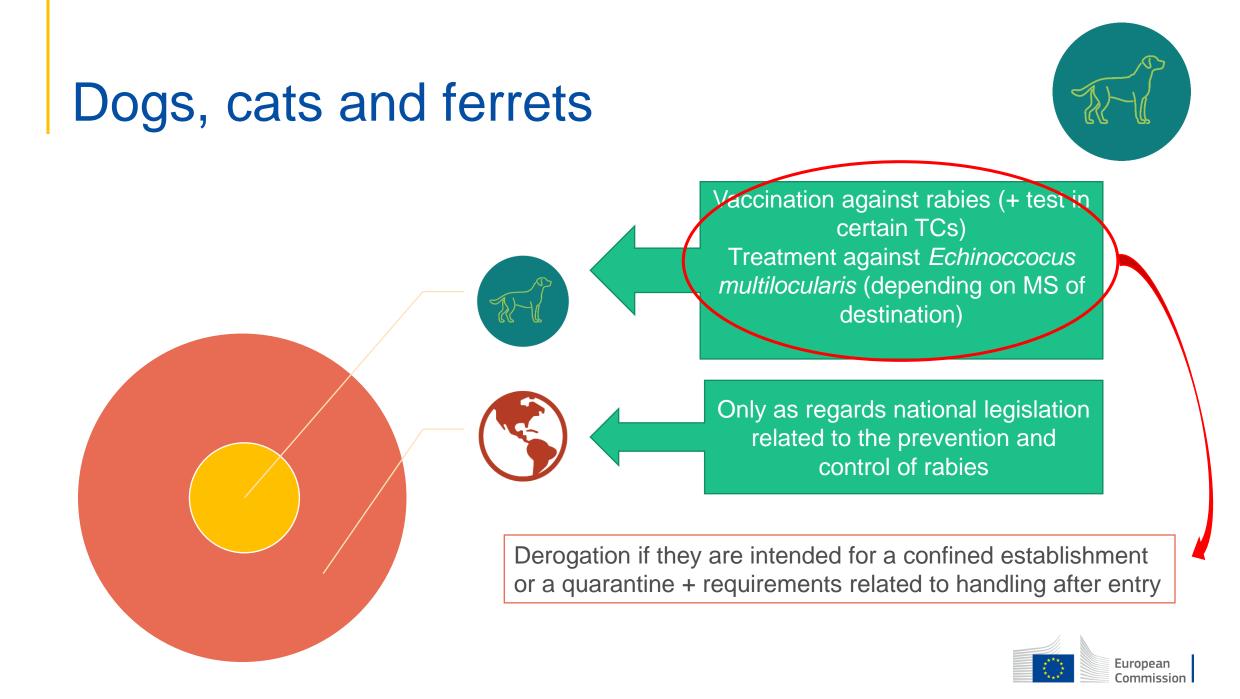


Part II.5 Dogs, cats and ferrets





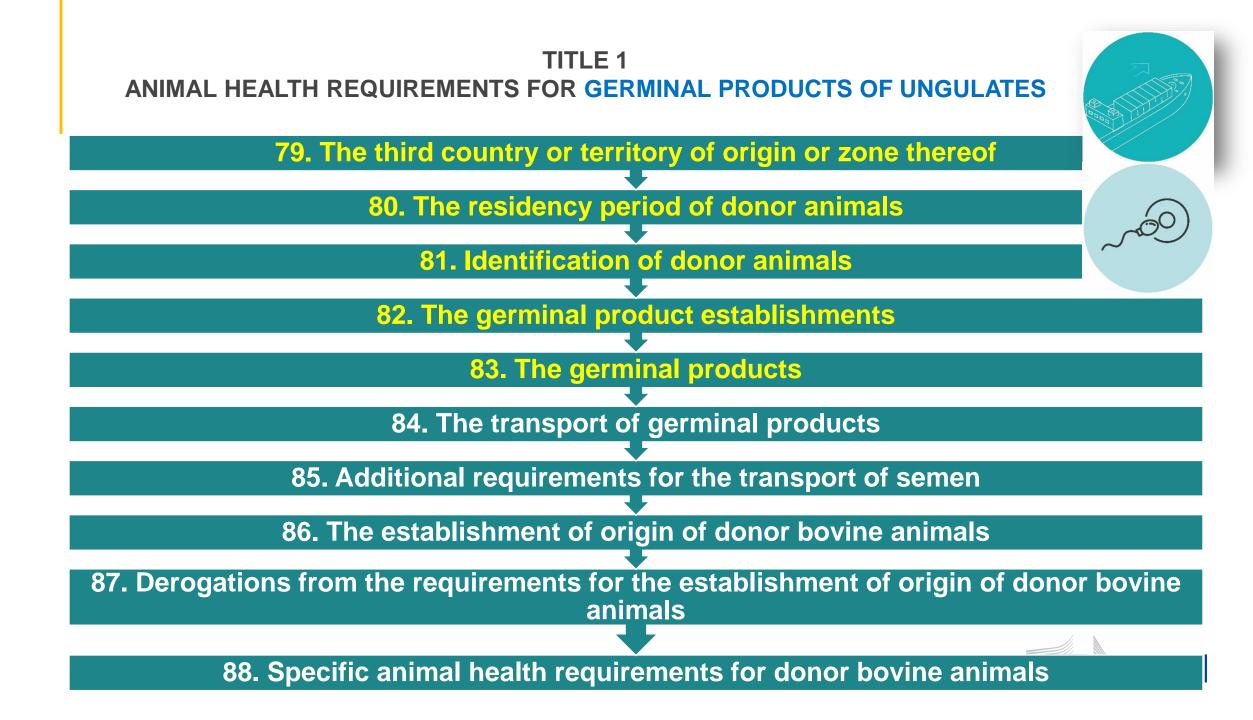


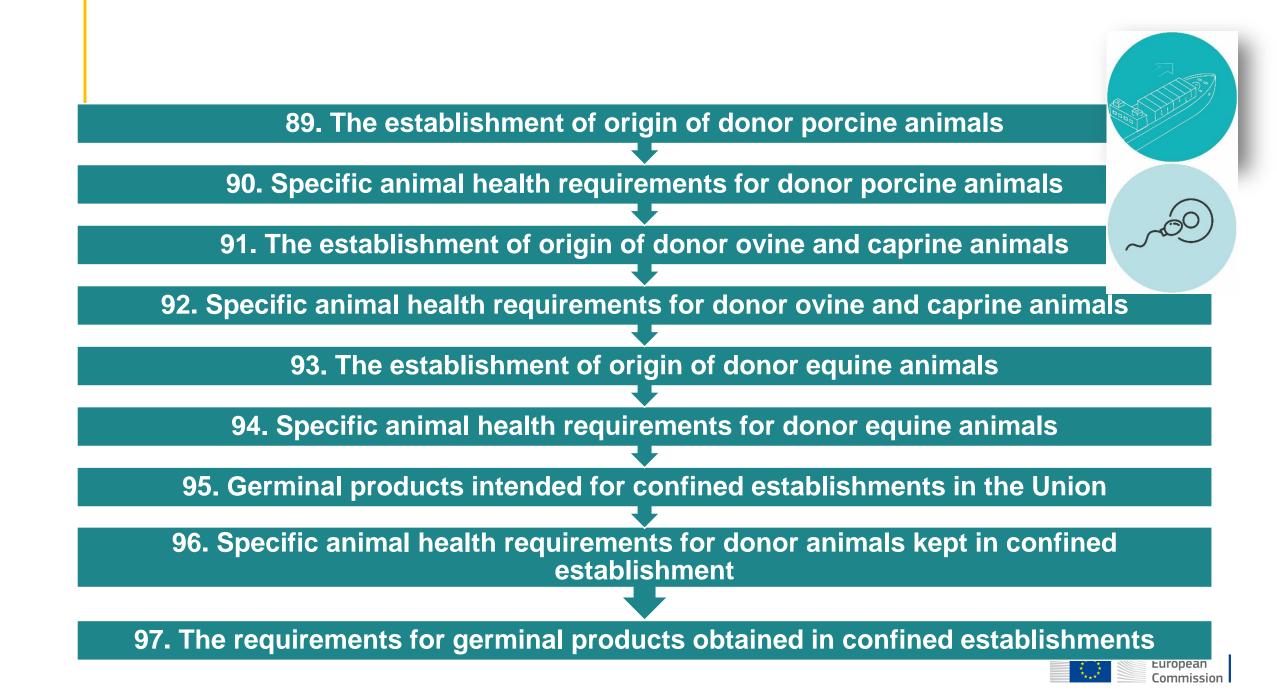


Part III.1 Germinal products of ungulates









Principles

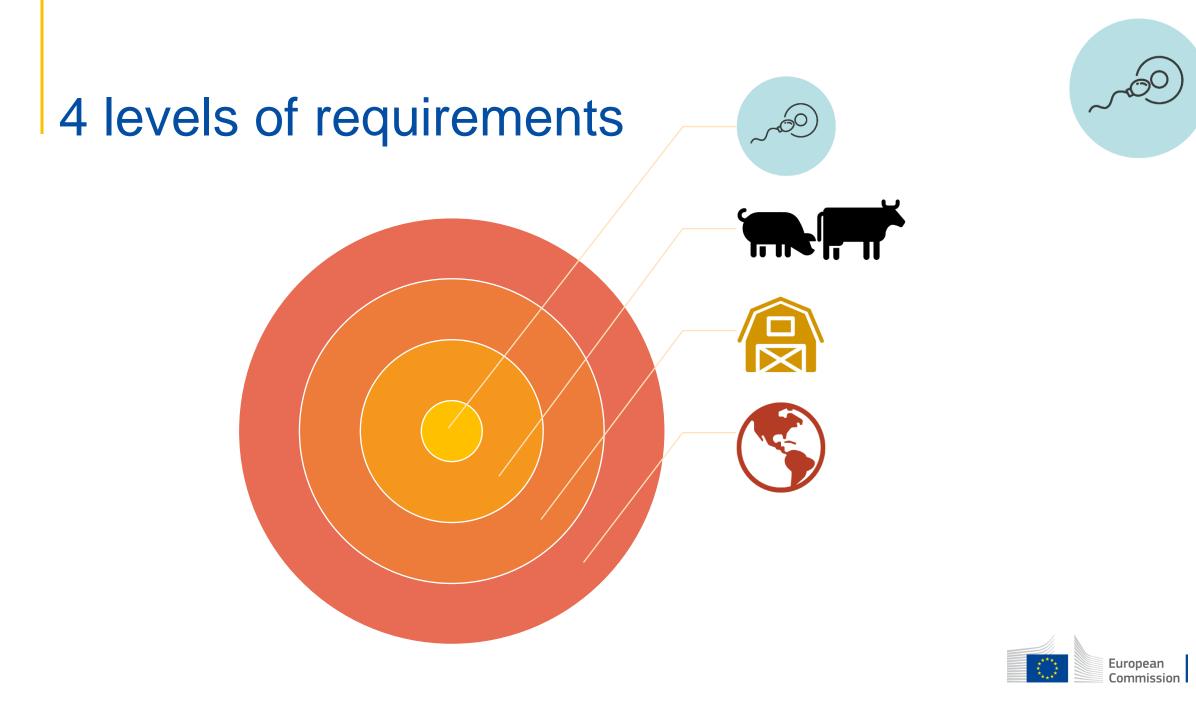


- The requirements for entry into the Union of germinal products based on the requirements for entry into the Union of live animals
- Requirements in Delegated Regulation (EU) 2020/692 reflect those established for the movements within the Union in Delegated Regulation (EU) 2020/686

DIFFERENCE:

 Rules on germinal products of ungulates and of animals kept at confined establishments (no rules on germinal products of dogs, cats, camelid and cervid animals)





TITLE 3

ANIMAL HEALTH REQUIREMENTS FOR GERMINAL PRODUCTS OF ANIMALS OTHER THAN UNGULATES AND OTHER THAN HATCHING EGGS OF POULTRY AND CAPTIVE BIRDS INTENDED FOR CONFINED ESTABLISHMENTS

117. Requirements for entry into the Union of consignments of germinal products of animals other than those referred to in point (a) and (b) of Article 1(4) dispatched from confined establishments

118. Specific animal health requirements for donor animals

119. The requirements for germinal products



Principles



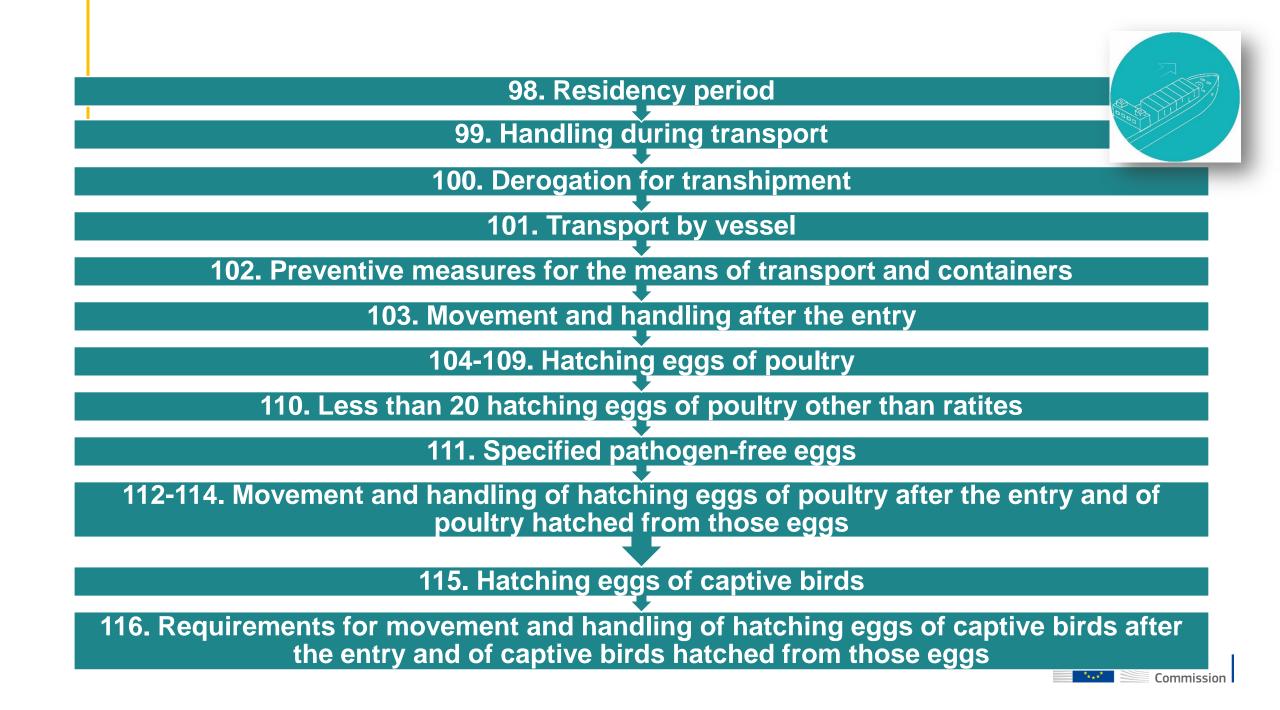
- An assessment carried out by the competent authority of the Member State of destination of the risks that the entry of those germinal products may present for the Union
- A third country, territory or zone listed and authorised for entry into the Union of the particular species and category of animals
- A confined establishment listed in accordance with Article 29 (entry of animals of specific species into the Union is authorised)
- The germinal products:
 - destined to a confined establishment in the Union, which is approved in accordance with Article 95 of Regulation (EU) 2016/429
 - transported directly to the confined establishment

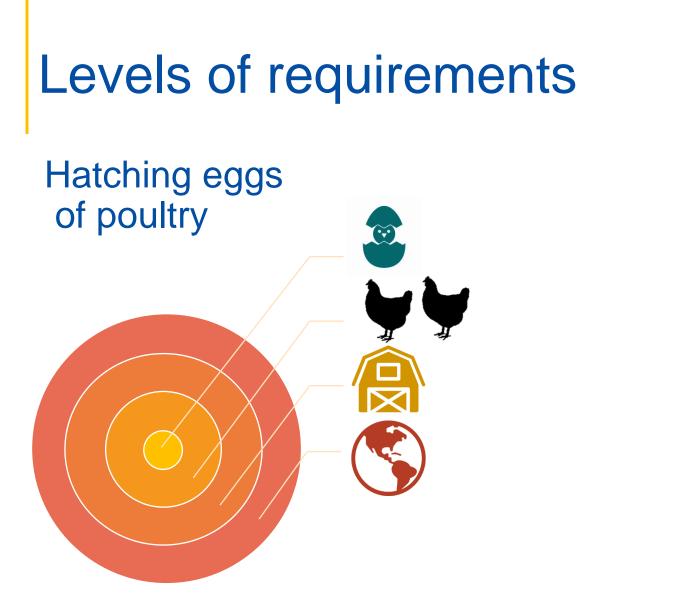


Part III.2 Hatching eggs of poultry and captive birds

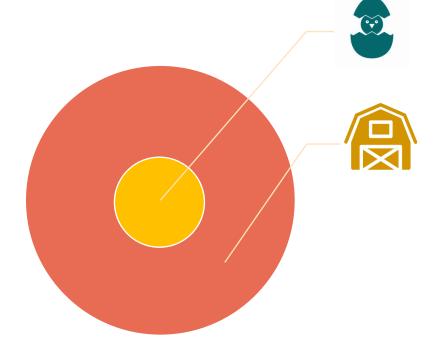






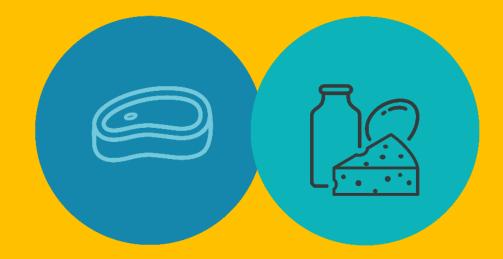


Hatching eggs of captive birds

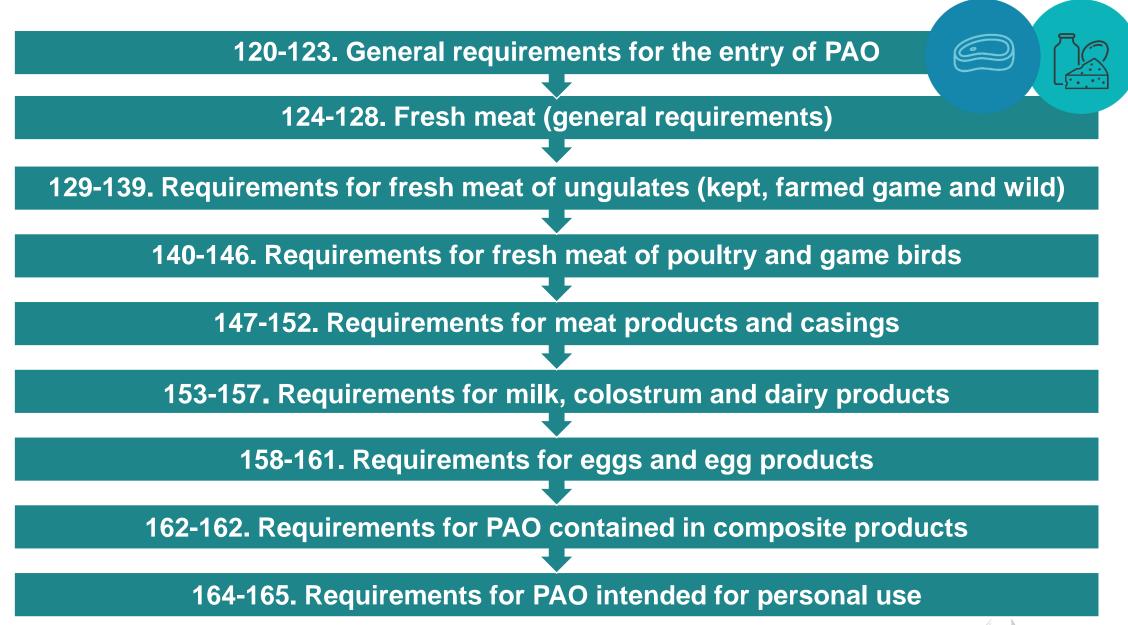




Part IV.1 Products of animal origin (PAO)









General requirements

Treatment requirements:

- Link to the list of TC
- The treatment must be applied in the TC that is authorised for entry into the Union
- Reference to the Annexes laying down the lists of possible treatments for each commodity
- Requirements for handling until packaging





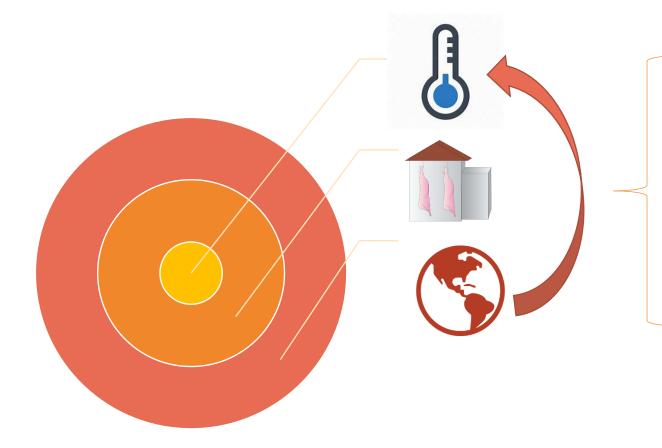
Fresh meat: 4 levels of requirements

Only for listed diseases referred to in Annex I for fresh meat



Meat products: 3 levels of requirements





Countries **not subject to a risk-mitigating treatment**: authorised for the entry of fresh meat

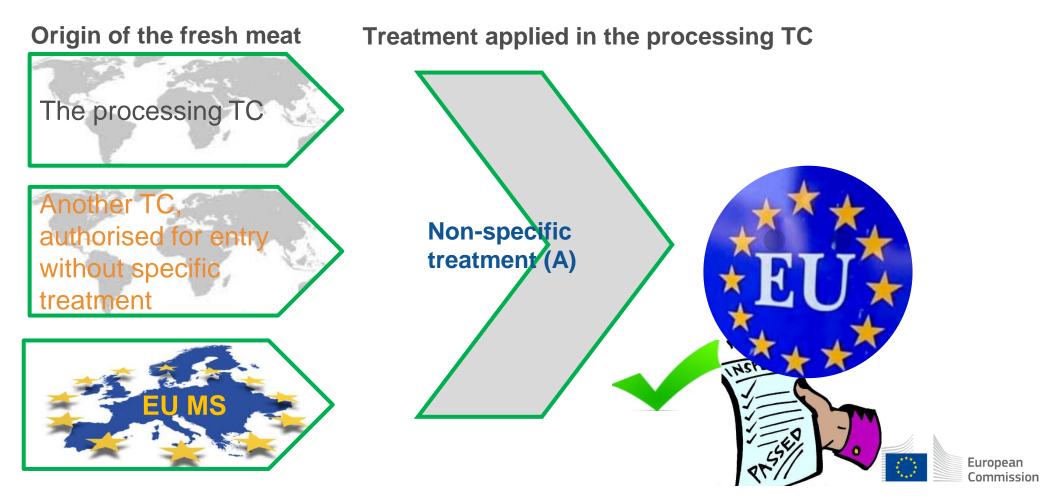
 Countries subject to a riskmitigating treatment



Meat products: triangulation rules (1)

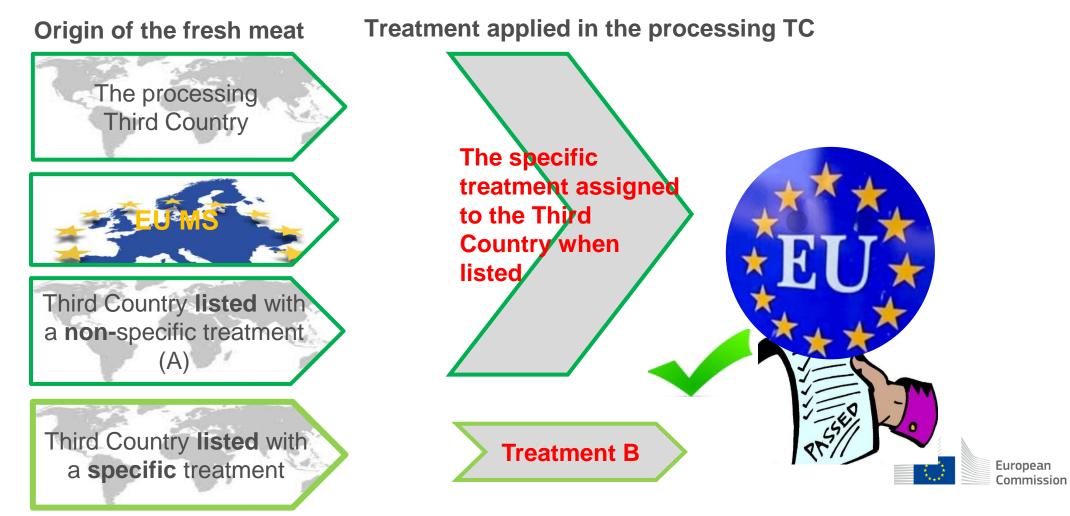


Meat products not subject to a risk-mitigating treatment



Meat products: triangulation rules (2)

Meat products subject to a specific treatment



✓ NEW TREATMENTS (+ new definition ← OIE):

Bovine, ovine, caprine and kept porcine animals

- Salting with sodium chloride (NaCl), either dry or as saturated brine (aw<0.8), for a continuous period of 30 days or longer at a temperature of 20°C or above
- Salting with phosphate supplemented salt containing 86,5%NaCl, 10,7% Na₂HPO₄ and 2,8%Na₃PO₄ (weight/weight/weight) either dry or as saturated brine (aw<0.8), for a continuous period of 30 days or longer at a temperature of 20°C or above

Other

- Salting with NaCl for 30 days
- Bleaching
- Drying after scraping

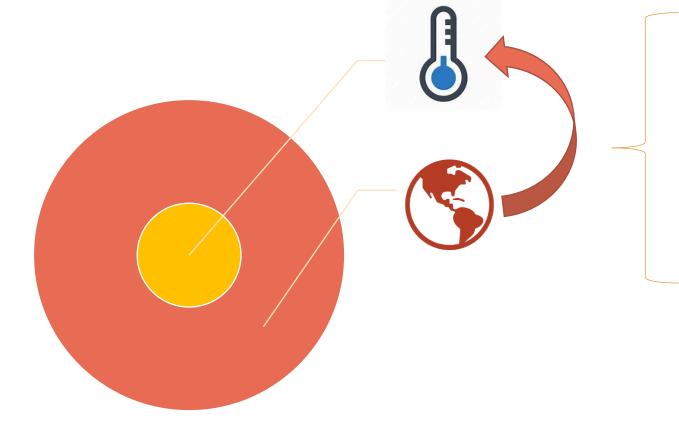






Milk, colostrum, colostrum-based products and dairy products

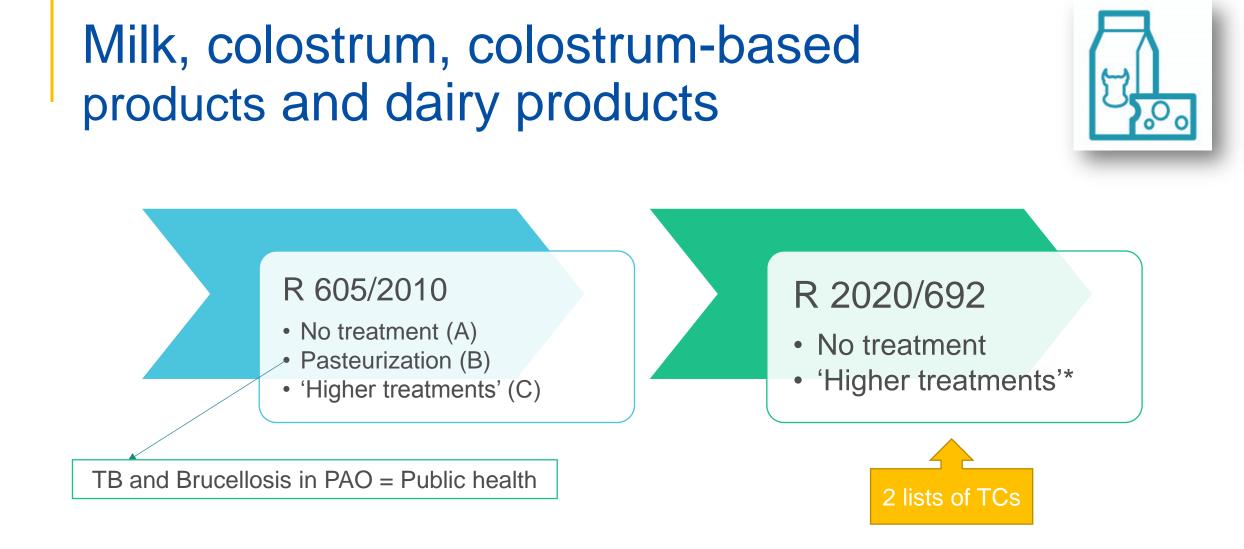




- Countries not subject to a risk-mitigating treatment
- Countries subject to a riskmitigating treatment







* Not applicable to colostrum and colostrum-based products (no scientific basis) \rightarrow only from TCs authorised for the entry of raw milk



Products of animal origin contained in composite products



Accompanied by a certificate

CP containing meat products (any quantity)

CP containing colostrum-based products

CP containing dairy products or egg products which have NOT been treated to become shelf-stable (any quantity)

Accompanied by a declaration

Shelf stable CP containing gelatin and/or collagen (as only meat products)

Shelf stable composite products containing dairy products and /or eggs products subject to specific-risk mitigating treatments



Products of animal origin intended for personal use

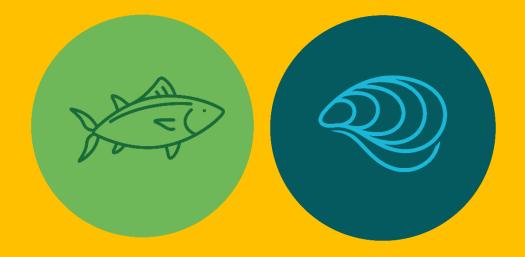


- Derogation from animal health requirements and additional requirements for entry into the Union of infant milk, infant food and special foods intended for personal use (max. 2 kg)
- ✓ Derogation from animal health requirements for products of animal origin intended for personal use originating from certain third countries or territories→ link to the lists of TCs
 - TCs with no maximum quantity (AD, CH, LI, SM)
 - ✓ TCs with a maximum quantity (10 kg) (FO, GL)

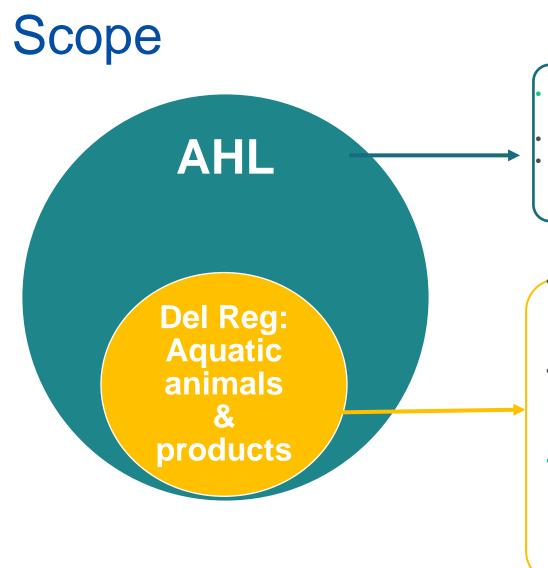




Part V Aquatic animals and products of animal origin from aquatic animals, other than live aquatic animals







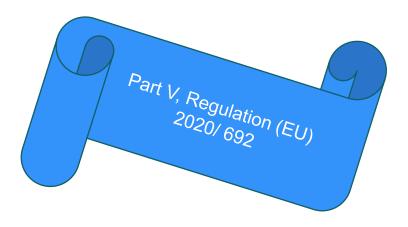
Fish of species belonging to the superclass *Agnatha* and to the classes *Chondrichthyes, Sarcopterygii and Actinopterygii;* Aquatic molluscs of species belonging to the phylum *Mollusca* Aquatic crustaceans of species belonging to the subphylum *Crustacea*

- Aquatic animals and PAO intended for further processing in the Union of species referred to above which are listed in Regulation 2018/1882 for Cat A, B and C diseases
- Aquatic animals and PAO intended for further processing in the Union of species which are susceptible to the diseases for which MS have national measures under Article 226 of the AHL
- Excluded:
 - PAO other than live aquatic animals intended for direct human consumption
 - Wild aquatic animals and products of animal origin from those wild aquatic animals landed from fishing vessels for direct human consumption



Specific requirements

Inspection of aquatic animals prior to dispatch	Article 166
Dispatch of aquatic animals	Article 167
Transport of aquatic animals by vessel	Article 168
Specific transport and labelling requirements of aquatic animals and PAO from aquatic animals, intended for further processing in the Union	Article 169
Requirements regarding the TC/ territory/zone/compartment/ establishment of origin	Article 170
Vector species – rules for live animals and rules for PAO	Article 171
Derogations Certain categories of aquatic animals	Article 172
Certain PAO from aquatic animals other than live aquatic animals intended for further processing	Article 173
Handling after entry in to the Union	Article 174





Prior inspection, dispatch & labelling

Aquatic animals other than those which have been packaged and labelled ready for human consumption, must be inspected within 72 hours of loading

Dispatched directly to the Union

Not transported under conditions that jeopardise the health status

Water exchange only possible:

- at land based points approved by the CA of the country/ territory
- for well-boats: >10km away from aquaculture establishments

Consignments need legible label or entry in ships manifest

In both cases - link to the health certificate issued for the consignment



Aquatic animals: Requirements regarding TC/territory/zone/compartment/ establishment of origin

Must be free from Cat A, Cat B, relevant Cat C diseases and diseases for which receiving MS has national measures

Must be free from Cat C diseases in all cases where animals are to be released into the wild

All entries from other TCs/ territories/ zones/ compartments, must come from disease-free TCs/ territories/ zones/ compartments*

Vaccination has not been carried out*

Establishment of origin must be registered / approved in accordance with requirements at least as stringent as those set out in Commission Delegated Regulation (EU) 2020/691*

* Also apply with regard to diseases for which MSs have taken national measures under Article 226 AHL



Vector species

Annex XXX of DA sets out the conditions under which the vector species set out in Column 4 of Regulation (EU) 2018/1882, act as vectors of listed aquatic diseases

Rules set out for PAO from aquatic animals intended for further processing in the Union apply only to susceptible species (listed in column 3 of Regulation (EU) 2018/1882), not to vector species (listed in column 4)



Derogations for certain categories of aquatic animals

The requirement to originate from a disease- free TC/ territory/zone/compartment does not apply to:

(i)	Animals destined for a disease control aquatic food establishment
(ii)	Animals destined for a confined establishment for research purposes
(iii)	Wild aquatic animals coming from an approved quarantine establishment or destined for one in the Union
(iv)	Molluscs and crustaceans packaged and labelled for human consumption in accordance with Regulation (EC) No. 853/2004.



PAO from aquatic animals entering the Union for processing

Are not required to originate from a disease- free TC/ territory/zone/compartment when they are:

Destined for a disease control aquatic establishment

Fish which have been slaughtered and eviscerated prior to dispatch



Handling after entry of aquatic animals and PAO intended for further processing

Aquatic animals must be transported directly to their destination

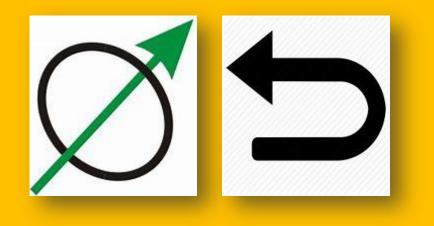
Handled appropriately to ensure that natural waters are not contaminated

May not be released or immersed in natural waters unless authorised by the CA

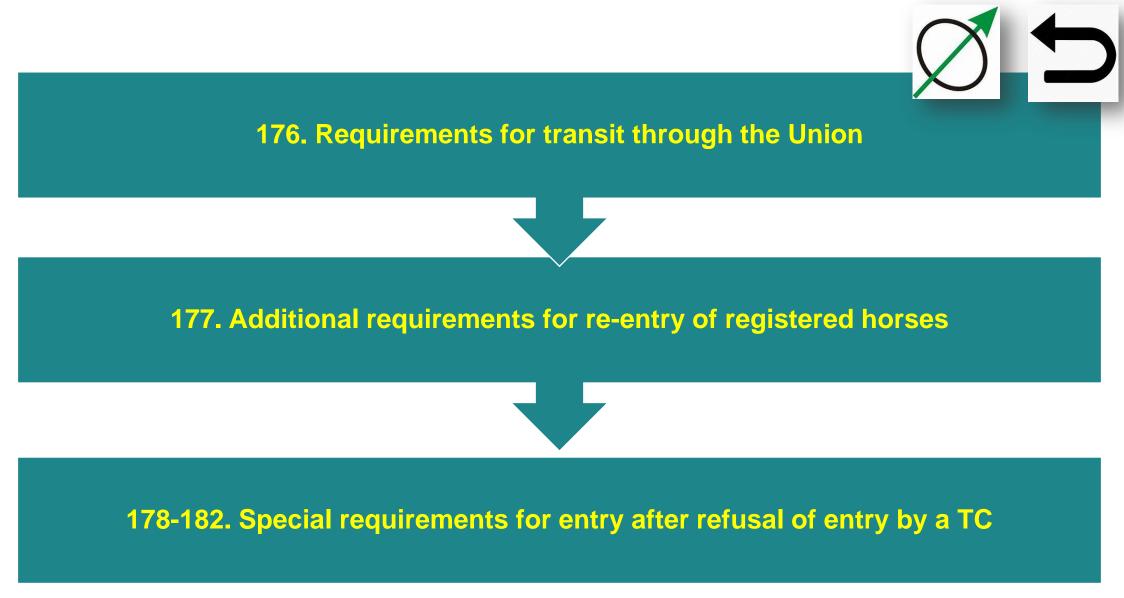
Transport water from consignments must also be handled appropriately



Part VI Transit and re-entry











Commission Implementing Regulation (EU) 2021/4040 laying down the lists of TCs authorised for the entry into the Union



Lists of TC replaced from 21 April 2021

- ✓ Decision 2006/168/EC
- ✓ Decision 2007/777/EC
- ✓ Decision 2008/636/EC
- ✓ Regulation (EC) No 798/2008
- ✓ *Regulation (EC)* No 1251/2008
- ✓ Regulation (EU) No 206/2010
- ✓ Decision 2010/472/EU
- ✓ Regulation (EU) No 605/2010

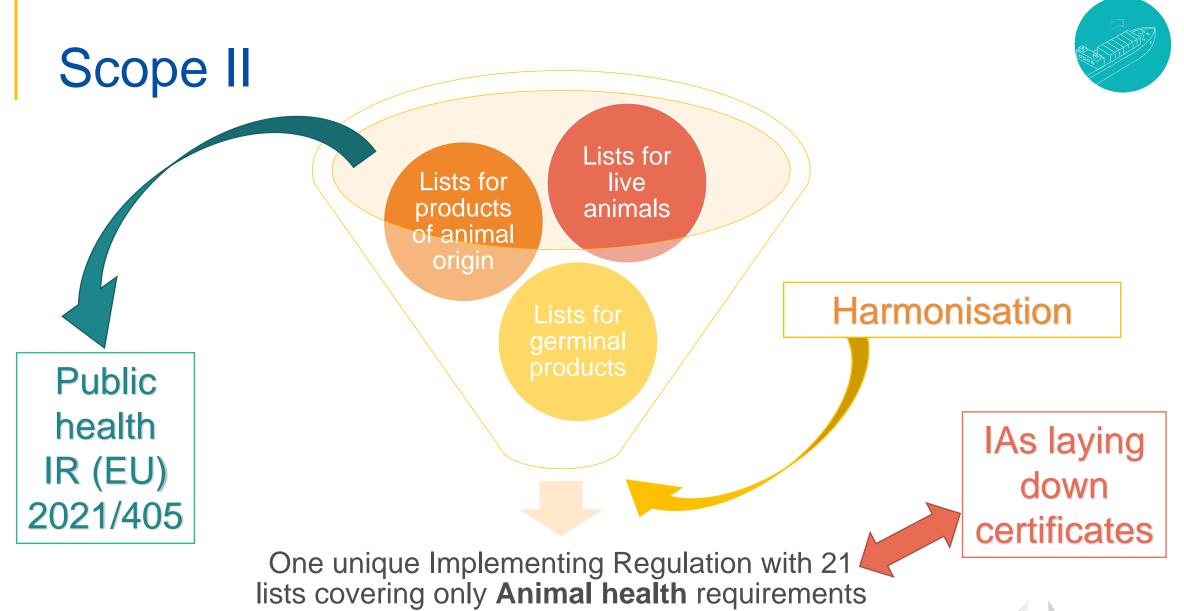
- ✓ Decision 2011/630/EU
- ✓ Regulation (EU) No 28/2012
- ✓ Decision 2012/137/EU
- ✓ Regulation (EU) No 139/2013
- ✓ *Regulation (EU) 2016/759*
- ✓ *Regulation (EU) 2018/659*
- ✓ Decision (EU) 2019/294



Scope

This IR covers all species and commodities included in the scope of R(EU) 2020/692





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New lists

Ungulates intended for confined establishments (no more references to other lists)

✓ **Bees** (no more references to other lists)

✓ **Dogs, cats and ferrets** (no more references to other lists)

✓ Casings

Products of animal origin intended for personal use (TCs covered by derogation)

Transit: compiles the specific conditions applicable to different kinds of transit that currently are in the relevant list



Main changes I



Poultry, hatching eggs, meat of poultry and game birds, and eggs and egg products have been split into 3 lists

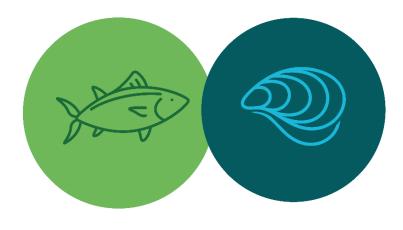
The list of milk and dairy products has been split into two. One corresponds to column A-B and the other to column C of R 605/2010, (only the FMD situation is taken into account for AH). Pasteurisation requirements (PH) for the establishments of origin will be reflected in TRACES (at the level of country-zone)



Main changes II



Aquatic animals: the list now covers only listed species as well as aquatic animals intended for aquaculture establishments, release into the wild and other specified purposes





General approach

✓ 1 Annex = 1 list = 1 commodity \rightarrow 21 lists

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\checkmark Each Annex = 4 parts
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- \checkmark Part 1 = list of TC and zones
- Part 2 = descriptions of zones
- Part 3 = descriptions of specific conditions
- Part 4 = description of animal health guarantees

Annex I provides for general rules applicable to Annexes II to XXII



Example: Annex II - Ungulates

ISO code and name of the third country or territory	Code of the zone as set out in Part 2	Species permitted to enter the Union	Categories permitted to enter the Union	Animal health certificates	Specific conditions as set out in Part 3	Animal health guarantees as set out in Part 4	Closing date	Opening date
1	2	3	4	5	6	7	8	9



Thank you



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