



# Regulation (EU) 2016/429 on transmissible animal diseases "Animal Health Law"

EURL Meeting, 31 May 2021

**Unit Animal Health and Welfare**  
**Directorate-General for Health and Food Safety**  
**European Commission**

# Topics today:

1. Update on **key Regulations**
2. Ongoing work
3. Main changes of interest to **EURLs / NRLs**



# Process overview



PART OF AHL	DA	Status	Point in the process	Comments
I	<p><b>General rules:</b></p> <p>Disease listing (Aquatic &amp; Terrestrial)</p> <p>Disease categorisation, listed species (Aquatic &amp; Terrestrial)</p>	Completed	Adopted	<p>Commission Delegated Regulation (EU) <b>2018/1629</b></p> <p>Commission Implementing Regulation (EU) <b>2018/1882</b></p>
II	<p><b>Surveillance, eradication programmes, disease freedom</b> (Aquatic &amp; Terrestrial)</p>	Completed	Adopted	<p>Commission Delegated Regulation (EU) <b>2020/689</b></p>
III	<p><b>Disease control</b> (Aquatic &amp; Terrestrial)</p>	Completed	Adopted	<p>Commission Delegated Regulation (EU) <b>2020/687</b></p>
IV.II	<p><b>Establishments and transporters</b> (Aquatic)</p>	Completed	Adopted	<p>Commission Delegated Regulation (EU) <b>2020/691</b></p>
IV.II	<p><b>Intra-EU movements</b> (Aquatic)</p>	Completed	Adopted	<p>Commission Delegated Regulation (EU) <b>2020/990</b></p>
V	<p><b>Entry into the EU</b> (Aquatic &amp; Terrestrial)</p>	Completed	Adopted	<p>Commission Delegated Regulation (EU) <b>2020/692</b></p>

# Recent developments & future focus

## ✓ Commission Implementing Regulations / Decisions

- **Certificates** – Aquatic certificates in 2 separate Regulations  
Implementing Regulations (EU) 2020/2235 (Terr & Aqua) and 2020/2236 (Aqua)  
10 new certificates
- **National measures** under Article 226 of the AHL  
Implementing Decision (EU) 2021/260  
Largely 'roll over' of current measures from Commission Decision 2010/221/EU ...but now also includes KHV
- **Exemptions** from registration and record-keeping  
In progress (SANTE/7162/2020)
- **Amendment of Regulation (EU) 2018/1882** (listed species)  
In progress
- **List of disease-free MS/zones/compartments >75%** of territory of MS & where supplying water catchment is not shared with another MS/TC  
Implementing Regulation (EU) 2021/620 (Terr & Aqua)  
Largely 'roll-over' of current statuses from Commission Decision 2009/177/EC)

# Ongoing & future focus

## ✓ Training, communications

- Better Training for Safer Food
- 5 Seminars for CAs between Jan & June
- Conference held 21-22 April
- Broader communications with stakeholders also planned
- 'Traditional' sectoral BTSF training late 2021/ 2022
- When in doubt, CAs should be able to help...

## Disease listing (finfish)

### Commission Delegated Regulation (EU) 2018/1629 (amending Annex II of the AHL)

- Epizootic haematopoietic necrosis (EHN)
- Viral haemorrhagic septicaemia (VHS)
- Infectious haematopoietic necrosis (IHN)
- Infection with HPR- deleted ISAV
- Koi herpes virus (KHV)



## **Disease listing (crustaceans)**

### **Commission Delegated Regulation (EU) 2018/1629 (amending Annex II of the AHL)**

- Infection with Taura Syndrome virus
- Infection with yellow head virus
- Infection with white spot syndrome virus



## Categorisation and listed species

### Commission Implementing Regulation (EU) 2018/1882

Disease	Category	Susceptible & vector species
EHN	A	As set out in CIR (EU) 2018/1882*
VHS	C	“
IHN	C	“
Infection with HPR-deleted ISAV	C	“
Koi herpes virus disease	E	“
Infection with Taura syndrome virus	A	“
Infection with yellow head virus	A	“
Infection with whitespot syndrome virus	C	“

\*Preparing to amend

## Commission Implementing Regulation (EU) 2018/1882

1. 'Cat A' approximates to 'exotic' under Dir 2006/88/EC
2. 'Cat C' approximates to 'non-exotic' under Dir 2006/88/EC
3. KHV 'non-exotic' under Dir 2006/88/EC but 'Cat E' under CIR (EU) 2018/1882 – 'diseases for which there is a need for surveillance' - MS can take national measures under Article 226 (AHL)

### Cat A

Diseases that do not normally occur in the Union and for which immediate eradication measures must be taken

### Cat C

Diseases which are of relevance to some Member States and which are subject to optional eradication

### A226

Similar to Article 43 of Dir 2006/88- 'national measures' - diseases which constitute a significant risk in a particular MS

# Surveillance, eradication programmes, disease freedom

1. **Notification** of suspicion of presence of listed and emerging diseases
1. **Investigation** of abnormal mortalities & other signs of serious disease – or significant decreased production rates with an undetermined cause- required in all cases
2. **Risk based surveillance** - required in certain approved establishments
  - simplified approach
  - set out details of risk factors to be taken into account when categorising establishments
  - 'high', 'medium' or 'low' risk
4. **Disease-freedom** may be achieved at MS/zone/compartment level
  - a number of pathways set out
  - comprehensive rules for eradication programmes

# Surveillance, eradication programmes, disease freedom

- **Directive 2006/88 : CAT III** – farms which are not known to be infected but not in a programme to gain freedom
- **BUT** after more than a decade.... > 80% of establishments growing finfish throughout the EU were in this category ..... this category has not been replicated under the new Delegated Regulations
- **Surveillance programmes instead**
  - carried out at establishment level and voluntary
  - once in the programme, frequency of visits and testing carried out by the CA in accordance with relevant chapter of Part III of Annex VI to Regulation (EU) 2020/689.



## Disease control measures

- ✓ Set out in detail for **Category A diseases** – measures to be taken by operators and competent authorities
  - ✓ on suspicion
  - ✓ on confirmation
- ✓ Cross references to control measures for **Category B & C diseases** which are set out in Delegated Regulation (EU) 2020/689



# Registration and approval of establishments

- ✓ Basic requirement for aquaculture establishments is **registration** but certain higher risk aquaculture establishments need to be **approved**
- ✓ **Derogations from the requirement for approval** for certain establishments are set out in Regulation (EU) 2016/ 429 and in Regulation (EU) 2020/691 e.g those producing small quantities for direct consumption/ local markets; P&Ts; closed ornamental; solely for release into the wild; extensive ponds..... when the risk they pose is insignificant
- ✓ Currently working on a new Regulation concerning **derogations from the requirement to be registered**
- ✓ AHL and DA set out **requirements for operators of registered establishments** e.g. notification, investigation, basic record keeping
- ✓ AHL and DA set out **requirements for operators of approved establishments** e.g. notification, investigation, record keeping, biosecurity measures, facilities & equipment, in certain cases participation in an RBS scheme

# Transitional measures – “grandfather rights”

Establishments and operators registered or approved in accordance with Directive 2006/88/EC before 21 April 2021 shall be deemed to be registered or approved in accordance with the requirements in the AHL and shall as such, be subject to its provisions



## Specific requirements for approval

Requirements **depend on the type of establishment** but in general, will include at least two of the following:

- Risk based surveillance
- Biosecurity measures
- Facilities and equipment





# Risk based surveillance proposal

- ✓ Applies to certain approved establishments
- ✓ Applies to those keeping **listed species for Cat C diseases** which the CA has categorised as 'high', 'medium' or 'low' risk
- ✓ Applies to those keeping
  - ✓ **non-listed species for Cat C diseases or**
  - ✓ **species listed as vectors of Cat C diseases in Implementing Regulation 2018/1882 but which have not been in contact with listed susceptible species**which the CA has categorised as 'high' risk
- ✓ See this as a more targeted application of RBS than that set out in Directive 2006/88/EC and **more suitable for detection of emerging diseases**
- ✓ Many aquaculture establishments in the EU keep species which are currently not listed => proposed that RBS will apply only to the **high risk** establishments growing those species

## Registers of establishments & record keeping

- The **CA must keep registers** containing certain information which relates to registered and approved establishments. Operators of **approved** establishments will be included in an inter-net based information page which is **publicly available**
- **Operators including transporters must keep records**
  - which will include the requirements set out in the AHL and supplemented by the requirements set out in Delegated Regulation (EU) 2020/691 – *traceability / proof of biosecurity measures etc...*
  - working on a new Regulation setting out certain derogations for low risk operators
- => similar to the requirements in Dir 2006/88/EC

# Movements of aquatic animals and products within the Union

- Rules for movements of aquatic animals within the EU are **broadly similar** to those set out in Directive 2006/88/EC
  - **OVERALL**: Movements shall not jeopardise the health status at the place of destination with regard to listed or emerging diseases
- New requirement for **self declaration documents** for movements between Member States in cases where certification is not required
- Self declaration documents relating to **surveillance programmes** will have relevant health attestations i.e. date and result from last test

# Entry into the EU

- **Delegated Regulation (EU) 2020/692** -covers only listed species for the listed diseases.
- Entry into the Union of non-listed species subject to national rules

- The animal health rules which apply to the entry into the Union of certain animals and products also apply to transit



- **Associated Implementing Acts**

- ✓ List of third countries (AH): Regulation (EU) 2021/404
- ✓ Certificates for entry into EU: Annex II to Regulation (EU) 2020/2236 and Chapters 28 & 31 of Annex III to Regulation (EU) 2020/2235

# Particular interest to EURLs/ NRLS

## Annex VI of Delegated Regulation (EU) 2020/689

- Largely based on Implementing Decision (EU)2015/1554 but some differences.....
  - **Part I**= Risk-based surveillance
    - General approach
    - Risk ranking of establishments
    - Frequency of risk-based animal health visits
  - **Part II** = Disease specific requirements for disease free status  
=>Chapters for VHS/IHN, Infection with HPR-deleted ISAV, Infection with WSSV
    - General requirements for health visits and sampling
    - Granting disease-free status when initial health status is 'unknown'
    - Granting disease-free status when initial health status is 'infected'
    - Maintaining disease-free status
    - Diagnostic and sampling methods

# Particular interest to EURLs/ NRLS

- Some significant differences however....
  - Detailed diagnostic methods and procedures currently set out in Annex II to 2015/1554 are **not included in Annex VI**. From 21 April 2021, these have been made available on EURL website.
  - **Part III of Annex VI: Surveillance programme for Category C diseases (new)**
    - General requirements for health visits
    - Requirements to demonstrate the implementation of a surveillance programme
    - Requirements to re-start a surveillance programme after a disease outbreak
    - Similar to requirements to maintain freedom

**THANK YOU**  
**for your attention**

