



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

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Topics today:

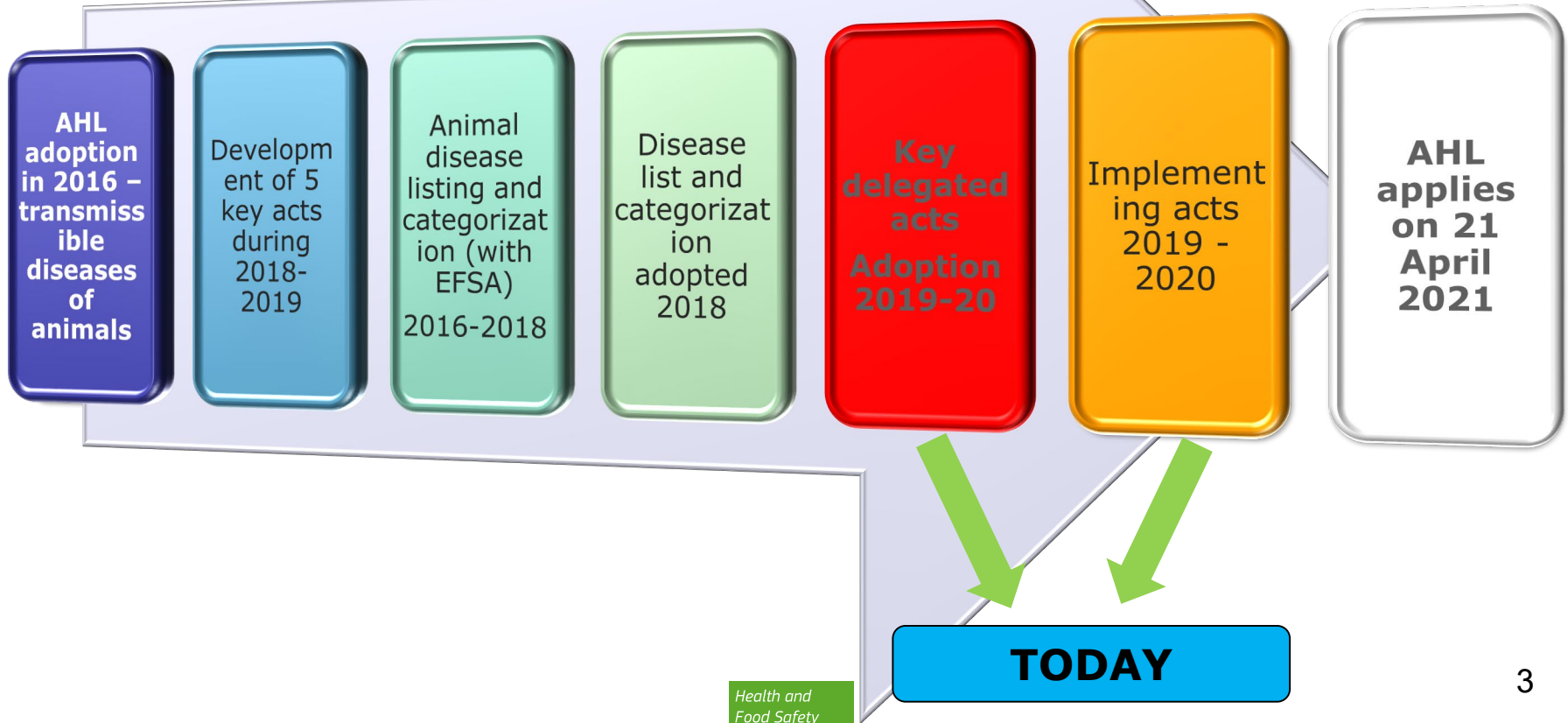
1. Update on **current state of play** with key delegated and implementing acts

2. Summary of **main changes**

3. Changes of interest to **EURL/NRLs**



Process overview





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



NEXT STEPS AND FUTURE ACTIONS

Ongoing & future focus

- ✓ Complete Commission Implementing Regulations
 - National measures under Article 226 of the AHL
 - Amendment of IR 2018/1882 (listed species)
 - Exemptions from registration and record-keeping
 - Certificates – 2 separate Regulations for aquatics (10 new certificates)

- ✓ Amendment of certain Commission Delegated Regulations
 - Several – but those relevant to aquatics are Regulations 2020/689 and 2020/692

- ✓ Training, supporting documents
 - Delays due to Covid -19
 - Communication phase – CAs & stakeholders
 - Better Training for Safer Food

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 - required in all cases
2. **Investigation** of abnormal mortalities & other signs of serious disease – or significant decreased production rates with an undetermined cause- required in all cases
3. **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

- **Existing 'CAT III'** – *farms which are not known to be infected but not in a programme to gain freedom* – provided for in Directive 2006/88/EC
- **BUT** after more than a decade... > 80% of APBs growing finfish throughout the EU are currently in this category – **significant problem**
- 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, testing must be carried out by the CA in accordance with the legislation



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
- ✓ 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

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 (e.g. sea bass and sea bream) =>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*
- => 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** -largely reflective of current aquatic legislation but covers only listed species for the listed diseases.
- **Associated Implementing Acts**
 1. List of third countries
 2. Certificates for entry into EU (under the AHL and **Article 90 of the OCR**)



Particular interest to EURLs/ NRLS

- Amendment of Implementing Regulation (EU) 2018/1882
- Annex VI to Commission Delegated Regulation (EU) 2020/689

Particular interest to EURLs/ NRLS

Amendment of Implementing Regulation (EU) 2018/1882

- EURL convened 2 expert groups – Fish & Crustaceans
- Review of species list (susceptible and vector)
- Report provided to EU Commission early September
- Amendment to CIR (EU) 2018/1882 in preparation
- Takes account of deliberations of OIE ad hoc groups
- Risk management step – Member States & EU Commission
- Ready for date of application of AHL

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 will instead be 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

