



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

Aquaculture Advisory Council Meeting
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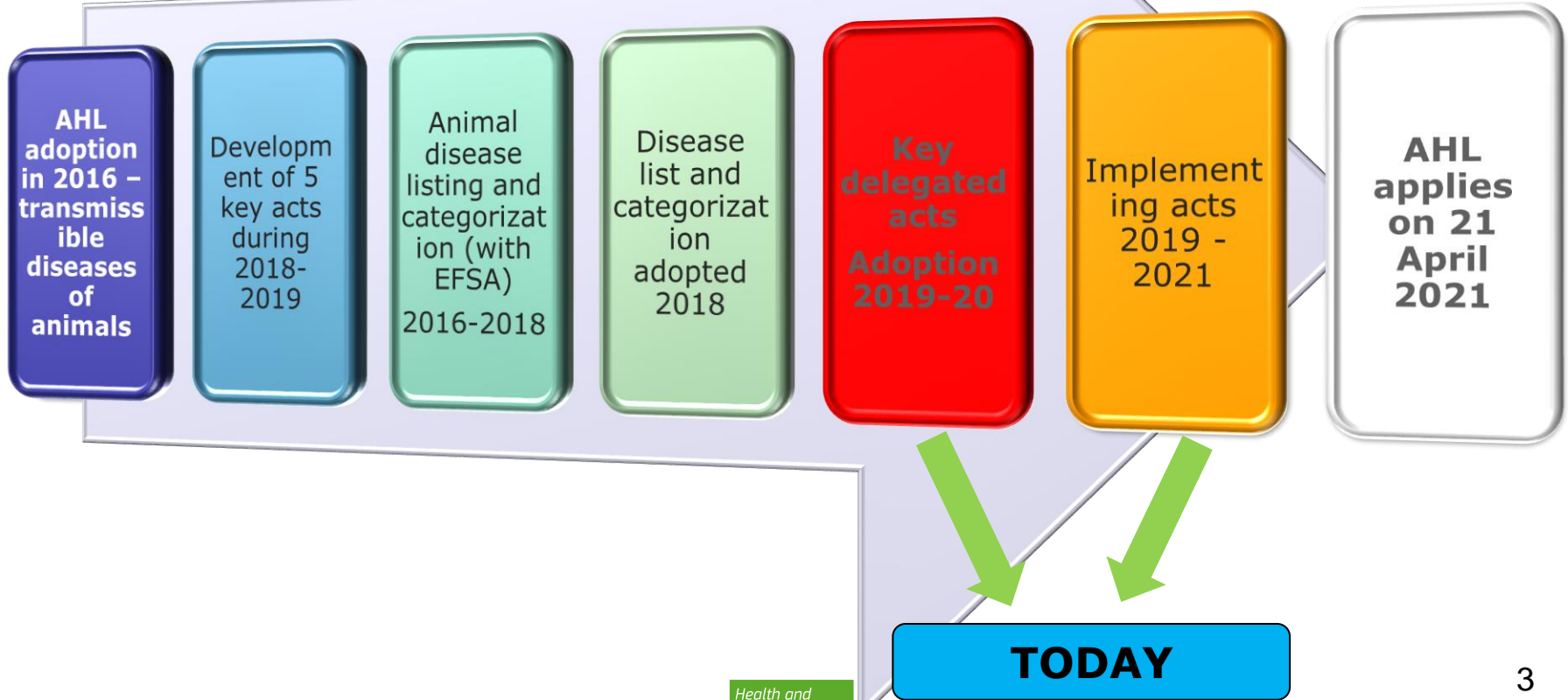
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Topics today:

1. Update on **key delegated acts**
2. **Ongoing & planned work** concerning implementing acts / Decisions
3. **Training**
4. **Main changes** of interest to operators of aquaculture establishments



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

Recent developments & future focus

✓ Commission Implementing Regulations / Decisions

- **Certificates** – 2 separate Regulations for aquatics
Implementing Regulations (EU) 2020/2235 (Terr & Aqua) and 2020/2236 (Aqua)
10 new certificates
- **National measures** under Article 226 of the AHL
SANTE/7164/2020 – Implementing Decision
Largely 'roll over' of current measures from Commission Decision 2010/221/EU
Sent for adoption
- **Exemptions** from registration and record-keeping
In progress
- **Amendment of Regulation (EU) 2018/1882** (listed species)
In progress
- **List of disease-free MS/zones >75%** of territory of MS
SANTE/7166/2020
Largely 'roll-over' of current statuses from Commission Decision 2009/177/EC (Terr & Aqua)
In progress

Ongoing & future focus

- ✓ **Amendment of certain Commission Delegated Regulations**
 - Regulations 2020/689 and 2020/692 with respect to aquatics
 - Mainly to fix errors or to provide increased clarity
 - Important amendment concerns Article 83 of Regulation (EU) 2020/689 concerning declarations (see later)

- ✓ **Training, communications**
 - Delays/ alternative arrangements due to Covid-19
 - Better Training for Safer Food
 - 5 Seminars between Jan & June – first held 19-21 Jan
 - Conference will be held 21-22 April
 - Broader communications also planned

Next:

Some points of interest
operationally.....



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
- ✓ **Derogations from the requirement to be registered** – in preparation
- ✓ 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



What are the requirements to be approved?

Operators must comply with requirements which relate to:

Regulation (EU)
2020/691, PART II,
Title I, Chapter 2

Biosecurity measures

- biosecurity plan which should consider the need for disinfection points, work clothing & footwear, cleaning & disinfection of equipment, visitor control, removal of dead animals, disinfection of eggs, biosecurity measures for transporters

Facilities and equipment

- generally relate to ensuring facilities, equipment & means of transport can be appropriately cleaned & disinfected, predator control, water treatment

Risk-based surveillance

in certain approved establishments - High risk 1visit/ year; Medium risk 1visit/2 years; Low risk 1visit/ 3 years

Risk based surveillance proposal

- ✓ 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

- ✓ More targeted application of RBS than that set out in Directive 2006/88/EC and **more suitable for detection of emerging diseases**

- ✓ Applies in certain approved establishments or in certain groups of approved establishments (common biosecurity measures & epidemiologically linked)

Risk-based surveillance

Many be combined with health visits and sampling which are carried out as part of:

- (a) eradication programmes
- (b) programmes to maintain freedom
- (c) surveillance programmes for Cat C diseases

Disease-free status

- Several pathways – Regulation (EU) 2020/689, Part II, Chapter 4
- Member State/ zone/ compartment
- Member State/ zone >75% of territory plus those sharing a water catchment with another MS => Comitology procedure and amendment to Implementing Regulation
- Otherwise, Article 83 of Regulation (EU) 2020/692
- Provisional declaration & 60 days if no concerns raised
- Increased autonomy to MSs
- Faster process
- Following upcoming amendment, this will also apply to approval of eradication programmes
- Publish on website of relevant CA

Certification/ notification/ self-declaration

- **Certification:** Listed species into disease-free areas or those subject to an eradication programme (Articles 208 & 209 AHL)- model certificates
- **Self-declaration:** Concerns trade between aquaculture establishments in different Member States when a certificate is not required (Article 218 AHL) – content set out but models not provided
- **Notification in TRACES:** Required in both cases (Articles 219 & 220 AHL)
- **Self- declaration / notification for movements between establishments subject to surveillance programmes in different Member States:** Date & results from lab testing

Self-declaration

Article 218 AHL

- Places of origin /destination/ places en route when relevant
- Means of transport
- Species, quantity, category
- Info needed to demonstrate compliance with Articles 191 to 207
 - Registered/ approved establishment
 - Not subject to movement restrictions or emergency measures
 - Disease prevention in relation to transport
 - Animals shall not be used for any purpose other than the intended one except when the new use does not increase the risk
 - No disease symptoms
 - No abnormal mortalities in establishment of origin unless in separate epidemiological unit

Article 14 & Annex II(B) Regulation (EU) 2020/990

- Date and result from last sample taken in establishments subject to a surveillance programme

Obligations of operators at place of destination



AHL Article 194

Check the health certificate or self-declaration document is present

Inform the CA at the place of destination of any irregularity in relation to the documents or the aquatic animals themselves

If an irregularity is observed, isolate the aquatic animals until the CA has taken a decision in relation to them

Surveillance Programmes -

Surveillance programmes instead of the Cat III establishments provided for in Directive 2006/88/EC

Carried out at establishment level and voluntary - once in the programme, testing must be carried out by the CA in accordance with the legislation

Frequency of visits and sample size set out in relevant chapter of Part III of Annex VI to Regulation (EU) 2020/689

Entry into the EU

- **Delegated Regulation (EU) 2020/692**

Covers only listed species for the listed diseases.

Non-listed species covered by MSs national rules

- **Associated Implementing Act**

List of third countries – concerns only listed species

List of third countries for non-listed species – national rules





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THANK YOU
for your attention

