



State of play: Animal Health Law, Official Controls Regulation and their tertiary rules most relevant for aquaculture

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Opening

- *Explore the new AHL and OCR*
- *Opportunities and constraints by the new legal frameworks*
- *Changes?*
- *Your role?*

Change of EU legal framework

- *Currently:*
 - Directive 2006/88/EC
 - Regulation (EC) No 882/2004 on official controls
- *Future:*
 - Regulation on transmissible diseases (EU) 2016/429: sectorial, animal health rules
 - Date of application: 21 April 2021
 - Regulation on official controls (EU) 2017/625: general rules across sectors
 - Date of application: 14 December 2019

Some new elements in the AHL

- *Regulation: applies directly*
- *Transmissible diseases*
- *Aquaculture together with terrestrial animals*
- *Not limited to trade and to diseases specific rules*
- *Responsibilities of keepers*
 - **Prevention**
- *Categories of diseases*
 - **Category A-E: KHV**
- *Definition of a zone*
 - **lake**

EU aquaculture rules to be replaced

- *CD 2008/392/EC on Internet-based info page*
- *CD 2008/896/EC on guidance for RBS*
- *CD 2008/946/EC on quarantine*
- *CR (EC) No 1251/2008 on movements*
- *CD 2009/177/EC on surveillance*
- *CD 2010/221/EU on national measures*
- *CID (EU) 2015/1554 on diagnostic methods*

Broad objectives

- *Keep the working concepts and approaches*
- *Identify and improve areas which did not achieve the desired objective and fix them*
- *Take account of new developments since 2006*
- *Take account of audit findings*

Already adopted Commission acts

- *Delegated Regulation 2018/1629*
 - **List of diseases**
- *Implementing Regulation 2018/1882*
 - **Categories of animal diseases and list of susceptible species**
- *Categories of diseases*
 - **Category A-E: KHV**
- *List of susceptible species*
 - **To be reviewed**

New delegated acts under construction

Together with terrestrial animals

- *On surveillance, eradication and freedom*
- *On control measures*
- *Entry into the Union*

Only aquaculture

- *Registration and approval of establishments*
- *Movements within the Union*

Some discussed topics

- *Derogation from approval*
 - **Extensive aquaculture, ponds**
- *Category III establishments*
 - **No information, too static, too many**
- *Dependent compartments*
 - **Protection against intrusion vs. assessment**
- *Maintenance of freedom for dependent compartments*
 - **Number of annual sampling and inspections**

Some discussed topics, contd.

- *Derogation for certification within MS*
- *Movements between two entities*
 - **Both in a programme**
- *Obligation of operators to participate in eradication programmes*
 - **If competent authority decides**
- *Details of diagnostic methods*
 - **Reduce details in EU rules**
 - **Use web page(s)**

New OCR: basics

- *General, across sectors*
- *Risk-based controls*
- *Comprehensive*
- *Article 1(2)(d): animal health requirements*

- *Official controls:*
 - **Verification of compliance with rules**
- *Other official activities:*
 - **Anything else, e.g. verification of presence of pathogens**
- *Article 2*
- *Article 1(5): a selection of Articles for other official activities*

New OCR: a few examples of its rules

- *General obligations of competent authorities*
- *Transparency of official controls*
- *Methods and technics of official controls*
- *Delegation of official tasks*
- *Methods used for sampling and analysis ("cascade")*
- *Second expert opinion*
- *Designation of official labs*
- *Obligations of official labs and derogations for them*
- *EU and national reference labs and centres*
- *Multi-annual national control plans and annual reports*
- *Etc.*

Designation of official labs

- *Article 37*
- *In another Member State too*
- *Article 37(4)(e): **accreditation***
 - **All methods**
 - **May be defined in a flexible manner**
- *Derogation for other official activities*
 - **Article 40(1)(b)**
- *Role of the national reference labs*
- *If results need confirmation:*
 - **In an accredited lab**
- *Permanent derogation*
 - **Commission delegated act under Article 41**
- *Temporary derogation:*
 - **Competent authorities under Article 42**

Cascade of methods

- *Article 34*
- *Established in Union rules*
- *Internationally recognised or by EURL*
- *National or by NRLs*
- *Validated by validation studies in accordance with internationally accepted scientific protocols*
- *Urgency opt-out*
- *Commission implementing act (may)*

Summary

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