



A: Aquaculture in the new Animal Health Law

B: Listing of fish diseases in EU legislation

C: Listing of susceptible species – report from an OIE working group

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Aquaculture in the new Animal Health Law

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This presentation does not necessarily represent the views of the European Commission

The New Animal Health Law

Regulation (EU) 2016/429 was adopted by the European parliament and the Council 31 March 2016.

The Regulation enters into force 1 April 2021.

Which impact will this have on the future aquatic animal health legislation?



Introduction

- The approach
- What's new?
- Supplementary rules
- Status today
- Further process and time frame

The approach

- **Regulation instead of directive**
- **Keep principles of Directive 2006/88/EC**
- **Align to the Lisbon Treaty**
- **Harmonise with terrestrial animals where appropriate**
- **Simplify and clarify where appropriate**
 - fewer definitions
 - simplified rules – details in delegated/implementing acts
 - added flexibility (in particular as regards movements and disease control)
 - Reduce administrative burden (registration, approval)

Some new elements

– **General responsibility for animal health**

- Operators
- Veterinarians/aquatic animal health professionals
- Mandatory health visits

– **Enhanced tools for controlling diseases in wild aquatic animals**

- Transport requirements
- Record keeping
- Movement requirements including health certification and self-declaration

Disease listing and categorisation

- New criteria for the listing of diseases
- Five categories of diseases (a, b, c, d and e)

Listing of diseases

Category a): Diseases not normally occurring in the Union

Category b): Diseases which must be controlled in all MS

Category c): Diseases subject to voluntary control in the MS

Category d): Diseases for which movement restriction measures may apply.

Category e): Diseases which shall be subject to surveillance

Animal Health Law - Status

- Adoption by EP and Council: 9 March 2016
- Publication – entering into force: 31 March 2016
- Transposition period: 5 years
 - Supplementary rules to be drafted and adopted: 36 months
 - Delegated acts
 - Implementing acts
 - Member States preparing period: 24 Months
- AHL will apply from : 1 April 2021

Important questions for the DA/IA process

- Structure of the DA and IA
- Priority of the optional acts
- What are the weaknesses of the current legislation – issues for improvement?
- Where are the "loop-wholes" to be filled?
- What is the best way to run the drafting and adoption process?

Most probable outcome – Delegated acts

- **One Delegated act for the listing of diseases** (both aquatic and terrestrial diseases)
- **One delegated act for diagnostic methods** (both aquatic and terrestrial diseases)
- **One delegated act for all other issued – aquatic animals:**
 - Requirements for registration and approval
 - Requirements for disease notification and control
 - Requirements for eradication programmes and disease free status
 - Requirements for intra Union movements incl. health certification
 - Requirements for entry into the Union of aquatic animals

Most probable outcome – implementing acts

- **One implementing act for surveillance, eradication and disease control**
 - Detailed requirements for surveillance- and eradication programmes and applications for disease free status
 - Practical implementation of contingency plans
- **One implementing act for Intra Union movement and entry**
 - Derogations from obligations to approve or register establishments
 - Animal health certificates – models
 - List of third countries
- **One implementing act for approval of national measures**
 - List of diseases subject to national measures
 - Approval of eradication programmes and disease free areas

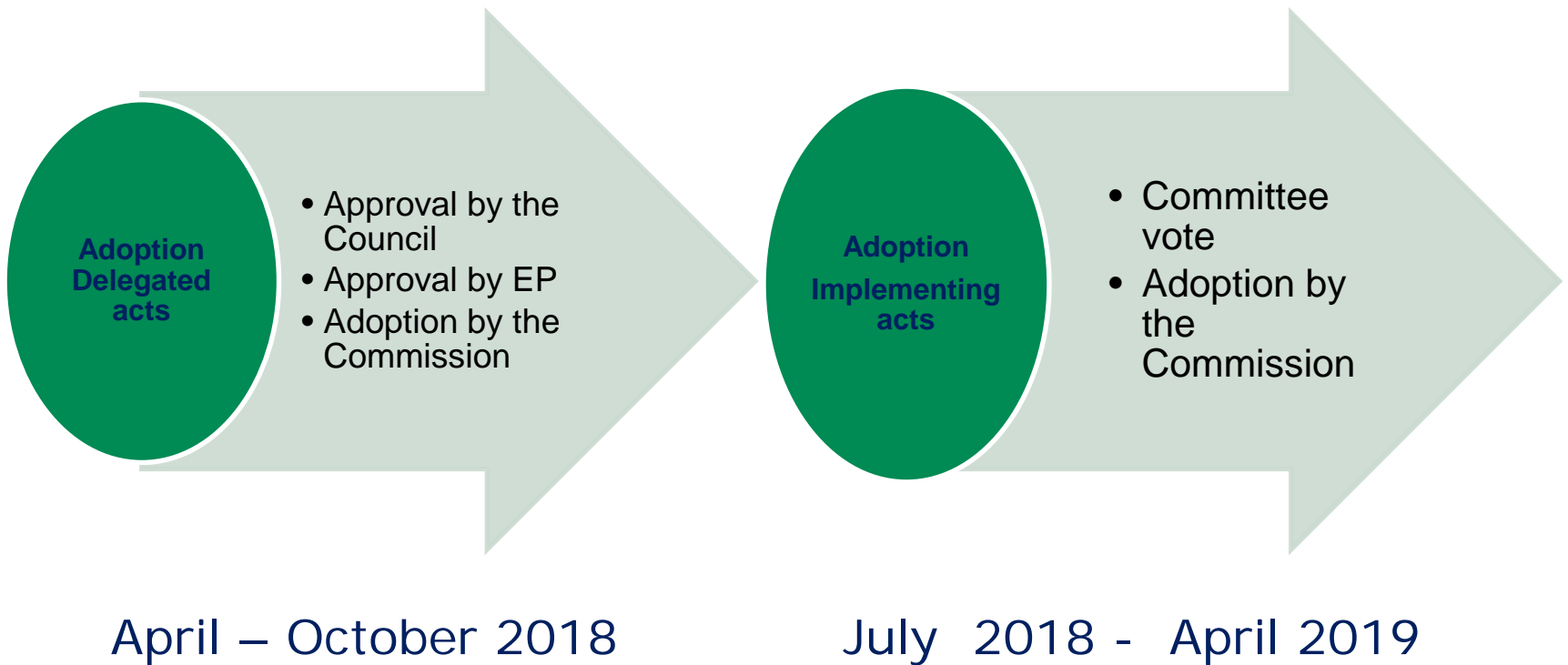
Important questions to be discussed in the drafting process

- The listing and categorisation of diseases
- Requirements for information to be kept in the register for aquaculture establishments
- Derogations from the requirements for movement of live aquatic animals
- Requirements for risk based surveillance and animal health visits
- Requirements for health certification
- Requirements for surveillance for the purpose of obtaining disease free status

Structure and time frame for the ongoing process



Structure and time frame



Listing of fish diseases in EU legislation

Assessment of the listing of all existing listed diseases + candidate diseases

- In order to provide the necessary background for evaluation of diseases the EURL Fish was asked to provide updated information based on scientific studies.

ASSESSMENT CRITERIA – Fish diseases

Disease	Salmonid alphavirus (SAV)
Source	
DISEASE PROFILE	
Animal species	
Morbidity and Mortality rates in animal populations	
Zoonotic character	
Resistant to treatments, AMR	
Persistence in the animal population or environment	
Routes and speed of transmission animals-animals	
Routes and speed of transmission animals-humans	
Absence, presence and distribution of the disease in the EU	
Risks of its introduction into the EU if absence in EU	
Existence of diagnostic and disease control tools	
IMPACT OF THE DISEASE ON	
Agricultural production:	
<ul style="list-style-type: none"> - level of presence of the disease - loss of production - other losses 	
Human health:	

<ul style="list-style-type: none"> - transmissibility - severity of human forms - effective prevention or medical treatments 	
Animal welfare	
Biodiversity and the environment	
POTENTIAL TO GENERATE A CRISIS SITUATION AND ITS POTENTIAL USE IN BIOTERRORISM	
Bi terrorism	No data
FEASIBILITY, AVAILABILITY AND EFFECTIVENES OF THE DISEASE PREVENTION AND CONTROL MEASURES	
Diagnostic tools and capacities	
Vaccination	
Medical treatments	
Biosecurity measures	
Restrictions on the movement of animals and products	
Killing of animals	
Disposal of carcasses and other relevant animal by-products	
IMPACT OF DISEASE PREVENTION AND CONTROL MEASURES	
Direct and indirect cost for the affected sector and the economy as a whole	
Social acceptance	
Welfare of affected subpopulations of kept and wild animals	
Environment and biodiversity	

New AHL: From 2 to 5 categories of listing

Exotic diseases
Non-exotic diseases



- Category a): Diseases not normally occurring in the Union
- Category b): Diseases which must be controlled in all MS
- Category c): Diseases subject to voluntary control in the MS
- Category d): Diseases for which movement restriction measures may apply.
- Category e): Diseases which shall be subject to surveillance

Assessment of VHS and IHN

Disease	Viral haemorrhagic septicaemia (VHS)		
Source	at 4°C (Frost and Wellhausen, 1974; Pietsch et al., 1977). VHSV is completely inactivated within hours at temperatures between 35 and 50 °C and within minutes at higher temperatures. For full survival estimates see FishEggTrade Work package 3 report: Pathogen survival outside the host, and susceptibility to disinfection . Some survivors of epizootics will become long-term carriers of the virus.		
Routes and speed of transmission animals-animals		update on the significance and the impact of the disease. Unfortunately exact data on the presence of VHS and losses due to VHS is almost impossible to achieve as the disease is endemic in large areas of EU and casualties are not reported. In Denmark 80 % of the farm were infected in 1965, in 2008 just before a final eradication only approximately 5 % (10-15 farms) were infected. An analysis of socio-economic benefits of a total eradication at that time was approx. 6.4 mill €/ year	
Routes and speed of transmission animals-humans			
Animal species	Absence, presence and distribution of the disease in the EU	Human health: - transmissibility - severity of human forms - effective prevention or medical treatments	
Morbidity and Mortality rates in animal populations	Risks of its introduction into the EU if absent in EU	Animal welfare	
	Existence of diagnostic and disease control tools	Biodiversity and the environment	
Zoonotic character			
Resistant to treatments, AMR			
Persistence in the animal population or environment			
	POTENT	Restrictions on the movement of animals and products	
	FEASIBILITY, A)	Killing of animals	
		Disposal of carcasses and other relevant animal by-products	
		IMPACT OF DISEASE PREVENTION AND CONTROL MEASURES	
		Direct and indirect cost for the affected sector and the economy as a whole	VHS have had a very significant impact on the economy of the aquaculture sector producing rainbow trout, olive flounder and turbot- especially in environments with water temperatures in the range of 5-15 C. A major reason for the international competitiveness of the Danish aquaculture sector is the eradication of VHS in 2009.
		Social acceptance	Well accepted
		Welfare of affected subpopulations of kept and wild animals	Fish welfare is not affected by preventative or control measures
		Environment and biodiversity	Outbreaks of some genotypes of VHS could cause serious impact on environment and +biodiversity.
		Medical treatments	
		Biosecurity measures	In order to prevent introduction and spreading of the disease into and between farms, a number of zoonosanitary measures can be used. Where possible, netting over the ponds and fencing the sides of the farms is strongly advisable in order to prevent herons

Assessment of ISA, EHN, SAV, VNN, KHV

- In the pipeline
- EFSA will be approached with regard to KHV

Current discussions

- Listing/ de-listing of KHV disease?
- Strain differentiation of VHS- delisting marine VHSV genotypes?
- ISAV HPR Δ >< HPR0- delisted in EU not in OIE
- SVC
- VNN

Players

- EURL
 - NRL and You!!
 - EFSA
 - EU Commission
-
- But very important: the farmer organizations where FEAP plays the most important role

In conclusion:

- New AHL will apply from 2021
- Maintains the principles from Directive 2006/88/EC
- Regulation directly binding for operators and MS
- More tools will be available for the purpose of introducing prevention and control measures
- 3 years period for the adoption of supplementary rules (Delegated and Implementing acts)
- Involvement from MS in this process will be very important!



Organisation Mondiale de la Santé Animale
World Organisation for Animal Health
Organización Mundial de Sanidad Animal

Technical University of Denmark



Listing of susceptible species – report from an OIE working group



WORLD ORGANISATION FOR ANIMAL HEALTH
Protecting animals, preserving our future

The OIE have established a working group

- *An ad hoc* Group on susceptibility of fish species to infection with OIE listed diseases will undertake assessments for the 10 OIE listed fish diseases.
- Develop a list of susceptible species for inclusion in the fish disease-specific chapters in the *Aquatic Code*.
- Develop a list of species with incomplete evidence for susceptibility for inclusion in *Aquatic Manual*

Members: Mark.Crane- Australa; Kei Yuasa Japan; Lori.L.Gustafson US; Sofie st Hilaire - Canada; Niels Jørgen Olesen Denmark

Background

- A new Chapter 1.5. 'Criteria for listing species as susceptible to infection with a specific pathogen' was introduced into the 2014 edition of the *Aquatic Code*.
- The purpose of this chapter is to provide criteria for determining which host species are listed as susceptible of each disease specific chapter in the *Aquatic Code*.
- The criteria are to be applied progressively to each disease specific chapter in the *Aquatic Code*.

Chapter 1.5.

Criteria for listing species as susceptible to infection with a specific pathogen

- The purpose to provide criteria for determining which species are listed as susceptible of each disease-specific chapter in the Aquatic Code.
- **Scope**
- Susceptibility may include clinical or non-clinical infection but does not include species that may carry the pathogenic agent without replication.
- The decision to list a species as susceptible should be based on a finding that the **evidence is definite**. However, **possible susceptibility** of a species is also important information and this should also be included in «Susceptible host species» of the relevant disease-specific chapter of the Aquatic Manual.

A 3-stage approach

1. criteria to determine whether the route of transmission is consistent with **natural pathways** for the infection
2. criteria to determine whether the pathogenic agent has been **adequately identified**
3. criteria to determine whether the evidence indicates that **presence of the pathogenic agent constitutes an infection.**

Stage 1: criteria to determine whether the route of transmission is consistent with natural pathways for the infection

- The evidence should be classified as transmission through:
 1. **natural occurrence**; includes situations where infection has occurred without experimental intervention e.g. infection in wild or farmed populations; or
 2. **non-invasive experimental** procedures; includes cohabitation with infected hosts, infection by immersion or ingestion; or

Stage 2: criteria to determine whether the pathogenic agent has been adequately identified

- The pathogenic agent should be identified and confirmed in accordance with the methods described in the Aquatic Manual, or other methods that have been demonstrated to be equivalent.

Stage 3: criteria to determine whether the evidence indicates that presence of the pathogenic agent constitutes an infection

- the pathogenic agent is **multiplying in the host**, or developing stages of the pathogenic agent are present in or on the host;
- viable pathogenic agent is **isolated from the proposed susceptible species**, or infectivity is demonstrated by way of transmission to naive individuals;
- **clinical or pathological changes** are associated with the infection;
- the **specific location** of the pathogen corresponds with the expected target tissues.

Outcomes of the assessment

The decision to list a species as susceptible:

- ✓ Transmission has been obtained naturally or by experimental procedures that mimic natural pathways for the infection

AND

- ✓ the identity of the pathogenic agent has been confirmed

AND

- ✓ there is evidence of infection with the pathogenic agent in the suspect host species.

Species for which there is incomplete evidence for susceptibility

- The decision to list a species as should be based on a finding that the evidence is definite.
- However, where there is **insufficient evidence** to demonstrate susceptibility through the approach information will be included in the relevant disease-specific chapter in the Aquatic Manual.
- If there is insufficient evidence to demonstrate susceptibility of a species, the Competent Authority should assess the risk of spread of the pathogen under consideration prior to the implementation of import health measures.

The OIE listed fish diseases

Article 1.3.1.

- EHN
- EU's
- G.sal
- ISA
- SAV
- IHN
- KHV
- RSBIV
- SVC
- VHS

The following *diseases* of fish are listed by the OIE:

- Epizootic haematopoietic necrosis disease
- Infection with *Aphanomyces invadans* (epizootic ulcerative syndrome)
- Infection with *Gyrodactylus salaris*
- Infection with HPR-deleted or HPR0 infectious salmon anaemia virus
- Infection with salmonid alphavirus
- Infectious haematopoietic necrosis
- Koi herpesvirus disease
- Red sea bream iridoviral disease
- Spring viraemia of carp
- Viral haemorrhagic septicaemia.

For each disease list with fish species assessed for susceptibility created giving them status as 1 (Code) 2 (Manual) 3 Not applicable (Neither Code nor Manual)

Genus	species	STAGE 1 - route of infection			STAGE 2 - path		STAGE 3 - Pathology. A: Agent replication. B: viable agent isolated from host. C: Disease signs. D: pathogen located in target tissues				Reference	Comments	OUTCO	OVERALL STATUS
		Route of transmissio	Natural	FR	Outbre	pathogen id.	Comments	A	B	C				
<i>Perca</i>	<i>P. fluviatilis</i>	Natural/E (non-inva)	Natural	Yes	incomplete	first report	Y	Y	Y	Y	Langdon et al 1986; Lan	PCR not available		1
<i>Perca</i>	<i>P. fluviatilis</i>	E (non-invasive)	Natural	No	Yes	PCR only	Y	Y	Y	Y	Borzym et Maj-Paluch 2	PCR only - no post experimental sequencing, but isolate used for infec		1
<i>Perca</i>	<i>P. fluviatilis</i>	E (non-invasive)	Natural	No	IFAT		Y	Y	Y	Y	Ariel et Bang Jensen 20	PCR not used, no post experimental sequencing, but isolate used for i		1
<i>Oncorhynchus</i>	<i>O. mykiss</i>	E (non-invasive)	Natural	No	Yes	PCR only	Y	Y	Y	Y	Borzym et Maj-Paluch 2	PCR only - no sequencing, no post experimental sequencing, but isolat		1
<i>Oncorhynchus</i>	<i>O. mykiss</i>	Natural/E (non-inva)	Natural	Yes	incomplete	first report	Y	Y	Y	Y	Langdon et al 1988; Lan	PCR not available		1
<i>Oncorhynchus</i>	<i>O. mykiss</i>	E (non-invasive)	Natural	No	IFAT		Y	Y	Y	Y	Ariel et Bang Jensen 20	PCR not used - no post experimental sequencing, but isolate used for i		1
<i>Oncorhynchus</i>	<i>O. mykiss</i>	Natural	Natural	Yes	ELISA		N	Y	Y	Y	Whittington et al 1994	PCR not used		1
<i>Sander</i>	<i>S. lucioperca</i>										Bang Jensen et al 2011			
<i>Cyprinus</i>	<i>C. carpio</i>										Bang Jensen et al 2011			
<i>Carassius</i>	<i>C. auratus</i>										Bang Jensen et al 2011			
<i>Macquaria</i>	<i>M. australasica</i>	E (non-invasive)	Natural	No	incomplete	first report	Y	Y	Y	Y	Langdon 1989	PCR not available		2
<i>Maccullachella</i>	<i>M. peeli</i>	E (invasive)	Natural	No	incomplete	first report	Y	Y	Y	Y	Langdon 1989	PCR not available		2
<i>Bidayanus</i>	<i>B. bidyanus</i>	E (non-invasive)	Natural	No	incomplete	first report	Y	Y	Y	Y	Langdon 1989	PCR not available		2
<i>Galaxias</i>	<i>G. olidus</i>	E (non-invasive)	Natural	No	incomplete	first report	Y	Y	Y	Y	Langdon 1989	PCR not available		2
<i>Gambusia</i>	<i>G. affinis</i>	E (non-invasive)	Natural	No	incomplete	first report	Y	Y	Y	Y	Langdon 1989	PCR not available		2
<i>Amelurus</i>	<i>A. melas</i>	E (non-invasive)	Natural	No	IFAT		N	Y	N	Y	Gobbo et al 2010	PCR not used		2
<i>Esax</i>	<i>E. lucius</i>	E (non-invasive)	Natural	No	IHC		Y	Y	Y	Y	Jensen et al 2009	PCR used for inoculum characterisation, isolate used was the same as		1
<i>Salmo salar</i>	<i>S. salar</i>	E (invasive)			incomplete	first report	nd	Y	Y	N	Langdon et al. 1986		2b	2
<i>Retrapinna</i>	<i>r. semoni</i>	E (non-invasive)					nd	nd	nd	nd	Langdon 1989			na
<i>Carassius</i>	<i>auratus</i>	E (non-invasive)/E (i					nd	nd	nd	nd	Langdon 1989			na
<i>Maqauria</i>	<i>navemaculeata</i>	E (non-invasive)/E (i					nd	nd	nd	nd	Langdon 1989			na
<i>Maqauria</i>	<i>ambigua</i>	E (non-invasive)/E (i					nd	nd	nd	nd	Langdon 1989			na
<i>Lates</i>	<i>calcarifer</i>	E (non-invasive)/E (i					nd	nd	nd	nd	Langdon 1989			na
<i>Capoeta</i>	<i>tetrazona</i>	E (non-invasive)					nd	nd	nd	nd	Langdon 1989			na
<i>Paratya</i>	<i>australiensis</i>	E (non-invasive)					nd	nd	nd	nd	Langdon 1989			na
<i>Daphnia</i>	<i>carinata</i>	E (non-invasive)					nd	nd	nd	nd	Langdon 1989			na
<i>Cherax</i>	<i>destructor</i>	E (non-invasive)					nd	nd	nd	nd	Langdon 1989			na
<i>Agarptocarixa</i>	<i>sp.</i>	E (non-invasive)					nd	nd	nd	nd	Langdon 1989			na
<i>Bidayanus</i>	<i>bidyanus</i>										Becker et al 2013			
<i>Craterocephalu</i>	<i>stercusmuscaru</i>										Becker et al 2013			
<i>Gambusia</i>	<i>halbrooki</i>										Becker et al 2013			
<i>Hypseleotris</i>	<i>spp.</i>										Becker et al 2013			
<i>Maccullachella</i>	<i>macquariensis</i>										Becker et al 2013			
<i>Maccullachella</i>	<i>peelii peelii</i>										Becker et al 2013			
<i>Macquaria</i>	<i>ambigua ambig</i>										Becker et al 2013			

In conclusion:

- Susceptible species for all 10 OIE listed diseases determined February 2018
- Comments from OIE Member States 2018
- Revised list in the Aquatic Code on susceptible species for the respective diseases.
- List of species with insufficient data to finally determine susceptibility.

Thank you for your attention