



The EU Animal Health Law (Regulation (EU) 2016/429 on transmissible animal diseases) and its role in disease prevention & control in molluscs

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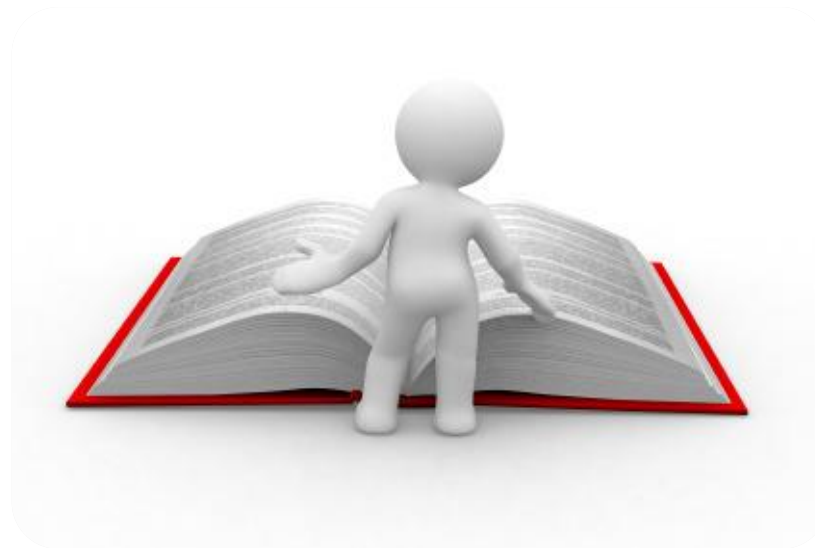
Outline

- ✓ About the AHL
- ✓ Approach to Delegated and Implementing Acts
- ✓ Main mollusc specific changes
- ✓ What next?



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Animal Health Law Introduction



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Animal Health Law (AHL)

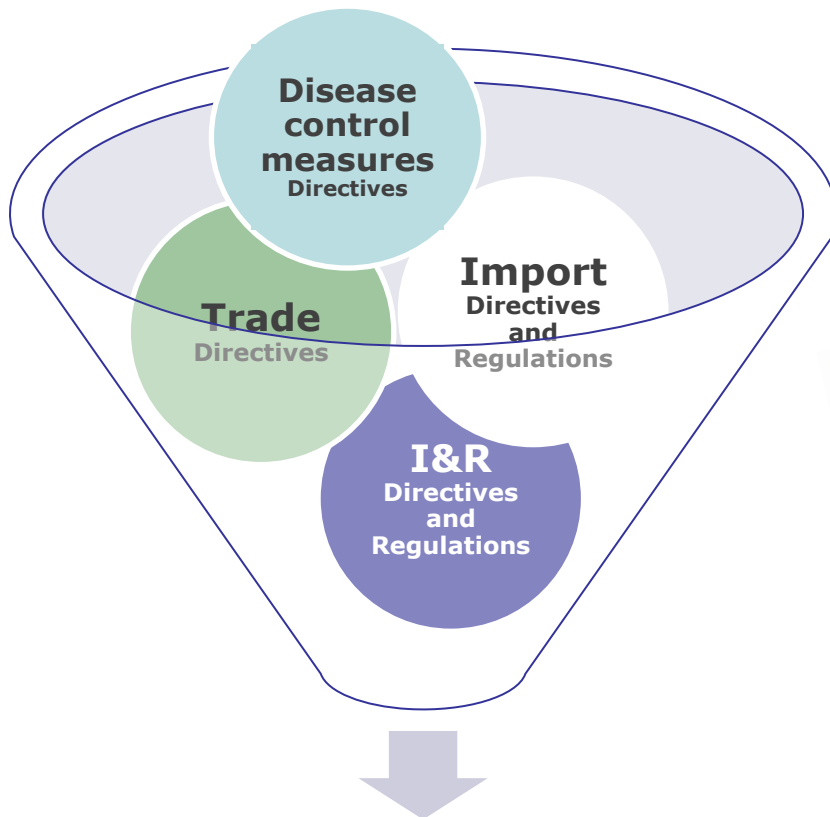
Regulation (EU) 2016/429 on transmissible animal diseases*

- ✓ Adopted : **9 March 2016**
- ✓ OJ publication: **31 March 2016**
- ✓ Regulation in force: **21 April 2016**
- ✓ Apply as of: **21 April 2021** (within 5 years of entry into force)

*Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (Text with EEA relevance)



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**AHL: one single legal framework
for the EU animal health policy**



A new **Animal Health Strategy**
for the European Union (2007-2013) where
"Prevention is better than cure"

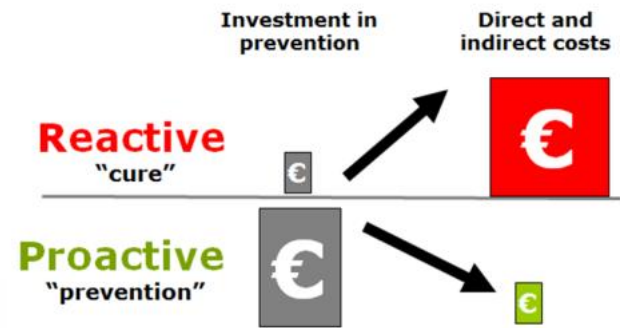


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AHL: Reasoning



Animals + Humans = One health



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AHL: what is about?

- ✓ Principles and rules for **transmissible animal diseases** in:
 - ✓ Kept and wild animals and their products
 - ✓ Terrestrial, aquatic and other animals (e.g. reptiles)

- ✓ Animal health rules for:
 - ✓ **Disease prevention**
 - ✓ **Disease surveillance, control and eradication**
 - ✓ **Intra-EU movements and entry into the EU of animals and products**
 - ✓ **Emergency measures**

Supplementing rules needed to ensure complete implementation



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AHL structure and supplementing regulatory acts



AHL: supplementing regulatory acts

- ✓ **Rules/acts to complement the basic act:**
 - ✓ Commission is empowered in all Parts of the AHL to adopt **"key"* legal acts to be adopted in 2019**
 - ✓ Other rules will be developed later (2019 onwards)
- ✓ **Structure of acts:**
 - ✓ Following different Parts (I to V) of the AHL

*"Key" acts determined by the EP and the Council (AHL, Article 274)



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PARTS OF AHL

I. GENERAL RULES

**II. DISEASE NOTIFICATION
AND REPORTING,
SURVEILLANCE,
ERADICATION PROGRAMMES,
DISEASE FREE-STATUS**

**III. DISEASE
AWARENESS,
PREPAREDNESS AND
CONTROL**

**IV. REGISTRATION,
APPROVAL,
TRACEABILITY AND
MOVEMENTS**

**V. ENTRY INTO THE
UNION AND EXPORT**

VI. NON-COMMERCIAL PETS

VII. EMERGENCY MEASURES

**VIII-IX. COMMON AND
TRANSITIONAL PROVISIONS**

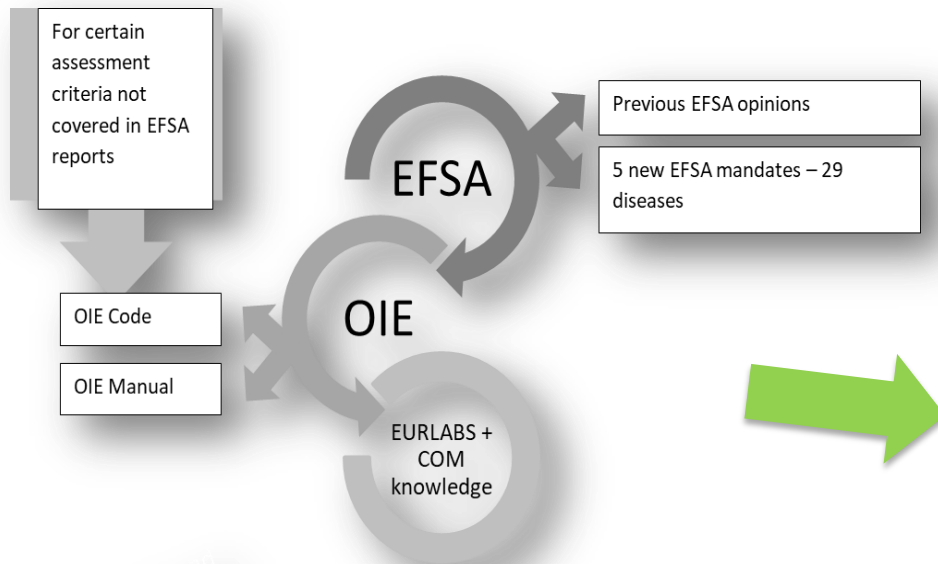
General approach for aquatics

- Retain the concepts from Directive 2006/88/EC which have been successful
- Fix those which have not
- Take account of new scientific developments
- Take account of fact-finding missions carried out in 2018 by Directorate F, DG SANTE



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List of animal diseases, disease categories and list of animal species (DA- PART 1 AHL)



Regulation (EU) 2018/1629
published on 31/10/2018
List of animal diseases (63- 5 of which
are mollusc diseases)

Regulation (EU) 2018/1882
published on 4/12/2018
Assigning to each listed disease a
category and animal species of
relevance



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List of mollusc diseases, disease categories and list of animal species (DA – PART I)

Category A diseases	Category B diseases	Category C diseases	Category D diseases	Category E diseases
<ul style="list-style-type: none">• Control measures in case of an outbreak• Infection with <i>M.mackini</i>• Infection with <i>P.marinus</i>	<ul style="list-style-type: none">• Compulsory eradication• None	<ul style="list-style-type: none">• Optional programme• Infection with <i>B.exitiosa</i>*• Infection with <i>B.ostreae</i>• Infection with <i>M.refringens</i>	<ul style="list-style-type: none">• Trade conditions• All of the above	<ul style="list-style-type: none">• Surveillance and notification• All of the above

Listed species for the listed diseases

- Commission Implementing Regulation 2018/1882
- Will apply from April 2021
- Will be subject to review again when the *ad hoc* OIE subgroup on species listing have completed deliberations
- Main change: Removal of *M.edulis* and *M.galloprovincialis* as listed species for *M.refringens*
- Takes account of scientific developments and feedback from Fact-finding missions



Categorisation and listed species (molluscs)

Commission Implementing Regulation (EU) 2018/1882

Disease	Category	Susceptible species	Vector species
Infection with <i>M.mackini</i>	A	C.gigas , <i>C.virginica</i> , <i>O.conchaphila</i> , O.edulis	N/A
Infection with <i>P.marinus</i>	A	C.gigas , <i>C.virginica</i>	<i>H.gammarus</i> , <i>Brachyura</i> spp., <i>C.destructor</i> , <i>M.rosenbergii</i> , <i>Palinurus</i> spp., <i>P.puber</i> , <i>S.serrata</i> , <i>P.indicus</i> , <i>P.japnicus</i> , <i>P.kerathurus</i> , <i>P.stylirostris</i> , <i>P.vannemi</i>
Infection with <i>B.exitiosa</i>	C	<i>O.angasi</i> , <i>O.chilensis</i> , <i>O.edulis</i>	<i>C.angulata</i> , <i>C.gigas</i> , <i>C.virginica</i>
Infection with <i>B.ostreae</i>	C	<i>O.angasi</i> , <i>O.chilensis</i> , <i>O.conchaphila</i> , <i>O.denselammellosa</i> , <i>O.edulis</i> , <i>O.puelchana</i>	<i>C.edule</i> , <i>D.trunculus</i> , <i>M.arenaria</i> , <i>M.mercenaria</i> , <i>M.lusoria</i> , <i>R.decussatus</i> , <i>R.philippinarum</i> , <i>V.aurea</i> , <i>V.pullastra</i> , <i>V.verrucosa</i> , <i>P.maximus</i>
Infection with <i>M.refringens</i>	C	<i>O.angasi</i> , <i>O.chilensis</i> , <i>O.edulis</i> , <i>O.puelchana</i>	<i>C.edule</i> , <i>D.trunculus</i> , <i>M.arenaria</i> , <i>M.mercenaria</i> , <i>M.lusoria</i> , <i>R.decussatus</i> , <i>R.philippinarum</i> , <i>V.aurea</i> , <i>V.pullastra</i> , <i>V.verrucosa</i>

Listed species for the listed diseases

As a result, the main focus of the new legislation will be on:

- Disease control measures in *O.edulis* (*B.ostreae*, *B.exitiosa*, *M.refringens*)
- Emerging diseases (all species)

Category III

- One of the **failures** in the implementation of Directive 2006/88/EC
 - completely ‘grey’ area
- **Very significant number** of establishments in the EU are currently in Cat III (*‘not known to be infected but not subject to a programme for achieving disease-free status’*)
- Sometimes **left in this category** even when known to be infected!
- If a MS is taking voluntary measures for any Cat C disease after April 2021, the options are:
 - Disease- free
 - In an eradication programme to achieve freedom
 - In a surveillance programme
 - Infected



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Registration & Approval of Establishments (DA under part IV.II)

- 'Grandfathering rule' in relation to those already authorised under Directive 2006/88/EC
- Set out more precise rules on which types of establishments can be registered or which need to be approved
- Have also introduced derogations for lower risk establishments, based on experience gained in past decade
- Clarification in relation to approval of 'groups of establishments'

Approval of groups of establishments

- Epidemiologically linked area
- Operate under a common biosecurity system
- Either:
 - all operators in the group are approved individually or
 - There is a single operator of the group

Importantly: risk based surveillance can be carried out at the level of the group



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Surveillance: DA under Part II

- Notification of suspicion of presence of listed and emerging diseases – passive surveillance required in all cases
- Investigation of increased mortality – required in all cases
- Risk based surveillance – approved establishments keeping listed species which are 'high', 'medium' or 'low' risk
- Risk based surveillance – approved establishments keeping non-listed species which are 'high' risk – important for emerging diseases
- Factors to be considered in the risk ranking set out in DA



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RBS : Frequency of health visits

Had this.....

Now have this.....

Future work DG SANTE

- ✓ Adopt remaining acts under Part IV of the AHL
- ✓ Complete work on animal health certificates
- ✓ Possibly amend Regulation 2018/1882 on foot of reports from OIE ad hoc groups
- ✓ BTSF training
- ✓ Missions from Directorate F



Thank you



Follow the process:

http://ec.europa.eu/food/animals/health/regulation/index_en.htm

https://ec.europa.eu/food/animals/health/expert_group_en

https://ec.europa.eu/food/animals/health/advisory_committees_en