

Update on Animal Health Legislation

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Oyster Industry Workshop
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Animal Health Law



❖ Regulation (EU) 2016/429 Lays down rules for the prevention and control of animal diseases which are transmissible to animals or humans

- In force since April 21st 2021
- Known as "Animal Health Law"
- Replaces Council Directive 2006/88/EC

31.3.2016 EN Official Journal of the European Union L 84/1

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(Legislative acts)

REGULATIONS

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)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(2), Article 114 and Article 168(4)(b) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee (1),

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure (3),

20 April 2023

Regulation 2016/429 -Key Features

- * Regulation directly applicable in Ireland
- Terrestrial and aquatic animals
- Contains general and specific (animal/disease) rules
- Content
 - Disease notification
 - Approval of establishments
 - Animal movements
 - Health Surveillance
 - Disease control





Regulation 2016/429 - Simplification?



Simplification

- All previous EU animal health directives and regulations into the one regulation
 - repeals >100 pieces of animal health regulation

But...

- is supported by various Delegated acts (13) and Implementing acts (12), which make it operational
- More difficult to navigate than previous directive?





What does this mean for you?

Little practical change for operators in Ireland

- Risk Based Surveillance frequency of inspections
- Approval for dispatch and purification centres
- Self-declaration forms
- Updates to existing fish health management plan

Risk-based surveillance



- Health surveillance inspections based on risk assessment
- (a) at least once **per year** in **high risk** establishments;
- (b) at least once every **two years** in **medium risk** establishments;
- (c) at least once every **three years** in **low risk** establishments.
- Previously 2 years for all oyster farms
- Risk assessment for each establishment
 - Movements
 - Size of operation
 - Previous compliance (local V.I. input)
- ❖ You may now be inspected every 1, 2 or 3 years



Fish Health Approval



- * Regulation (EU) 2016/429 requires that **purification and dispatch** centres are approved by the competent authority
- Derogation applied (article 3 of delegated regulation 2020/691) for purification or dispatch centres which:
 - (i) are approved in accordance with Article 4 of Regulation (EC) No 853/2004 and
 - (ii) receive molluscs only from within the epidemiological area in which the establishment is located;
- Establishments have been approved and are now part of the health surveillance programme

20 April 2023

Self-Declaration Form



- ❖ Article 218 of Regulation (EU) 2021/429 requires that a selfdeclaration form accompanies each consignment of aquatic animals between Member States (where a health certificate is not required)
- Provides details of the establishment and consignment and declares that.....
 - animals show no mortality or symptoms of disease
- Applies to oysters for ongrowing/farming or for further treatment (depuration, relaying, packing) before consumption
- Maintain records (incoming/outgoing)

Template available from Marine Institute Fish Health website

https://www.fishhealth.ie/fhu/movingfish-shellfish/self-declaration-formtemplate

Self-Declaration Document for Movements of Aquaculture Animals within European Union

Operators at origin site are obligated to issue a self-declaration document for movement of oysters to another Member State, as detailed under Article 218 of Regulation (EU) 2016/429.

The self-declaration form is ONLY required when consignments of aquaculture animals are not accompanied by an animal health certificate.

I.1 Consignor Details		I.2 Consignee Details		
Name:		Name:		
Address:		Address:		
Country: Company fish health approval number:		Country: Unique registration or approval number (if relevant):		
I.3 Departure Details		I.4 Approval Details		
Date:	Time:	Movement Approval Reference:		
		(Movement number as	issued by	Marine Institute "EXP-XXXX")
I.6 Means of Transport		I.7 Transporter Details		
Road vehicle		Name:		
Aircraft Other Please Specify:		Address:		
		I.8 Description of Consignr	nent	I.10 Intended Us
Species:		Further Ongrowing		Purification Centres
Age: Seed □ Ha	Ifgrown Adult	Relaying		Dispatch Centres
Quantity (numbers/volume or weight):		Other (Please Specify:)		Research Purposes
I.12 Declaration				
I, the undersigned, hereby ce	ertify that:			
	as referred to above are not su concerned (unless derogations a		restrictio	ns or emergency measures affecting
2. The consignment of aquat	ic animals show no mortality or	r symptom of disease.		
Declaration by Opera	ator			
Name (in block capita	ls):			
Signature:	-			
Date:				



Health Management Plans

- ❖ New Shellfish Health Record Folders will be provided by VIs during health surveillance inspection
 - Update regulations
 - Terminolgy Approval, biosecurity plan, establishment

- New Shellfish Biosecurity Plan to be completed during next inspection
 - Surveillance inspection frequency
 - Requirement to keep self-declaration forms



As a business approved under the animal health legislation, you are legally obliged to keep accurate records.

Failure to do so will result in your inability to move molluses to and from your site and may ultimately lead to the withdrawal of your approval which will result in the loss of your aquaculture license.



Summary



- Regulation (EU) 2016/429 in force since April 2021
- Minimal practical changes to requirements of directive 2006/88/EC
 - Changes to inspection frequency 1-3 years based on risk
 - Health approval & surveillance of purification and dispatch centres
 - Self declaration forms
 - Update record folders and biosecurity plans during inspections

THANK YOU



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