

**LEGAL NORMS CONCERNING AQUATIC ANIMAL  
DISEASES IN REGULATION (EU) 2016/429  
– ANIMAL HEALTH LAW**

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**Abstract**

This study analysed the latest changes in European health regulations in the aquaculture sector. The following research methods were used: grammatic, systemic, teleological and pro-European interpretation of legal texts. The basic normative act subjected to analysis and interpretation was the Animal Health Law (Regulation (EU) 2016/429). Although the existence of ‘codification’ trends has been found in European law, it has been shown that the tools used are not adequate to the intended purposes and the works are carried out in a non-holistic manner and of a compilation nature. A shortage of normative regulations, as well as inconsistencies and non-fulfilment of obligations by EU bodies, was also indicated. This paper analysed the extent the studied area is another sphere of influence of European law on the national legal orders of the Member States, as well as the mutual relations of veterinary law and veterinary medicine concerning fish, shellfish and molluscs.

## Introduction

The Animal Health Law (AHL), i.e. the Regulation (EU) 2016/429 on transmissible animal diseases and amending and repealing certain acts in the area of animal health approved by the European Parliament and the European Council on the March 9, 2016, is one of the most significant normative acts on animal health. This AHL was published on March 31, 2016, in the Official Journal of the European Union (OJ) L 84 and entered into force on the April 21, 2016 and shall be applied from April 21, 2021.

The AHL comprises the numerous existing, yet not unified, regulations on animal health in one legal act, including the laws on the elimination of infectious diseases in animals, operation of the national animal market and animal-derived products (TERECH-MAJEWSKA et al. 2011). This legal act provides a unified and simplified regulation basis; it is not only a compilation but also serves as the recodification of 39 normative acts in total, such as the directives: 64/432/EEC, 77/391/EEC, 78/52/EEC, 80/1095/EEC, 82/894/EEC, 88/407/EEC, 89/556/EEC, 90/429/EEC, 91/68/EEC, 91/666/EEC, 92/35/EEC, 92/65/EEC, 92/66/EEC, 92/118/EEC, 92/119/EC, 2000/75/EC, 2001/89/EC, 2002/60/EC, 2002/99/EC, 2003/85/EC, 2004/68/EC, 2005/94/EC, 2006/88/EC, 2008/71/EC, 2009/156/EC, 2009/158/EC; decision 95/410/EC; and regulations 1760/2000 (EC), 21/2004 (EC), and 576/2013 (EU).

The objective of the paper is an objective analysis of the Animal Health Law to improve the productivity and efficiency of the veterinary administration bodies in public health and environment protection.

## Material and Methods

This study analysed the latest changes in European health regulations in the aquaculture sector, particularly the Animal Health Law (Regulation (EU) 2016/429). The analysis was carried out with legal interpretation and analysis methods, such as grammatic, systemic, teleological, purposive and pro-European interpretation.

### The Subject and Objectives of the AHL

The investigated regulation establishes the laws on the prevention of infectious diseases in animals, which are transmissible or transmitted on animals or humans, as well as the laws on the eradication of these diseases. Importantly, considering the Polish veterinary nomenclature, not only is the translation of the individual sections of the legal statements

incorrect, but the title of the Act is also mistranslated: *choroby przenośne* instead of the correct name *choroby zakaźne*, or at least *choroby transmisyjne*. The mistakes and inconsistencies demonstrate the low level of the Act's legislative quality, and they present an additional challenge for the interpretation and implementation of this law.

The objective of these laws consists in the veterinary *rationes* and those related to the public health protection, such as improving the health of animals, reducing the negative effects on animal health, public health and the environment caused by the diseases included in the legislation as well as supporting sustainable aquaculture and agricultural production in the European Union. They are intended to improve the efficiency of the European internal market and address the practical demands of the environment and the resources of the aquaculture industry (ANTYCHOWICZ 2010, MALINOWSKA and BŁOŃSKA-WLAZŁOWSKA 2004, KENIG-WITKOWSKA 2011, TERECH-MAJEWSKA et al. 2011).

The implemented legal norms include the relations between the animal health and the public health and the environment, such as biological diversity; precious genetic resources; consequences of progressing climate changes; food and feed safety as well as animal welfare, such as reducing unnecessary pain, stress or suffering, antimicrobial resistance and food safety (POSYNIAK 2015). They also encompass the economic and social (legal, cultural and environmental) effects caused by the implementation of disease prevention and eradication tools (BIAŁEK et al. 2015, FELSMANN et al. 2019, SIWICKI 2020, ZWIĄZEK 2016).

### **Secondary and Delegated Legislation**

The European Commission was obliged to approve the key delegated and secondary legislation (KENIG-WITKOWSKA 2011) to the investigated regulation within three years from the enforcement date, i.e. until March 31, 2019, to ensure that the member states have enough time for transposition (Table 1).

Table 1  
Delegations of the European Commission – competence to issue acts based  
on the Regulation 2016/429 (UE)

Delegated acts (DA)		Implementing acts (IA)	
No. of delegations	No. of key acts (a)	No. of delegations	No. of key acts (a)
111+2 (b)	41	69+1 (c)	21

Explanations: (a) – so-called key acts – the European Commission has a legal obligation to issue and publish them; (b) – references to delegations in various articles on the basis of Art. 223, 225 of the discussed regulation; (c) – references to Art. 221, 225 of the discussed regulation

With the delegated acts, the Commission can complement less important elements and implement some minor changes, for example, to determine the specific tools; if the European Parliament and the European Council do not object, these acts will come into force (KENIG-WITKOWSKA 2011). The secondary legislation is used by the Commission – via the supervision of the committees composed of the EU member state representatives – to determine the conditions that will ensure unified implementation of the law throughout the European community.

To date (legislation in force as of April 1, 2020), the national implementation legislation, respective for the discussed area, has not been released.

### **Comparison of the Former and New Normative Arguments Relating to Aquatic Animals**

The current European legislation on aquatic animals and aquaculture is based on the basic act, i.e. the European Council Directive 2006/88/EC on animal health requirements for aquaculture animals and products, and the prevention and control of certain diseases in aquatic animals. The Directive was amended by the European Commission Directive 2008/53/EC and the Implementing Directives of the European Commission 2012/31 and 2014/22. The other important acts of European law on the discussed subject include the European Commission Decisions 2008/392, 1251/2008, and 2008/892, as well as the European Commission Regulation 1251/2008.

The norms specific for the aquaculture animals include the requirements for the marketing, import and transit of these animals and their products; minimal preventive measures; minimal tools for disease eradication; the tools to be implemented in the case of a suspected or sudden outbreak of some diseases of the aquatic animals; and the background procedures for possible outbreaks of aquatic animal diseases, such as increasing the awareness and preparedness of the public authorities, entrepreneurs and other bodies.

In the existing EU legislation, there have been individual regulations on terrestrial animal health and separate ones on the aquatic animal health (KENIG-WITKOWSKA 2011, JEDLECKA 2002). In most cases, the major rules determining the good management of animal health and good animal production practices apply to both groups of animals: terrestrial and aquatic species. This conclusion has empowered a change in European norms.

A novel approach of the European Union authorities to the health of aquatic animals and the respective regulations is not evident in the AHL. It interferes with the existing legislation on the aquatic animals and

aquaculture that was combined with the regulations referring to terrestrial animal health and other animals. The aquatic animals (at each stage of their development (so not only the adult specimens but also the eggs, sperm cells and gametes) are defined in the legal context as fish classified in the Agnatha superclass (*Agnatha*) and the Chondrichthyes class (*Chondrichthyes*), the Sacropterygii clade (*Sarcopterygii*), and the Actinopterygii class (*Actinopterygii*), aquatic molluscs are classified in the *Mollusca* phylum and aquatic crustaceans are classified in the *Crustacea* taxon. Terrestrial animals are defined in a legal context, as opposed to zoology, as birds and terrestrial mammals as well as bees and bumblebees.

Harmonisation of the European legal regulations can be achieved not only on the member-state level, i.e. via the implementation of new legal norms that are consistent with the European assumptions (different types of implementation) but also within European Union law in a broader sense (MALINOWSKA and BŁOŃSKA 2014, KENIG-WITKOWSKA 2011). To that end, the AHL consolidates and mutually adjusts the regulations, in the specific cases, on the animal health matter of different species.

The basic normative act referring to the aquatic animals, i.e. Directive 2006/88/WE, has been included in the AHL using the compilation and correlation method (KENIG-WITKOWSKA 2011). This directive shall expire on April 21, 2021, like the other 30 European legal acts (mainly directives, with some decisions and regulations). The references to the acts that precede the AHL should be considered as AHL cross-references, according to the correlation table included in Annex 5, item 26, concerning art. 270, section 2 of the AHL.

However, the regulations referring to the registrations and authorization of production sites and traceability and transfer of animals within the European Union have not been completely harmonised and consolidated. Unfortunately, a unified and codex act encompassing the whole legislation on animal health has not thus been developed. The approach adopted in the past is still applied for some areas, according to it, separate legal acts and individual regulations are legislated on animal health for both terrestrial and aquatic animals due to their different habitats and, therefore, specific requirements for health protection. For instance, part 4, section 2 (Art. 172–226) of the AHL applies to aquatic animals and non-aquatic animals that can transmit diseases of aquatic animals and to the animal-derived products from, or of, aquatic animals.

The delegated, secondary (Table 2) and implementing acts on the aquaculture animals should have been released by the European Commission by March 31, 2019, but this has not yet happened.

Table 2  
The material scope of acts of lower rank, on the basis of the AHL

Delegated acts (DA)	Implementing acts (IA)
health requirements for aquaculture animals and products derived therefrom, their movement within the EU and import into the EU from third countries;	surveillance, eradication, establishment of freedom from disease and control measures for certain diseases in aquaculture animals
prevention and control of certain diseases in aquaculture animals	registration and approval of establishments keeping aquaculture animals, and health requirements for the movement of aquaculture animals within the EU and import into the EU

### Previous and New Lists of the Diseases of the Aquatic Animals and Their Classifications

The previous criteria on listing the diseases of aquatic animals are regulated by the Directive 2006/88/EC, whose wording distinguishes between the exotic and non-exotic diseases of aquatic animals, according to the specific criteria.

Exotic diseases (Table 3) have been defined as diseases that are not found in European aquaculture, yet the data on the distribution of a given pathogen in the European Union waters has been missing (this fact is interpreted as a lack of scientific reports or even actual reports).

Table 3  
List of exotic diseases and susceptible animals in accordance with the Directive 2006/88/WE

Exotic diseases		
specification	disease	animals susceptible
Fish	Epizootic haematopoietic necrosis (EHN)	<i>Oncorhynchus mykiss, Perca fluviatilis</i>
	Epizootic ulcerative syndrome (EUS)	<i>Catla, Labeo, Mastacembelus, Mugil, Puntius, Trichogaster, Channa</i>
Moluscs	<i>Bonamia exitiosa</i> infection	<i>Ostrea angasi, Ostrea chilensis</i>
	<i>Perkinsus marinus</i> infection	<i>Crassostrea gigas, Crassostrea virginica</i>
	<i>Microcytos mackini</i> infection	<i>Crassostrea gigas, Crassostrea virginica, Ostrea edulis, Ostrea conchaphila</i>
Crustacea	Taura syndrome	<i>Penaeus setiferus, Penaeus stylirostris, Penaeus vannamei</i>
	Yellowhead disease	<i>Penaeus aztecus, Penaeus duorarum, Penaeus japonicus, Penaeus monodon, Penaeus setiferus, Penaeus stylirostris, Penaeus vannamei</i>

Moreover, it was emphasized that at least one of the following premises is met: a potentially significant impact of the given disease on the European Union economy if the disease is introduced in its territory, due to production losses in the aquaculture or restricted trade of aquaculture animals and the products derived from them; or a potentially negative effect on the environment if the disease is introduced in the territory of the EU and is then transmitted to wild populations of aquatic animals, particularly involving a species that should be protected by EU law or treaties.

Table 4  
List of non-exotic diseases and susceptible animals in accordance with the Directive  
2006/88/WE

Non-exotic diseases		
specification	disease	animals susceptible
Fish	Viral haemorrhagic septicaemia (VHS)	<i>Clupea, Coregonus, Esox lucius, Gadus aeglefinus, Gadus macrocephalus, Gadus morhua, Oncorhynchus, Oncorhynchus mykiss, Onos mustelus, Salmo trutta, Scophthalmus maximus, Sprattus sprattus, Thymallus thymallus</i>
	Infectious haematopoietic necrosis (IHN)	<i>Oncorhynchus keta, Oncorhynchus kisutch, Oncorhynchus masou, Oncorhynchus mykiss, Oncorhynchus nerka, Oncorhynchus rhodurus, Oncorhynchus tshawytscha, Salmo salar</i>
	Koi herpes virus infection (KHV)	<i>Cyprinus carpio</i> (incl. Koi)
	Infectious salmon anemia (ISA)	<i>Oncorhynchus mykiss, Salmo salar, Salmo trutta</i>
Molluscs	<i>Marteilia refringens</i> infection	<i>Ostrea edulis, Ostrea angasi, Ostrea puelchana, Ostrea chilensis, Mytilus edulis, Mytilus galloprovincialis</i>
	<i>Bonamia ostreae</i> infection	<i>Ostrea angasi, Ostrea chilensis, Ostrea conchaphila, Ostrea denselammellosa, Ostrea edulis, Ostrea puelchana</i>
Crustacea	White Spot Syndrome	<i>Decapoda</i>

Non-exotic diseases (Table 4) are defined as diseases with the following accumulative criteria:

- absence in at least some member states or their regions,
- problems with eradication and control of the disease at the farm level or in the mollusc production area without the implementation of rigorous eradication tools and trade restrictions,
- an opportunity for the eradication of the disease at the member state level, which results from long-term experience in settling and main-

taining the zones or enclaves free from a given disease (maintenance provides the best value of money),

- there is a risk of disease transmission on previously intact areas when the aquaculture animals are marketed,
- there are reliable, simple, specific and sensitive tests for diagnosing infections in aquatic animals, and the testing method is harmonised at the European level.

Apart from the discussed data, a given disease should meet at least one of the following premises: introduction of the disease into a disease-free member state can have a significant effect on the economy due to production losses, with the annual costs associated with the disease and its eradication is more than 5% of the value of production of a susceptible aquaculture animal species in the region, or due to the restricted international trade of aquaculture animals and the products derived from them, or it has been demonstrated (which is interpreted as scientific argumentation) that introducing the disease into a disease-free member state has a negative impact in the environment and the populations of wild aquatic animals representing the species that should be protected by European law or treaties.

Importantly, the European Commission, due to lobbying by the carp producers, has decided to exclude spring viremia of carp (SVC) from the above-mentioned list (previously included in Part 2 of Annex 4 to the Directive 2006/88/EC), under the Directive 2008/53/EC of April 30, 2008.

The basis and criteria necessary to create a new list of diseases are included in Art. 5, sec. 3 of the AHL. Together with Art. 7 of this regulation, the mentioned provision represents the criteria and parameters for disease assessment and states that five accumulative obligatory criteria and at least one of the five supplemental criteria should be met (Table 5).

Viral haemorrhagic septicemia (VHS) of Salmonidae is an example of the detailed analysis of the inclusion criteria for the disease list (BARJA 2004, BALE 2009, ITO 2016, MATRAS 2010). The etiologic virus (VHSV) is eliminated by the infected fish with urine and body fluids, so this disease is transmissible. Most species are classified in the teleost infraclass (Osteichthyes is the largest division in the Actinopterygii class, alongside the Holostei and the paraphyletic Chondrostei; it includes approx. 96% of all fish, over 2,600 species ranked in 40 orders and 448 families). Rainbow trout, turbot and olive flounder are most susceptible to infection. The disease has many negative effects on animal health: mortality varies depending on the environment and physiological characteristics, e.g. in rainbow trout, mortality can reach from 5% to 90% (regardless of the fish size).

Table 5

Method of disease evaluation based on the AHL (Art. 5), based on four primary fish diseases  
(positive evaluation – the disease is listed)

Disease	Mandatory, cumulative criteria (all must be met)					Additional, accessory criteria (at least one must be met)					Result positive
	(i)	(ii)	(iii)	(iv)	(v)	(a)	(b)	(c)	(d)	(e)	
KHV	+	+	+	+	+		-		-	+-	
ISA	+	+	+	+	+		-		-	-	
VHS	+	+	+	+	+		-		-		
IHN	+	+	+	+	+		-		-	-	

Explanations: (i) – the scientific data show the transmissible (infectious and contagious) nature of the disease; (ii) – in the EU, there are animal species that are susceptible to this disease or are vectors or a reservoir of the disease; (iii) – the disease has negative effects on animal health or presents a risk to public health (is zoonotic); (iv) – there are diagnostic tools available for a given disease; (v) – the risk-reducing measures and allowing a reduction of the surveillance scope of a given disease in appropriate cases are effective and proportional to the risk that the disease creates in the EU; (a) – the disease has, or may have, substantial negative effects on animal health within the EU or represents (or may represent) a substantial risk to public health (is zoonotic); (b) – the disease agent has become resistant to treatment and presents a major risk to public or animal health in the EU; (c) – the disease leads (or might lead) to significant negative economic effects in agricultural production or aquaculture in the EU; (d) – the disease may cause a crisis scenario, or the disease agent can be used for bioterrorism; (e) – the disease has (or might have) a substantial negative effect on the environment, including biodiversity, in the EU; KHV – koi herpes virus; ISA – infectious salmon anaemia; VHS – viral haemorrhagic septicaemia; IHN – infectious haematopoietic necrosis

The diagnostic tools are based on the multiplication of cell culture and a specific and sensitive RT-PCR test as well as on the detection of the antigen (while serology is not routinely used). In the EU, there are tools for securing biological safety and reducing the risk, such as mounting nets above the fish ponds and fencing the fish farms; preventing water leaks from the trucks used to transport fish to the farms; preventing feeding the livestock fish with fresh fish and the non-transfer of live fish from sea water into fresh water. No commercial vaccine is yet available. The wide distribution of VHSV among the wild fish species in Northern Europe raises some concerns about the health status of the coastal zone and the risk of transmitting VHS into the inland waters due to upstream migrations of the diadromous fish. The disease is not zoonotic and cannot be used as a bioterrorism tool; however, it brings about significant economic consequences in the aquaculture industry, specifically in rainbow trout, olive flounder and turbot production in the 5–15°C range. Furthermore, it may have a major negative impact on the environment; particularly if genotype 4 is introduced to Europe, massive mortality in wild fish is expected (both fresh and sea water), as in the US and Canada. The disease out-

breaks caused by some VHS genotypes may have a significant (negative) effect on biodiversity.

Annex 2 of the Regulation 2016/429 (EU) has been amended with the delegated regulation of the European Commission 2018/1629 (UE), and these changes will enter into force from April 21, 2021. The amendment includes the following diseases: epizootic haematopoietic necrosis (EHN), viral haemorrhagic septicaemia (VHS), infectious hematopoietic necrosis (IHN), infectious salmon anaemia (ISA) with a deletion in the polymorphic HPR region, Koi herpesvirus, microcytosis (*Mikrocytos mackini*), perkinsosis (*Perkinsus marinus*), bonamiosis (*B. ostreae*, *B. exitiosa*), marteiliosis (*Marteilia refringens*), Taura syndrome, Yellowhead disease and *White Spot Syndrome*. Epizootic ulcerative syndrome (EUS) has been removed from the list included in Annex 2 (EFSA 2011).

The classification of diseases is the mainstay for diversified implementation and diverse effects of the legislation on the prevention and eradication of diseases, depending on the disease category featured on the list and the respectively susceptible species by Regulation 2018/1882 (EU). The regulations on prevention and eradication of the listed diseases should apply only to the species and species groups that are susceptible to these diseases or are vectors (they can transmit these diseases). The listed diseases should be addressed with different measures that are determined in the discussed regulation. These measures encompass not only the scope of basic responsibilities, such as reporting and communicating on the occurrence or suspected occurrence of the listed diseases, but also a wide scope of vigilant surveillance of the specific diseases and their eradication. They also refer to transporting the animals and animal-derived products in the EU and marketing these commodities in the EU member states from third countries.

The AHL enforces the need for authorization of the aquaculture sites (that farm the aquaculture animals for transferring them live or as the animal-derived aquaculture products from the site) by the District Veterinary Officer (Art. 176). To this end, there is also a need to meet the specific requirements referring to husbandry, such as biosecurity, by the fish farms (Art. 177–184).

The Art. 8, secs. 2 and 3, And art. 9, secs. 1 and 2, and Annex 4 to the AHL specify the inclusion criteria for the species or species groups and the methods for applying the regulations on disease prevention and eradication, as well as the rules for implementing individual provisions, depending on the disease category.

The listed disease categories have been legislated in art. 9, section 1, items a-e of the AHL, and subsequently, they have been clarified in the Regulation 2018/1882 (EU) as follows:

- Category *A* includes diseases that do not typically occur in the EU member states, and the immediate eradication measures to eliminate the disease outbreak must be implemented when the disease is detected,
- Category *B* includes diseases that must be eradicated in all EU member states (art. 9, section 1, item b of the AHL),
- Category *C* includes diseases that are important only in some of the member states, and their further transmission into the other parts of the EU must be prevented (areas that are officially free from the disease; areas in which the eradication plans have been implemented),
- Category *D* includes diseases for which the transmission must be prevented due to their occurrence in, or transfer between, the EU member states,
- Category *E* includes the diseases that must be surveyed.

It is possible to classify a given disease in one or multiple categories, e.g. by the above-mentioned norms: Koi herpes virus is considered a Category *E* disease; epizootic haematopoietic necrosis, microcytosis, dermo disease (perkinsosis), Yellowhead disease and Taura syndrome are categorized in the *A*, *D* and *E* groups; and viral haemorrhagic septicaemia, viral haemorrhagic septicaemia of the Salmonidae, infectious salmon anaemia, WWS, marteiliosis and bonamiosis are classified in *C*, *D* and *E* groups.

The regulations on the prevention and eradication of diseases are applied to the listed diseases, while the actual implementation of these provisions depends on the disease category and the animal species group in which there is a substantial risk of disease transmission and transmission of animals spreading the disease (vectors).

## Conclusions

In European law, there are noticeable tendencies that, to put it simply, can be called *codifying*. The meticulous analysis of the measures, methods, specific objectives and scopes of the individual procedures undertaken by the EU bodies leads to the conclusion that by nature, they are merely compilatory and aimed at compiling and partly systematizing the existing and fragmented legislation that has been created throughout the whole European Union development into its current legal and system model. Furthermore, a major part of these procedures do not cover or address the wholeness of the discussed subject; even if the title or preamble of the given legislative act represents it as being comprehensive legislation on a certain subject, an analysis of the individual provisions of the legislative act does not indicate a holistic approach or the exhaustive codification of a certain part of the law.

As a matter of fact, the EU authorities strive to unify the regulations in the member states, particularly in such an important area – from the veterinary perspective as well as the public health – as the health of fish and mollusc. However, the measures undertaken by the EU bodies happen to be inadequate to the assumed targets. There is also a lack (or excessive procrastination) of legislative work, which is required by law, on the secondary legislation and implementing legislation, both on the European and national levels.

Even though the discussed laws on animal health warrant editorial revision and further complementation referring to registration, authorization and identification of animal movement, in their existing form, they still encompass dozens of previous normative acts and represent the legal norms that facilitate using the veterinary laws, including those referring to the diseases of animals.

The advantage of the investigated legislation is an approach that addresses the broad relationship between public health and the environment using the conceptualization of biodiversity and varied surveillance and control. The inclusion of fish and mollusc diseases in the legislation associated with the regulations on the health of the other animal is evidence of their common and progressive integration. This has been reflected in the legal provisions on management and control in animal health and production, both for the terrestrial and aquatic species.

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