Proposals of the Aquaculture Advisory Council (AAC) on Delegated and Implementing Acts regarding the application of Reg. EU 429/2016 on Aquatic Animal

Position Paper

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Aquaculture Advisory Council

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1 Introduction

As background as well the various positions adopted during the WG1 Fish and the WG2 Shellfish AAC meetings, this document should focus on the application of AHL (Reg. 429/2016) taking into account of the bottlenecks and weaknesses of Dir 2006/88/EC. The Fish working group also should take a look at the Overview elaborated by DG SANTE in which are reported the findings of the missions carried out by FVO in 2014 and 2015 on the implementation of the rules on fish aquaculture in EU.

EU Commission road map:
During the last Animal Health Advisory Committee (14 March 2017) the Commission presenting the future work on Delegated and Implementing acts of the EU AHL regarding Aquatic animals will be adopted and ready by April 2019.

The Commission defined the following objectives to be reached by 20/04/2019:

- Delegated Act (DA)

Animal health requirements for aquatic animals and products of animal origin thereof, their movements within the Union and the entry into the Union and prevention and control of certain diseases in aquatic animals.

- Implementing Acts (IA):

Surveillance, eradication, disease freedom and disease control measures with regard to certain diseases of aquatic animals
Registration and approval of establishments keeping aquaculture animals, and animal health requirements for the movements within the Union of aquatic animals and products of aquatic animal origin and their entry into the Union.

There are also DA and IA transversely covering other aspects, an example for all to the list of disease and listed species.

Below are the main points of discussion for the application on AHL at aquatic animal sector:

- List of notifiable disease and related list of carrier species Categorization
- Simplification of mandatory procedures (to achieve and maintain health status; for registration and approval of establishments keeping aquatic animals)
- Transport and movements of aquaculture animals
- Specific issues related to Put&Take Fisheries and Slaughterhouses

EU aquaculture production is extremely diverse as regards species and production systems, and this diversification is rapidly increasing. This may require, assured the premises to pursue an adequate state of welfare and health for the animals, more attention to: simplification, flexibility, risk analysis and assessment of cost benefits of the measures implemented.

The recommendations below result from the synthesis of works from Fish Working Group and Shellfish Working Group of AAC.

2 Fish Working Group AAC recommendations

2.1 List of disease and listed species

The revision and drafting of the List of notifiable disease and listed species shall take in to account with specific reference for the stakeholder point of view: of what stated in article n.7 (e) *"the impact of disease prevention and control measures, as regards:*

i) *the direct and indirect costs for the affected sectors and the economy as a whole;*
ii) *their societal acceptance;*
iii) *the welfare of affected subpopulations of kept and wild animals;*
iv) *the environment and biodiversity.*

The assessment of the list will made by EU reference labs (RL), National RL and EFSA on the basis of OIE list; but it is necessary to listen and involve stakeholders in the revision process.

This means that several aspects must be evaluated: state of the art, proposal to delete/insert diseases from /to the list, epidemiological data, risk assessment, costs and benefits evaluations.

As a reference point in this case can be reported on the case of Spring Viraemia of Carp (SVC) which was delisted from the list of non-exotic diseases in Part II of Annex IV to Directive 2006/88/EC also with the following motivation: "*it is appropriate to consider whether SVC may be controlled at Member State level and whether such control is cost-beneficial. Due to the hydrographical situation and the structure of the carp aquaculture in the main carp producing Member States, the costs related to measures to eradicate that disease would be disproportionate to the economic losses caused by the disease*" (Directive 2008/53/EC premise 6).

As an example, not exhaustive, below certain diseases currently present in3 the list for finfish for which it is considered necessary a revaluation (*to improve with motivations and scientific literature*): Koi Herpes Virus (on similar basis of SVC) caused from some strains of VHSV and ISAV (based on the studies of strains with different pathogenicity and risk evaluation).

2.2 Categorization of the farms/areas/zones as regards the health status

In the common understanding one of the main principles of the AHL is that the categorization should be based on the health status (disease free or not – surveillance or not/eradication). Category 3 'unknown' as currently envisaged by Directive 2006/88/EC has allowed to classify the health status of areas or zones in which it is impossible to achieve disease free status for structural, hydrogeological and /or epidemiological reasons (*this for finfish occurs / occurred many cases, and we suppose also happen in the case of shellfish*). Often the categorization or the achievement of a specific health status determines / enter into conflict with other rules (eg. with WFD -Directive 2000/60/EC - when prompted to maintain the continuity of the flow of a river between the upstream and downstream of a dam; in this example if the risk is to high maintaining the discontinuity of the flow shall be considered).

However, applying biosecurity measures, the interactions between health and welfare of fish and environmental aspects should be taken into account on the basis of risk assessment which shall be established both on scientific and empirical basis and after listening to stakeholders.

In this specific case the IAs must provide a gradual and "smooth" transition between the categorization laid down by current rule and as provided by AHL with specific reference to the diseases listed as indicated in article 9 of Reg. (EU) 2016/429.

2.3 Simplification of mandatory procedures

With regard to delegated and implementing acts, there is a need to simplify and clarify where appropriate, have added flexibility, in particular as regards movements and disease control, and to reduce administrative burden concerning for example registration, approval zones or compartments.

As indicated in the Overview Report an example of good practice could be:

"*One-stop-shop for licensing applications, thus avoiding the bureaucracy of dealing with multiple administrations. This approach involves a simplification of the process where applicants for aquaculture licenses send one application form to a defined responsible administration. This service then sends the application to relevant sector authorities, and after receiving the invited comments, makes the final decision on the application. Each sector authority has a time limit for submitting its comments on the application and for granting or refusing in accordance with the legislation under its responsibility.*"

This is particularly important in small businesses particularly micro enterprises and shall be related not only to the administrative practices but also to the analysis for the achievement and maintenance of the health status.

In this sense to achieve free status from the listed diseases against article 9 regarding the areas / compartments should provide simplified procedures with an assessment by the Member State and subsequent approval by the Commission.

2.4 Certification/Movements of live fish

TRACES notifications for all movements of live fish are verified to ensure that the movement has been pre-approved in line with national requirements thus ensuring that health status of the recipient and dispatch farm is correctly assessed.

Also in this field simplification is required through the DA & IAs, we could look into the time for movements between two places with specific reference to5 Article 218 Reg 429/2016 – Self-declaration by operators for movements of aquaculture animals to other Member States and delegated acts. Therefore when the requirements related to the farms authorization and live fish traceability are guaranteed, introduction of data in the TRACES system could be transferred directly to the operators (e.g. through certified Veterinarians or Aquatic Animal Health Professionals) instead of the competent veterinary authorities, thus minimising costs and bureaucracy.

The certificate requirements could also be linked to the requirements of the surveillance programs.

2.5 Put and take fisheries - Slaughterhouses

As confirmed in the Overview report quoted above, many MS have used blanket derogations for 'put and take fisheries' without necessarily taking the risks associated with each operation into account. In addition, some MS applied the option for derogation laid down in Article 4(4) of Directive 2006/88/EC for small/medium sized APBs producing 'small' amounts of fish for the local market.

It is necessary that the IAs take account of simplification and flexibility methods but it is also extremely necessary that such procedures should be harmonized.

Registration, however, must be compulsory for put and take fisheries.

There are indeed slaughterhouses related to hobby farms and farms, but some slaughterhouses are receiving fish from different farms, which can be source of health problems. Also in this case biosecurity measures and approval procedures dressed case by case on the basis of the different specificities of the farms must be provided in the IAs.

3 Shellfish Working Group (SWG) AAC recommendations

Regarding especially molluscs, the SWG suggests to remove Bonamia exitiosa from the list of exotic diseases (see the table page 8) because it is endemic of the whole of Europe and not causes episodes of mortality.

SWG recommends to search ways of preventing or minimizing the deadly effects of pathogens: to monitor and control the health status of production areas through regular pathogen controls (presence/absence and prevalence, of both listed end emerging diseases), mortality rates (using standardized methods) and environmental variables (temperature and salinity).

SWG notes that the systems and strategies for animal health developed in the Regulation are difficult to adapt to bivalves for the following reasons:

- Shellfish farming takes place in the open natural environment without unique water flow-in and flow-out;
- Molluscs do not present clinical symptoms (so the only way to detect an animal health problem is usually when a large mortality occurs or through complex samples analysis);
- Bivalve molluscs do not have a specific immune system so vaccination is not possible;
- Farming populations interact continuously with wild populations;
- All species of bivalves are in some way considered as carriers of diseases because, as filtering organisms, they can contain infective stages of the different pathogens.
- The absence and / or insufficient care of wild shellfish beds and deposits can increase the carriers and the pathogen concentration.

For these reasons, it is considered appropriate that the future delegated acts on the implementation of the rules consider the objective difficulties encountered in applying these principles to bivalve molluscs.

Modifications of the Annex IV, Part II of the Animal Health Law 2006/88/EC

EXOTIC DISEASES		
	DISEASE	SUSCEPTIBLE SPECIES
FISH	Epizootic haematopoietic necrosis	Rainbow trout (*Oncorhynchus mykiss*) and redfin perch (*Perca fluviatilis*)
	Epizootic ulcerative syndrome	*Genera: Catla, Channa, Labeo, Mastacembelus, Mugil, Puntius and Trichogaster.*
MOLLUSCS	~~Infection with *Bonamia exitiosa*~~	~~Australian mud oyster (*Ostrea angasi*) and Chilean flat oyster (*O. chilensis*)~~
	Infection with *Perkinsus marinus*	Pacific oyster (*Crassostrea gigas*) and Eastern oyster (*C. virginica*)
	Infection with *Microcytos mackini*	Pacific oyster (*Crassostrea gigas*), Eastern oyster (*C. virginica*), Olympia flat oyster (*Ostrea conchaphila*) and European flat oyster (*O. edulis*)
CRUSTACEANS	Taura syndrome	Gulf white shrimp (*Penaeus setiferus*), Pacific blue shrimp (*P. stylirostris*), and Pacific white shrimp (*P. vannamei*)
	Yellowhead disease	Gulf brown shrimp (*Penaeus aztecus*), Gulf pink shrimp (*P. duorarum*), Kuruma prawn (*P. japonicus*), black tiger shrimp (*P. monodon*), Gulf white shrimp (*P. setiferus*), Pacific blue shrimp (*P. stylirostris*), and Pacific white shrimp (*P. vannamei*)

NON-EXOTIC DISEASES		
	DISEASE	SUSCEPTIBLE SPECIES
FISH	Spring viraemia of carp (SVC)	Bighead carp (*Aristichthys nobilis*), goldfish (*Carassius auratus*), crucian carp (*C. carassius*), grass carp (*Ctenopharyngodon idellus*), common carp and koi carp (*Cyprinus carpio*), silver carp (*Hypophthalmichthys molitrix*), sheatfish (*Silurus glanis*) and tench (*Tinca tinca*)
	Viral haemorrhagic septicaemia (VHS)	Herring (*Clupea spp.*), whitefish (*Coregonussp.*), pike (*Esox lucius*), haddock (*Gadusaeglefinus*), Pacific cod (*G. macrocephalus*), Atlantic cod (*G. morhua*), Pacific salmon (*Oncorhynchus spp.*) rainbow trout (*O. mykiss*), rockling (*Onos mustelus*), brown trout (*Salmo trutta*), turbot (*Scophthalmus maximus*), sprat (*Sprattussprattus*) and grayling (*Thymallus thymallus*)
	Infectious haematopoietic necrosis (IHN)	Chum salmon (*Oncorhynchus keta*), coho salmon (*O. kisutch*), Masou salmon (*O. masou*), rainbow or steelhead trout (*O. mykiss*), sockeye salmon (*O. nerka*), pink salmon (*O. rhodurus*) chinook salmon (*O.tshawytscha*), and Atlantic salmon (*Salmo salar*)
	Koi herpes virus (KHV) disease	Common carp and koi carp (*Cyprinus carpio*).
	Infectious salmon anaemia (ISA)	Rainbow trout (*Oncorhynchus mykiss*), Atlantic salmon (*Salmo salar*), and brown and sea trout (*S. trutta*).
MOLLUSCS	Infection with *Marteilia refringens*	Australian mud oyster (*Ostrea angasi*), Chilean flat oyster (*O. chilensis*), European flat oyster (*O. edulis*), Argentinian oyster (*O. puelchana*), blue mussel (*Mytilus edulis*) and Mediterranean mussel (*M. galloprovincialis*)
	Infection with *Bonamia ostreae*	Australian mud oyster (*Ostrea angasi*), Chilean flat oyster (*O. chilensis*), Olympia flat oyster (*O. conchaphila*), Asiatic oyster (*O. denselammellosa*), European flat oyster (*O. edulis*), and Argentinian oyster (*O. puelchana*).
CRUSTACEANS	White spot disease	All decapod crustaceans (order *Decapoda*).

4 Reference documents

- Overview report of a series of fact-finding missions carried out in 2014 and 2015 on the implementation of the rules on finfish aquaculture. (DG(SANTE) 2015-7406 – MR)

- 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)
- Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals
- Commission Directive 2008/53/EC of 30 April 2008

5 Contact Persons

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