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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

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Subject:	ANNEXES to the COMMISSION DELEGATED REGULATION (EU) .../... supplementing Regulation (EU) 2016/429 of the European Parliament and of Council as regards rules for aquaculture establishments and transporters of aquatic animals

Delegations will find attached document C(2020) 415 final ANNEXES 1 to 2.

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Brussels, 30.1.2020
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ANNEXES 1 to 2

ANNEXES

to the

COMMISSION DELEGATED REGULATION (EU) .../...

supplementing Regulation (EU) 2016/429 of the European Parliament and of Council as regards rules for aquaculture establishments and transporters of aquatic animals

ANNEX I

REQUIREMENTS FOR GRANTING APPROVAL OF AQUACULTURE ESTABLISHMENTS, AS REFERRED TO IN CHAPTER 2 OF TITLE I OF PART II

Part 1

Requirements for granting approval of aquaculture establishments where aquaculture animals are kept with a view to being moved therefrom either alive or as products of aquaculture animal origin as referred to in Article 7

1. The requirements in relation to biosecurity measures of aquaculture establishments where aquaculture animals are kept with a view to being moved therefrom either alive or as products of aquaculture animal origin as referred to in point (b) of Article 7, shall be the following:
 - (a) operators shall implement a biosecurity plan in accordance with Article 5, which must take the following elements into consideration:
 - (i) disinfection points must be installed at critical locations in the aquaculture establishment;
 - (ii) where the following functional units exist within the same aquaculture establishment, they must be separated using appropriate hygiene barriers:
 - hatchery units,
 - fattening units,
 - processing units,
 - dispatch centre;
 - (iii) work clothing and footwear for personnel must be kept solely for use at the aquaculture establishment and cleaned and disinfected regularly;
 - (iv) equipment must not be shared between aquaculture establishments but where this is unavoidable, an appropriate protocol for cleaning and disinfection of the equipment must be followed;
 - (v) visitors to the aquaculture establishment must be controlled in cases where they pose a disease risk; these visitors must either:
 - wear protective clothing and footwear provided at the aquaculture establishment; or
 - clean and disinfect any protective clothing and footwear they bring onto the aquaculture establishment on arrival and in the case of non-disposable clothing and footwear, on departure;
 - (vi) dead animals must be removed from all production units at a frequency that ensures infective pressure is kept to a minimum but which is practicable given the production method used, and disposed of in

compliance with Article 13 of Regulation (EC) No 1069/2009 of the European Parliament and of the Council¹;

- (vii) as far as possible, equipment in the aquaculture establishment must be cleaned and disinfected at the end of each production cycle;
 - (viii) where aquaculture establishments receive fertilised eggs from other establishments, and where biologically feasible, these eggs must be disinfected appropriately on arrival and all packaging must be disinfected or disposed of in a biosecure manner;
 - (ix) the cleaning and disinfection records of transporters must be verified before aquatic animals are loaded or unloaded at the aquaculture establishment;
- (b) operators shall nominate a named person to be in charge of implementing the biosecurity plan for the aquaculture establishment with other personnel reporting to that individual in relation to biosecurity matters.
2. The requirements in relation to facilities and equipment of aquaculture establishments as referred to in point (c) of Article 7, shall be the following:
- (a) suitable equipment and facilities must be available for the purpose of maintaining appropriate husbandry conditions for the aquaculture animals kept on the aquaculture establishment;
 - (b) the aquaculture establishment must provide for good standards of hygiene and allow adequate health monitoring to be carried out;
 - (c) as far as possible, equipment and facilities must be made from materials which can be appropriately cleaned and disinfected;
 - (d) appropriate predator control measures must be put in place, taking into account the risk of disease spread these predators pose and the environmental constraints of the aquaculture establishment;
 - (e) appropriate equipment must be available for the cleaning and disinfection of facilities, equipment and means of transport.

¹ Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

Part 2

Requirements for granting approval of groups of aquaculture establishments where aquaculture animals are kept with a view to being moved therefrom either alive or as products of aquaculture animal origin as referred to in Article 8

1. The requirements in relation to biosecurity measures of groups of aquaculture establishments where aquaculture animals are kept with a view to being moved therefrom as referred to in point (b) of Article 8, shall be the following:
 - (a) operators shall implement a biosecurity plan in accordance with Article 5, and in developing their biosecurity plan, the operators must take the following elements into consideration:
 - (i) disinfection points must be installed at critical locations in each aquaculture establishment in the group;
 - (ii) where the following functional units exist within the same aquaculture establishment, they must be separated using appropriate hygiene barriers:
 - hatchery units,
 - fattening units,
 - processing units,
 - dispatch centre;
 - (iii) work clothing and footwear for personnel must be kept solely for use at each aquaculture establishment and cleaned and disinfected regularly;
 - (iv) equipment must not be shared between aquaculture establishments but where this is unavoidable, an appropriate protocol for cleaning and disinfection of the equipment must be followed;
 - (v) visitors to the aquaculture establishment must be controlled where they pose a disease risk; these visitors must either:
 - wear protective clothing and footwear provided at each aquaculture establishment; or
 - clean and disinfect any protective clothing and footwear they bring onto the aquaculture establishment on arrival and in the case of non-disposable clothing and footwear, on departure;
 - (vi) dead aquaculture animals must be removed from all production units at a frequency that ensures infective pressure is kept to a minimum but which is practicable given the production method used, and disposed of in compliance with Article 13 of Regulation (EC) No 1069/2009;
 - (vii) as far as possible, equipment in each aquaculture establishment must be cleaned and disinfected at the end of each production cycle;
 - (viii) where aquaculture establishments receive fertilised eggs from other establishments, and where biologically feasible, these eggs must be disinfected appropriately on arrival and all packaging must be disinfected or disposed of in a biosecure manner;

- (ix) the cleaning and disinfection records of transporters must be verified before aquaculture animals are loaded or unloaded at the aquaculture establishment;
 - (b) responsibility for the implementation of the measures set out in the biosecurity plan shall be with:
 - (i) the operator of each individual aquaculture establishment in a group of aquaculture establishments approved in accordance with point (a) of Article 177 of Regulation (EU) 2016/429;
 - (ii) the operator of a group of aquaculture establishments approved in accordance with point (b) of Article 177 of Regulation (EU) 2016/429.
2. The requirements in relation to facilities and equipment of groups of aquaculture establishments as referred to in point (c) of Article 8, shall be the following:
- (a) suitable equipment and facilities must be available for the purpose of maintaining appropriate husbandry conditions for the aquaculture animals kept in each aquaculture establishment in the group;
 - (b) each aquaculture establishment in the group must have good standards of hygiene and allow health monitoring to be carried out;
 - (c) equipment and facilities in each aquaculture establishment in the group must be made from materials which can be readily cleaned and disinfected;
 - (d) appropriate predator control measures must be put in place in each aquaculture establishment in the group, taking into account the risk of disease spread these predators pose and the environmental constraints of the aquaculture establishment;
 - (e) appropriate equipment must be available in each aquaculture establishment in the group for cleaning and disinfection of facilities, equipment and means of transport.

Part 3

Requirements for granting approval of confined aquaculture establishments referred to in Article 9

1. The requirements in relation to the biosecurity measures of confined aquaculture establishments as referred to in point (b) of Article 9, shall be the following:
 - (a) operators shall implement the biosecurity plan in accordance with Article 5, which must take the following elements into consideration:
 - (i) disinfection points must be installed at critical locations in the confined aquaculture establishment;
 - (ii) where different functional units exist within the same confined aquaculture establishment, they must be kept separate using hygiene barriers;
 - (iii) work clothing and footwear for personnel must be kept at the confined aquaculture establishment and cleaned and disinfected regularly;
 - (iv) visitors must wear protective clothing and footwear provided by the operator;
 - (v) equipment shall not be shared with other aquaculture establishments;
 - (vi) dead animals must be removed at a frequency that ensures infective pressure is kept to a minimum, and disposed of in compliance with Article 13 of Regulation (EC) No 1069/2009;
 - (vii) the equipment in the confined aquaculture establishment must be cleaned and disinfected at an appropriate frequency;
 - (viii) where confined aquaculture establishments receive fertilised eggs from other establishments, where biologically feasible and where it does not interfere with research objectives, these eggs must be disinfected appropriately on arrival, and all packaging must be disinfected or disposed of in a biosecure manner;
 - (ix) the cleaning and disinfection records of transporters must be verified before aquaculture animals are loaded or unloaded at the establishment;
 - (b) operators shall nominate a named person to be in charge of implementing the biosecurity plan for the confined aquaculture establishment with other personnel reporting to that individual in relation to biosecurity matters.
2. The requirements in relation to surveillance and control measures of confined aquaculture establishments as referred to in point (c) of Article 9, shall be the following:
 - (a) a disease surveillance plan must be implemented, which must include appropriate controls for diseases of aquaculture animals, and it must be updated according to the number and species of the aquaculture animals present in the confined aquaculture establishment, and to the epidemiological situation in and around the confined aquaculture establishment as regards listed and emerging diseases;

- (b) aquaculture animals suspected of being infected with listed or emerging disease agents must be subjected to clinical, laboratory or post-mortem testing;
 - (c) the vaccination and treatment of aquaculture animals against transmissible diseases is carried out as appropriate.
3. The requirements in relation to facilities and equipment of confined aquaculture establishments as referred to in point (d) of Article 9, shall be the following:
- (a) the boundaries of the confined aquaculture establishments must be clearly demarcated and the access of aquatic animals and humans to animal facilities must be controlled;
 - (b) where necessary, adequate facilities suited for the quarantine of aquaculture animals introduced from other establishments must be available;
 - (c) adequate means for isolating aquaculture animals must be available;
 - (d) tanks and other holding facilities must be of a suitable standard and constructed so that:
 - (i) contact with aquatic animals outside is prevented and that inspections and any necessary treatments can be easily carried out;
 - (ii) floors, walls and all other material or equipment can be readily cleaned and disinfected;
 - (e) suitable equipment and facilities must be available for the purpose of maintaining appropriate husbandry conditions for the aquaculture animals kept in the confined aquaculture establishment;
 - (f) the confined aquaculture establishment must provide for good standards of hygiene and allow adequate health monitoring to be carried out;
 - (g) appropriate equipment must be available for the cleaning and disinfection of facilities, equipment and means of transport;
 - (h) appropriate predator control measures must be put in place, taking into account the risk of disease spread these predators pose;
 - (i) appropriate disinfection equipment must be in place to ensure that all wastewater which is discharged from the confined aquaculture establishment is treated to a level which ensures that any infectious agents of listed or emerging diseases which are present are fully inactivated before discharge.

Part 4

Requirements for granting approval of disease control aquatic food establishments referred to in Article 11

1. The requirements in relation to biosecurity measures of disease control aquatic food establishments as referred to in point (a) of Article 11, shall be the following:
 - (a) operators shall implement the biosecurity plan for the disease control aquatic food establishment in accordance with Article 5, which must take account of at least the following elements when animals which are infected with a listed or emerging disease are slaughtered or processed on the premises:
 - (i) visitors to the establishment must be avoided, but when such visits are unavoidable, they must be controlled and protective clothing and footwear must be provided by the operator which are safely disposed of or cleaned and disinfected after use;
 - (ii) the personnel of the disease control aquatic food establishment must wear work clothing and footwear which must be cleaned and disinfected at an appropriate frequency;
 - (iii) an appropriate disinfection system must be in place to ensure that waste water from the disease control aquatic food establishment is appropriately treated so that any disease agents which are present are inactivated before the water is discharged;
 - (iv) an appropriate system must be in place to ensure the collection and appropriate disposal of animal by-products; such by-products shall be processed as Category 1 or Category 2 material in compliance with Article 12 or Article 13 of Regulation (EC) No 1069/2009;
 - (v) appropriate cleaning and disinfecting operations must be completed prior to the arrival of any new consignment of aquatic animals for processing;
 - (vi) appropriate measures must be in place to ensure that all means of transport and their containers which are used to deliver aquatic animals to a disease control aquatic food establishment are cleaned and disinfected before they leave the establishment.
2. The requirements in relation to facilities and equipment of disease control aquatic food establishments as referred to in point (b) of Article 11, shall be the following:
 - (a) floors, walls and all other material or equipment must be easily cleaned and disinfected;
 - (b) appropriate disinfection equipment must be in place to ensure that all waste water which is discharged from the disease control aquatic food establishment is treated to a level which ensures that any infectious agents of listed or emerging diseases which are present are fully inactivated before discharge;
 - (c) appropriate equipment, compatible with the type of production activities conducted, must be available for the cleaning and disinfection of facilities, equipment and means of transport;
 - (d) appropriate predator control measures must be put in place, taking into account the risk of disease spread these predators pose.

Part 5

Requirements for granting approval of purification centres as referred to in Article 12

1. The requirements in relation to biosecurity measures of purification centres as referred to in point (a) of Article 12, shall be the following
 - (a) operators shall implement the biosecurity plan in accordance with Article 5, which must take the following elements into consideration:
 - (i) disinfection points must be installed at critical locations in the purification centre;
 - (ii) the work clothing and footwear for personnel must be kept solely for use at the purification centre and cleaned and disinfected regularly;
 - (iii) equipment must not be shared between establishments but where this is unavoidable, an appropriate protocol for cleaning and disinfection of the equipment must be put in place;
 - (iv) visitors to the purification centre must be controlled where they pose a risk for the spread of disease; these visitors must either:
 - wear protective clothing and footwear provided at the purification centre; or
 - clean and disinfect any protective clothing and footwear they bring onto the purification centre on arrival and in the case of non-disposable clothing and footwear, on departure;
 - (v) equipment in the purification centre must be cleaned and disinfected at the end of the purification cycle;
 - (vi) wastewater from the purification centre must not be discharged without appropriate treatment directly into water bodies when the health status of aquatic animals may be jeopardised with respect to listed or emerging diseases.
2. The requirements in relation to facilities and equipment of purification centres as referred to in point (b) of Article 12, shall be the following:
 - (a) the purification centre must provide for good standards of hygiene;
 - (b) equipment and facilities must be made from materials which can be appropriately cleaned and disinfected;
 - (c) appropriate equipment must be available for cleaning and disinfection of facilities, equipment and means of transport;
 - (d) appropriate predator control measures must be put in place, taking into account the risk of disease spread these predators pose;
 - (e) appropriate disinfection equipment must be put in place to ensure that wastewater which is discharged from the purification centre is treated when required to ensure that any agents of listed or emerging diseases which are present are inactivated prior to discharge.

Part 6

Requirements for granting approval of dispatch centres as referred to in Article 13

1. The requirements in relation to biosecurity measures of dispatch centres as referred to in point (a) of Article 13, shall be the following:
 - (a) operators shall implement the biosecurity plan in accordance with Article 5, which must take the following elements into consideration:
 - (i) disinfection points must be installed at critical locations in the dispatch centre;
 - (ii) work clothing and footwear for personnel must be kept solely for use at the dispatch centre and cleaned and disinfected regularly;
 - (iii) equipment must not be shared between establishments but where this is unavoidable, an appropriate protocol for cleaning and disinfection of the equipment must be put in place;
 - (iv) visitors to the dispatch centre must be controlled in cases where they pose a risk for the spread of disease; these visitors must either:
 - wear protective clothing and footwear provided at the establishment; or
 - clean and disinfect any protective clothing and footwear they bring onto the establishment on arrival and in the case of non-disposable clothing and footwear, on departure;
 - (v) equipment in the dispatch centre must be cleaned and disinfected at the end of the dispatch operation;
 - (vi) wastewater from the dispatch centre must not be discharged without appropriate treatment directly into water bodies when the health status of aquatic animals may be jeopardised with respect to listed or emerging diseases.
2. The requirements in relation to facilities and equipment of dispatch centres as referred to in point (b) of Article 13, shall be the following:
 - (a) the dispatch centre must provide for good standards of hygiene;
 - (b) equipment and facilities must be made from materials which can be appropriately cleaned and disinfected;
 - (c) appropriate equipment must be available for cleaning and disinfection of facilities, equipment and means of transport;
 - (d) appropriate predator control measures must be put in place, taking into account the risk of disease spread these predators pose;
 - (e) appropriate disinfection equipment must be in place to ensure that waste water which is discharged from the dispatch centre is treated when required to ensure that any agents of listed or emerging diseases which are present are inactivated prior to discharge.

Part 7

Requirements for granting approval of relaying areas as referred to in Article 14

1. The requirements in relation to biosecurity measures of relaying areas as referred to in point (a) of Article 14, shall be the following:
 - (a) operators shall implement the biosecurity plan in accordance with Article 5, which must take the following elements into consideration:
 - (i) disinfection points must be installed at critical locations in the relaying area;
 - (ii) work clothing and footwear for personnel must be kept solely for use at the relaying area and cleaned and disinfected regularly;
 - (iii) equipment must not be shared between aquaculture establishments but in cases where this is unavoidable, an appropriate protocol for cleaning and disinfection of the equipment must be put in place;
 - (iv) visitors to the relaying area must be controlled in cases where they pose a risk for the spread of disease; these visitors must either:
 - wear protective clothing and footwear provided at the relaying area; or
 - clean and disinfect any protective clothing and footwear they bring onto the relaying area on arrival and in the case of non-disposable clothing and footwear, on departure;
 - (v) as far as possible, equipment in the relaying area must be cleaned and disinfected at the end of the purification cycle.
2. The requirements in relation to facilities and equipment of relaying areas as referred to in point (b) of Article 14, shall be the following:
 - (a) as far as possible, the relaying area must provide for good standards of hygiene;
 - (b) as far as possible, equipment and facilities must be made from materials which can be appropriately cleaned and disinfected;
 - (c) appropriate equipment must be available for cleaning and disinfection of facilities where relevant, and equipment and means of transport;
 - (d) appropriate predator control measures must be put in place, taking into account the risk of disease spread these predators pose and the environmental constraints of the relaying area.

Part 8

Requirements for granting approval of quarantine establishments as referred to in Article 15

1. The requirements in relation to biosecurity measures of quarantine establishments for aquatic animals as referred to in point (a) of Article 15 shall be the following:
 - (a) the quarantine establishment must be located at a secure distance from other quarantine establishments, aquaculture establishments or groups of aquaculture establishments by a distance specified by the competent authority on the basis of a risk assessment which must take into account the epidemiology of the relevant listed and emerging diseases;
 - (b) the operator shall implement the biosecurity plan which is provided for in Article 5 and which must include at least the following elements:
 - (i) disinfection points must be installed at critical locations as identified in the biosecurity plan;
 - (ii) where they exist within the same quarantine establishment, measures must be taken to ensure that quarantine units remain epidemiologically separate from each other;
 - (iii) work clothing and footwear for personnel must be kept at the quarantine establishment and cleaned and disinfected regularly;
 - (iv) equipment must not be shared between quarantine units within the quarantine establishment, but in cases where this is unavoidable, an appropriate protocol for cleaning and disinfection of the equipment must be put in place; equipment must not be shared with other establishments;
 - (v) only authorised persons may enter the quarantine establishment;
 - (vi) persons entering the quarantine establishment must wear the protective clothing and footwear provided and these must be safely disposed of or cleaned and disinfected after use;
 - (vii) dead animals must be removed from all quarantine units at a frequency that ensures infective pressure is kept to a minimum and disposed of as Category 1 or Category 2 material in compliance with Article 12 or Article 13 of Regulation (EC) No 1069/2009;
 - (viii) all equipment in the quarantine establishments must be cleaned and disinfected at the end of each quarantine period;
 - (ix) the required quarantine period must start when the last aquatic animal in the cohort to be quarantined is introduced;
 - (x) each quarantine unit must be emptied of animals, cleaned and disinfected at the end of the quarantine period and be kept free of animals for a period of at least seven days before new aquatic animals are introduced;
 - (xi) precautions must be taken to prevent cross-contamination between incoming and outgoing consignments of aquatic animals;

- (xii) animals released from the quarantine establishment must meet the requirements for movements of aquaculture animals between Member States;
 - (c) a named person must be in charge of implementing the biosecurity plan for the quarantine establishment with other personnel reporting to that individual in relation to biosecurity matters, where necessary.
2. The requirements in relation to surveillance and control measures of quarantine establishments for aquaculture animals, as referred to in point (b) of Article 15, shall be the following:
- (a) environmental conditions which are conducive to the clinical expression of the relevant listed or emerging disease must be kept in the quarantine establishment throughout the entire quarantine period;
 - (b) all aquaculture animals that die or show symptoms of disease *during* the quarantine period must be clinically inspected by a veterinarian and testing of samples must be carried out at a laboratory designated by the competent authority for that purpose;
 - (c) fish, molluscs and crustaceans of listed species must be quarantined under the conditions set out in point (a) for a period of at least 90 days;
 - (d) within a period of 15 days from the date of expiry of the quarantine period, samples must be taken from a number of aquaculture animals that will ensure the detection of the relevant pathogen with a 95% confidence if the target prevalence is 2%. These aquaculture animals may be taken from the cohort which is undergoing quarantine or from co-habiting sentinel aquaculture animals which are susceptible to the relevant listed or emerging disease and which are used as a diagnostic aid during the quarantine period.
3. The requirements in relation to facilities and equipment of quarantine establishments for aquaculture animals, as referred to in point (c) of Article 15, shall be the following:
- (a) the water supply to the quarantine establishment must be free of agents of the relevant listed or emerging disease;
 - (b) the waste water from the quarantine establishment must be treated appropriately to ensure that the infectious agent(s) of listed and emerging diseases are inactivated before discharge;
 - (c) the waste water treatment system must be fitted with a fail-safe backup mechanism to ensure its continuous operation and the complete containment of the relevant infectious agent(s);
 - (d) the quarantine establishments must be clearly demarcated and the access of animals and humans must be controlled;
 - (e) staff responsible for carrying out veterinary checks must have sufficiently equipped premises at their disposal, where necessary, including changing rooms and showers;
 - (f) adequate means for isolating aquaculture animals must be available for use when required;

- (g) floors, walls and all other material or equipment must be constructed so that they can be adequately cleaned and disinfected;
- (h) an appropriate system must be in place to ensure the collection and appropriate disposal of animal by-products in compliance with Article 13 of Regulation (EC) No 1069/2009;
- (i) appropriate predator control measures are put in place, taking into account the risk of disease spread that these predators pose;
- (j) the part of the quarantine establishment accommodating the aquaculture animals must be of a suitable standard and so constructed that contact with water and animals outside is prevented and that inspection and any necessary husbandry procedures can be easily carried out.

Part 9

Requirements for granting approval of aquaculture establishments keeping aquaculture animals of vector species in isolation, until such time as they are no longer regarded as vectors, as referred to in Article 16

1. The requirements in relation to biosecurity measures of aquaculture establishments keeping aquaculture animals of listed species which are vectors in isolation until such time as they are no longer regarded as vectors, as referred to in point (a) of Article 16 shall be the following:
 - (a) operators shall implement the biosecurity plan in accordance Article 5, which must include at least the following elements:
 - (i) disinfection points must be installed at critical locations in the aquaculture establishment;
 - (ii) where different isolation units exist within the same aquaculture establishment, appropriate measures must be taken to ensure they remain epidemiologically separate from each other;
 - (iii) work clothing and footwear for personnel must be kept solely for use at the aquaculture establishment and cleaned and disinfected regularly;
 - (iv) equipment must not be shared between isolation units within the aquaculture establishment but where this is unavoidable, an appropriate protocol for cleaning and disinfection of the equipment must be put in place; equipment must not be shared with other establishments;
 - (v) only authorised persons must enter the aquaculture establishment;
 - (vi) persons entering the aquaculture establishment must wear the protective clothing and footwear provided and these must be safely disposed of or cleaned and disinfected after use;
 - (vii) dead animals must be removed from all production units in the establishment at a frequency that ensures infective pressure is kept to a minimum, and must be disposed of in compliance with Article 13 of Regulation (EC) No 1069/2009;
 - (viii) all equipment in the aquaculture establishment, or in the relevant isolation unit, if the aquaculture establishment consists of more than one such unit, must be cleaned and disinfected at the end of each isolation period;
 - (ix) the isolation period referred to in point 2 shall only start when the last animal in the cohort is introduced to the aquaculture establishment, or when there are a number of isolation units in the aquaculture establishment, the isolation period shall only start when the last animal in the cohort is introduced to the isolation unit;
 - (x) each isolation unit in the aquaculture establishment must be emptied of animals, and cleaned and disinfected at the end of the isolation period;
 - (xi) precautions must be taken to prevent cross-contamination between incoming and outgoing consignments of aquatic animals;

- (xii) animals released from the aquaculture establishment in which the isolation period has been undergone shall meet the requirements for movements of aquatic animals between Member States.
 - (b) operators shall ensure that a named person is charged with implementing the biosecurity plan for the aquaculture establishment with other personnel reporting to that individual in relation to biosecurity matters, where necessary.
- 2. The requirements in relation to surveillance and control measures of establishments keeping aquaculture animals of listed species which are vectors in isolation until such time as they are no longer regarded as vectors, as referred to in point (b) of Article 16, shall be the following:
 - (a) fish, molluscs and crustaceans of listed species shall be kept in isolation for a period of at least 90 days;
 - (b) all aquaculture animals that die or show symptoms of disease during the 90 day isolation period must be clinically inspected by a veterinarian and testing of samples must be carried out at a laboratory designated by the competent authority for that purpose.
- 3. The requirements in relation to facilities and equipment of aquaculture establishments keeping aquaculture animals of listed species which are vectors in isolation until such time as they are no longer regarded as vectors, as referred to in point (c) of Article 16, shall be the following:
 - (a) adequate means of keeping aquaculture animals in isolation must be available;
 - (b) the water supply to the aquaculture establishment must be free of listed species and of agents of the relevant listed and emerging diseases;
 - (c) where this is necessary so as not to jeopardise the health status of receiving waters, the waste water from the aquaculture establishment must be treated appropriately to ensure that the infectious agent(s) of listed and emerging diseases are inactivated before discharge;
 - (d) the access of animals to the aquaculture establishment is controlled;
 - (e) floors, walls and all other material or equipment are constructed so that they can be adequately cleaned and disinfected;
 - (f) an appropriate system is in place to ensure the collection and appropriate disposal of animal by-products in compliance with Article 13 of Regulation (EC) No 1069/2009;
 - (g) appropriate predator control measures are put in place, taking into account the risk of disease spread that these predators pose.

Part 10

Requirements for granting approval of aquaculture establishments which are closed facilities keeping aquaculture animals for ornamental purposes as referred to in Article 17

1. The requirements in relation to biosecurity measures of aquaculture establishments which are closed facilities keeping aquaculture animals for ornamental purposes which, because of their movement patterns, create a significant disease risk, as referred to in Article 17 shall be the following:
 - (a) the operator shall implement the biosecurity plan in accordance with Article 5, which must take the following elements into consideration:
 - (i) disinfection points must be installed at critical locations in the establishment;
 - (ii) work clothing and footwear for personnel must be kept solely for use at the aquaculture establishment and cleaned and disinfected regularly;
 - (iii) visitors to the aquaculture establishment must be controlled in cases where they pose a disease risk. These visitors must either:
 - wear protective clothing and footwear provided at the aquaculture establishment; or
 - clean and disinfect any protective clothing and footwear they bring onto the aquaculture establishment on arrival and in the case of non-disposable clothing and footwear, on departure;
 - (iv) dead animals must be removed from all production units at a frequency that ensures infective pressure is kept to a minimum and disposed of in compliance with Article 13 of Regulation (EC) No 1069/2009.
 - (b) a named person must be in charge of implementing the biosecurity plan for the aquaculture establishment with other personnel reporting to that individual in relation to biosecurity matters, where necessary.
2. The requirements in relation to facilities and equipment of the aquaculture establishments which are closed facilities keeping aquaculture animals for ornamental purposes which, because of their movement patterns, create a significant disease risk, as referred to in point (c) of Article 17, shall be the following:
 - (a) suitable equipment and facilities must be available for the purpose of maintaining appropriate husbandry conditions for the animals kept in the establishment;
 - (b) the aquaculture establishment must provide for good standards of hygiene and allow health monitoring to be carried out;
 - (c) the equipment and facilities must be made from materials which can be readily cleaned and disinfected;
 - (d) appropriate equipment must be available for cleaning and disinfection of facilities, equipment and means of transport;
 - (e) appropriate predator control measures must be put in place, taking into account the risk of disease spread that these predators pose;

- (f) an appropriate system must be in place to ensure the collection and appropriate disposal of animal by-products in compliance with Article 13 of Regulation (EC) No 1069/2009;

Part 11

Requirements for granting approval of aquaculture establishments which are open facilities keeping aquaculture animals for ornamental purposes as referred to in Article 18

1. The requirements in relation to biosecurity measures of aquaculture establishments which are open facilities keeping aquaculture animals for ornamental purposes as referred to in point (b) of Article 18, shall be the following:
 - (a) the operator shall implement the biosecurity plan in accordance with Article 5, which must take the following elements into consideration:
 - (i) disinfection points must be installed at critical locations in the aquaculture establishment;
 - (ii) where they exist within the same aquaculture establishment, functional units must be kept separate using appropriate hygiene measures;
 - (iii) work clothing and footwear for personnel must be kept at the aquaculture establishment and cleaned and disinfected regularly;
 - (iv) equipment must not be shared between aquaculture establishments but in cases where this unavoidable, an appropriate protocol for cleaning and disinfection of the equipment must be put in place;
 - (v) visitors to the aquaculture establishment must be controlled in cases where they pose a disease risk. These visitors must either:
 - wear protective clothing and footwear provided at the aquaculture establishment; or
 - clean and disinfect any protective clothing and footwear they bring onto the aquaculture establishment on arrival and in the case of non-disposable clothing and footwear, on departure;
 - (vi) dead animals must be removed from all production units at a frequency that ensures infective pressure is kept to a minimum and disposed of in compliance with Article 13 of Regulation (EC) No 1069/2009;
 - (vii) as far as possible, equipment in the aquaculture establishment must be cleaned and disinfected at the end of each production cycle;
 - (viii) the cleaning and disinfection records of transporters must be verified before animals are loaded or unloaded at the aquaculture establishment;
 - (b) operators shall ensure that a named person is charged with implementing the biosecurity plan for the aquaculture establishment with other personnel reporting to that individual in relation to biosecurity matters, where necessary.
2. The requirements in relation to facilities and equipment of aquaculture establishments which are open facilities keeping aquaculture animals for ornamental purposes as referred to in point (c) of Article 18, shall be the following:
 - (a) suitable equipment and facilities must be available for the purpose of maintaining appropriate husbandry conditions for the animals kept in the aquaculture establishment;
 - (b) the establishment must provide for good standards of hygiene and allow adequate health monitoring to be carried out;

- (c) as far as possible, equipment and facilities must be made from materials which can be appropriately cleaned and disinfected;
- (d) appropriate predator control measures must be put in place, taking into account the risk these predators pose and the environmental constraints of the aquaculture establishment;
- (e) appropriate equipment must be available for the cleaning and disinfection of facilities, equipment and means of transport;
- (f) an appropriate system is in place to ensure the collection and appropriate disposal of animal by-products in compliance with Article 13 of Regulation (EC) No 1069/2009.

Part 12

Requirements for granting approval of vessels or other mobile premises where aquaculture animals are kept temporarily to be treated or to undergo another husbandry related procedure as referred to in Article 19

1. The requirements in relation to biosecurity measures of vessels or other mobile premises where aquaculture animals are kept temporarily to be treated or to undergo another husbandry related procedure as referred to in point (a) of Article 19, shall be the following:
 - (a) the operator shall implement the biosecurity plan in accordance with Article 5, which must take the following elements into consideration:
 - (i) the vessel or mobile premises and all equipment used during the treatment process must be cleaned and disinfected when a treatment has been completed and before it moves to another aquaculture establishment;
 - (ii) work clothing and footwear for personnel must be kept at the aquaculture establishment and cleaned and disinfected regularly;
 - (iii) equipment must not be shared with other aquaculture establishments but in cases where this is unavoidable, an appropriate protocol for cleaning and disinfection of the equipment must be put in place and evidence of its implementation kept;
 - (iv) visitors to the aquaculture establishment must be controlled in cases where they cause a disease risk; these visitors must either:
 - wear protective clothing and footwear provided at the aquaculture establishment; or
 - clean and disinfect any protective clothing and footwear they bring onto the aquaculture establishment on arrival and in the case of non-disposable clothing and footwear, on departure;
 - (v) the cause of any mortality which occurs during a treatment must be recorded and dead animals must be removed from the aquaculture establishment at a frequency that minimises infective pressure and which is practicable given the treatment schedule for the aquaculture animals concerned;
 - (vi) dead animals are removed at a frequency that ensures infective pressure is kept to a minimum and disposed of in compliance with Article 13 of Regulation (EC) No 1069/2009.
 - (c) operators shall ensure that a named person is charged with implementing the biosecurity plan for the establishment, with other personnel reporting to that individual in relation to biosecurity matters, where necessary.
2. The requirements in relation to facilities and equipment of vessels or other mobile premises where aquaculture animals are kept temporarily to be treated or to undergo another husbandry-related procedure as referred to in point (b) of Article 19, shall be the following:

- (a) suitable equipment and facilities must be available for the purpose of maintaining appropriate husbandry conditions for the aquaculture animals kept in the establishment;
- (b) as far as possible, equipment and facilities must be made from materials which can be readily cleaned and disinfected;
- (c) appropriate equipment must be available for cleaning and disinfection of facilities and equipment;
- (d) where automated cleaning and disinfection systems are used, their efficacy must be validated before their initial use and at appropriate frequencies thereafter;
- (e) an appropriate system is in place to ensure the collection and appropriate disposal of animal by-products in compliance with Article 13 of Regulation (EC) No 1069/2009.

ANNEX II

RISK-BASED SURVEILLANCE TO BE CARRIED OUT IN CERTAIN APPROVED ESTABLISHMENTS

Part 1

Risk-based surveillance in aquaculture establishments and groups thereof referred to in Articles 7, 8, 17 and 18

Risk-based surveillance shall be implemented as follows in the aquaculture establishments, and groups thereof, which are referred to in Articles 7, 8, 17 and 18:

- (a) aquaculture establishments keeping listed species of aquaculture animals other than the species referred to in point (b)(ii) of this Part, shall implement risk-based surveillance according to their ranking as ‘high’, ‘medium’ or ‘low’ risk as a result of a risk assessment carried out in accordance with Part I of Annex VI to Commission Delegated Regulation (EU) .../... [C(2019) 4056]²;
- (b) aquaculture establishments keeping the species of aquaculture animals referred to in points (i) and (ii) shall implement risk-based surveillance if they have been ranked as ‘high’ risk as a result of a risk assessment carried out in accordance with Part I of Annex VI to Commission Delegated Regulation (EU) .../... [C(2019) 4056] :
 - (i) non-listed species;
 - (ii) listed species referred to in the fourth column of the table set out in the Annex to Implementing Regulation (EU) 2018/1882; but those listed species must be in contact with the listed species referred to in the third column of that table in order to be classified as vectors species, and that contact has not occurred.

² Delegated Regulation (EU) .../... supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes and disease-free status for certain listed and emerging diseases [C(2019) 4056].

Part 2

Content of risk-based surveillance at aquaculture establishments or groups thereof conducted in accordance with Article 26 of Regulation (EU) 2016/429

1. Record checks, clinical inspections and laboratory examinations at the approved aquaculture establishments referred to in Articles 7, 17 and 18 shall be carried out as follows:
 - (a) the relevant records kept in accordance with the record-keeping obligations of Article 186 of Regulation (EU) No 2016/429 and with Articles 23, 32 and 33 of this Regulation must be examined to assess if there are any indications of increased mortality or the presence of a listed or emerging disease in the aquaculture establishment which must be taken into account during the visit by a veterinarian;
 - (b) all parts of the aquaculture establishment must be examined with particular attention being paid to those production units where increased mortalities have been indicated in the records referred to in point (a);
 - (c) where there are no indications of the presence of a listed or emerging disease either from an examination of the records or from the clinical inspection of all production units, there shall be no requirement to take samples for laboratory examination;
 - (d) where recently dead or moribund aquaculture animals are identified, a representative selection of these aquaculture animals must be examined clinically, both externally and internally, to determine if pathological changes are present; that examination must in particular, aim at detecting listed or emerging diseases;
 - (e) if the outcome of the clinical examination provided for in point (d) leads to a suspicion of the presence of such a listed or emerging disease in an aquaculture establishment in a Member State, zone or compartment in which an eradication programme is being implemented, or which has been declared free from that particular disease, a sample of aquaculture animals from that aquaculture establishment shall be collected and subjected to a laboratory examination in accordance with the relevant Chapter of Part II of Annex VI to Delegated Regulation (EU) .../... [C(2019) 4056];
 - (f) if the outcome of the clinical examination provided for in point (d) leads to a suspicion of the presence of a listed disease in an aquaculture establishment in which a surveillance programme is being implemented for that particular category C disease, a sample of aquaculture animals from the aquaculture establishment shall be collected and subjected to a laboratory examination in accordance with the relevant Chapter of Part III of Annex VI to Delegated Regulation (EU) .../... [C(2019) 4056];
 - (g) if the outcome of the clinical examination provided for in point (d) leads to the suspicion of an emerging disease, a sample of aquaculture animals from the aquaculture establishment shall be collected and subjected to a laboratory examination with the objective of identifying the emerging disease in question.
2. Record checks and clinical and laboratory examinations at the approved groups of aquaculture establishments referred to in Article 8 shall be carried out as follows:

- (a) the relevant records kept by or on behalf of each aquaculture establishment in the group of aquaculture establishments in accordance with Article 186 of Regulation (EU) No 2016/429 and with Article 24 of this Regulation, must be examined to assess if there are indications of increased mortality or of the presence of a listed or emerging disease which must be taken into account when deciding which aquaculture establishment in the group is required to be visited for the purpose of risk-based surveillance;
- (b) when the examination of records referred to in point (a) indicates increased mortality or the presence of a listed or emerging disease in a particular aquaculture establishment within the group, that establishment must be visited for the purpose of risk based surveillance; the steps outlined in point 1 (b) to (g) must be followed during that visit;
- (c) when the examination of records referred to in point (a) does not indicate increased mortality or the presence of a listed or emerging disease in any aquaculture establishment within the group, the risk-based surveillance visit or visits shall be carried out either:
 - (i) after risk assessment, in the aquaculture establishment or aquaculture establishments within the group which pose the highest risk of disease introduction; or
 - (ii) to the establishment which has had the greatest number of movements of aquaculture animals for further farming, since the last risk-based surveillance visit was carried out.

In either case, the steps outlined in point 1 (c) to (g) must be followed during the risk-based surveillance visit.