

SUBMISSION OF INFORMATION FOR RECOGNITION OF DISEASE-FREE STATUS FOR CATEGORY C DISEASES OF AQUATIC ANIMALS IN ACCORDANCE WITH [CHAPTER 4 OF PART II OF REGULATION \(EU\) 2020/689](#) AND ARTICLE 11 OF [COMMISSION IMPLEMENTING REGULATION \(EU\) 2020/2002](#)

1. Date of submission
2. Name of Member State and details of contact point
3. Name of Category C disease
4. Identification of the grounds for recognition of disease-free status:
 - (a) absence of listed species
 - (b) disease agent's incapacity to survive
 - (c) historical and surveillance data
 - (d) completion of an eradication programme
5. Territorial scope:
 - (a) zone
 - (b) compartment
6. Declarations of disease-free status of compartments shall contain the following information:
 - (a) In the case of independent compartments as referred to in point (a) of Article 73(2) of Regulation (EU) 2020/689, documentation to substantiate that:
 - (i) the water is supplied through a water treatment plant which inactivates the relevant pathogen or that the water is supplied directly from a well, a borehole or a spring;
 - (ii) where such water originates from a source outside the establishment, it is channelled directly to it by means which afford appropriate protection from infection;

- (iii) there are natural or artificial barriers that prevent aquatic animals from entering each establishment in the compartment from surrounding natural waters;
 - (iv) where appropriate, the establishments in the compartment are protected against flooding and infiltration of water from surrounding natural waters.
- (b) In the case of **dependent compartments** as referred to in point of Article 73(2) of Regulation (EU) 2020/689:
 - (i) the assessment referred to in point (a) of Article 73(3) of the same Regulation; and
 - (ii) details of any measures which were imposed by the competent authority to prevent the introduction of the relevant disease to the compartment.
- 7. Statement confirming that the relevant general criteria in accordance with point (a) of Article 66 of Regulation (EU) 2020/689 for zones, or with point (a) of Article 73(1) of that Regulation for aquatic compartments, are complied with.
- 8. When the grounds for recognition of disease-free status are the **absence of listed species**, documentary evidence to substantiate that:
 - (a) the criteria laid down in points (a)(i) and (a)(ii) of Article 66 or Article 73(1) of Regulation (EU) 2020/689 (as relevant) have been fulfilled for an eligibility period of at least 5 years and the disease has not been detected;
 - (b) the listed species relevant to the Category C disease are absent from kept and wild animal populations;
 - (c) disease-free status can be sustained because:
 - (i) the likelihood of the presence of animals from listed species in the zone/compartment was assessed and found to be negligible; and
 - (ii) the likelihood of introduction of animals of listed species to the zone/compartment was found to be negligible.

9. When the grounds for recognition of disease-free status is based on the disease agents incapacity to survive:
 - (a) documentary evidence to substantiate that:
 - (i) the criteria laid down in points (a)(i) and (a)(ii) of Article 66 or Article 73(1) of Regulation (EU) 2020/689 (as relevant) have been fulfilled for an eligibility period of at least 5 years and the disease has not been detected;
 - (ii) the disease has never been reported, or if reported, it has been demonstrated that the disease agent did not survive;
 - (b) scientific evidence to substantiate that:
 - (i) the value of at least one critical environmental parameter that is not compatible with the survival of the disease is reached;
 - (ii) the disease agent is exposed to that critical environmental parameter for a period of time that is sufficient to destroy it.

10. When there are grounds for recognition of disease-free status based on historical and surveillance data because a Member State is new, or concerning infection with *B.exitiosa* or infection with WSSV for existing Member States for a period between 21 April 2021 and 21 April 2023, the following must be supplied:
 - (a) documentary evidence to substantiate that:
 - (i) the disease has never been reported in the zone/ compartment, or it has been eradicated in the zone/compartment, and not reported for at least 25 years; or
 - (ii) the disease has been reported in the past 25 years, but it has been eradicated in the zone/compartment thereof and the disease specific requirements referred to in Article 72 or 78 of Regulation (EU) 2020/689 (as relevant) are complied with.

- (b) Documentary evidence to demonstrate the implementation of the following measures for at least 10 years when the zone/compartment complies with paragraph (a)(i):
 - (i) disease surveillance in kept animals of listed species;
 - (ii) prevention to control the introduction of the disease agent;
 - (iii) ban on vaccination against the disease;
 - (iv) disease surveillance substantiating the fact that the disease is not known to be established in wild animals in the zone/compartment.
- 11. When the grounds for recognition of disease-free status is based on the completion of an **eradication programme**, for each year of the programme, information must be supplied concerning:
 - (a) The aquaculture establishments and where relevant, the sampling points in the wild in the zone/compartment:
 - (i) Number of approved aquaculture establishments in the programme;
 - (ii) Number of registered aquaculture establishments in the programme (where relevant);
 - (iii) Number of sampling points in wild populations (where relevant);
 - (iv) Maps showing approved and registered aquaculture establishments, and where relevant, sampling points in the wild;
 - (v) Number of aquaculture establishments, and where relevant, sampling points in the wild, out of the total number of aquaculture establishments and sampling points in the wild, which are not infected;
 - (vi) Number of aquaculture establishments, and where relevant, sampling points in the wild, out of the total number of aquaculture establishments and sampling points in the wild, with confirmed cases;

- (vii) Number of new aquaculture establishments, and where relevant, sampling points in the wild, out of the total number of aquaculture establishments and sampling points in the wild, with confirmed cases.
- (b) animal health visits and sampling which have been completed:
- (i) Number of health visits per approved and where relevant, per registered aquaculture establishment;
 - (ii) Number of samplings per approved, and where relevant, per registered aquaculture establishment, or samplings in wild populations;
 - (iii) Number of animals sampled at each sampling event;
 - (iv) Species sampled;
 - (v) Results from each laboratory examination (positive/ negative for the pathogen in question);
 - (vi) Results from each clinical inspection;
 - (vii) Water temperature at the time of sampling.