



Amendment to Commission Implementing Regulation (EU) 2018/1882

EURL Meeting (Fish & Crustaceans)

31 May 2021

Outline

- Background
- Input received from EURLs for fish & crustaceans concerning listing of
 - (a) susceptible species
 - (b) vector species
- Approach to be taken to the amendment of Regulation (EU) 2018/1882

Background

Objectives:

- (a) To review species set out in Regulation (EU) 2018/1882 to **update** and take account of **new findings** – **commitment given to Member States**
- (b) To ensure listing complies with **Article 8** of Regulation (EU) 2016/429
- (c) To ensure the methodology used for listing is **robust and will stand up to scrutiny**, including that of TCs via SPS
- (d) Where this is possible, to aim at the **appropriate level of convergence with OIE Standards**

Article 8 of Regulation (EU) 2016/429: Listing of species

1. The disease-specific rules for listed diseases provided for in this Regulation and the rules adopted pursuant to this Regulation shall apply to listed species.
2. The Commission shall, by means of implementing acts, establish a list of species as referred to in paragraph 1 of this Article that fulfil the criteria set out in paragraph 3 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

That list shall comprise those animal species, or groups of animal species which **pose a considerable risk for the spread of specific listed diseases**, based on the following criteria:

- (a) the **susceptibility** of the animal population at risk;
 - (b) the duration of the incubation period and infective period for the animals concerned;
 - (c) the **capability of those animals to carry those specific diseases**.
3. Animal species or groups of animal species **shall be added to the list if they are affected or if they pose a risk for the spread of a specific listed disease** because:
 - (a) they **are susceptible** to a specific listed disease or scientific evidence indicates that **such susceptibility is likely**; or
 - (b) they are **vector species or reservoirs for that disease**, or **scientific evidence indicates that such role is likely**.
 4. The Commission shall, by means of implementing acts, **remove animal species or groups of animal species from the list** when:
 - (a) the relevant **listed disease** in relation to which the animal species or group of animal species concerned has been listed has been **removed from the list of diseases**; or
 - (b) scientific evidence indicates that the species or group of species concerned **no longer fulfils the criteria set out in paragraph 3**.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Involvement of EURLs

- Request made to EURLs for Fish, Crustaceans and Molluscs
- Request made in context of Article 94(2)(f) of OCR: *‘providing scientific and technical assistance to the Commission within the scope of their mission’*
- 3 small groups of experts convened by EURL Directors
- Groups met virtually several times between May and early September 2020
- 3 separate reports furnished to EU Commission by mid-September
- Reports reviewed and discussed with Member States on 29 March last

Listed species for listed diseases of FISH

(a) SUSCEPTIBLE SPECIES

- Fortunate to be able to avail of recent assessments carried out by OIE *ad hoc* groups established to complete the same task
- Significant work completed by EURL – based primarily on OIE assessments
- Criteria for susceptibility to infection based on evidence of (i) natural pathways for infection (ii) adequate identification of the pathogen and (iii) evidence of infection based on:
 - A. Replication
 - B. Viability/ Infectivity
 - C. Pathology/ Clinical signs
 - D. Location
- Hosts were considered to be infected when they fulfilled either criterion A, or at least two of criteria B, C and D i.e. same approach as OIE

Listed species for listed diseases of FISH

(a) SUSCEPTIBLE SPECIES (continued)

- Outcome of assessment by the EURL Group resulted in all species which the OIE *ad hoc* Group had listed as 'Category I' (i.e. susceptible), also being listed as susceptible by the EURL Group => **FULL CONVERGENCE WITH OIE**
- For each disease of fish, this will result in:
 - certain susceptible species which are currently listed in Regulation (EU) 2018/1882, remaining on the list,
 - certain other species will be deleted and
 - certain new species will be added to the list

(b) VECTOR SPECIES

See later slides

Listed species for listed diseases of CRUSTACEANS

(a) SUSCEPTIBLE SPECIES

- Fortunate to be able to avail of recent assessments carried out by OIE *ad hoc* groups established to complete the same task
- Significant work completed by the EURL Group – based primarily on OIE assessments
- **Criteria for susceptibility to infection** based on evidence of (i) natural pathways for infection (ii) adequate identification of the pathogen and (iii) evidence of infection based on:
 - A. Replication
 - B. Viability/ Infectivity
 - C. Pathology/ Clinical signs
 - D. Location
- Hosts were considered to be infected when they fulfilled either criterion A, or at least two of criteria B, C and D i.e. same approach as OIE

Listed species for listed diseases of CRUSTACEANS

(a) SUSCEPTIBLE SPECIES (continued)

- Outcome of assessment by the EURL Group resulted in all species which the OIE *ad hoc* Group had listed as 'Category I' (i.e. susceptible), for **Taura Syndrome and Yellowhead Virus** also being listed as susceptible by the EURL Group => **FULL CONVERGENCE WITH OIE**
- For **Taura Syndrome and Yellowhead Virus**, this will result in:
 - certain susceptible species which are currently listed in Regulation (EU) 2018/1882, remaining on the list,
 - certain other species will be deleted
 - certain new species will be added to the list

Listed species for listed diseases of CRUSTACEANS

(a) SUSCEPTIBLE SPECIES (continued)

- Outcome of assessment by the EURL Group concerning **WSSV** resulted in the possibility to remove the reference to 'all decapod crustaceans' from the list of susceptible species for WSSV and to replace it with **50 individual species** for which the literature provides evidence of susceptibility
- However, from a risk management point of view, and because of all the species which have been tested to date, no decapod crustaceans have been reported to be refractory to infection with WSSV, **it has been agreed to retain the reference to 'all decapod crustaceans' as being susceptible to WSSV**

(b) VECTOR SPECIES

See later slides

Vector species for listed diseases of Fish & Crustaceans

- OIE does not have a list of vector species
- OIE *ad hoc* Groups characterised 3 different lists of species:
 - Category 1 list – meet the criteria for susceptibility
 - Category 2 list (OIE Manual) – species for which the literature indicates partial evidence of susceptibility
 - Category 3 list (OIE Manual) – species in which positive PCR results have been detected
- Fish/ Crustacean Groups worked with these lists and assessed the relevant literature to determine if it indicated that the species listed in Categories 2 & 3 could ‘pose a considerable risk for the spread of specific listed diseases’

Vector species for listed diseases of Fish & Crustaceans

- Approach taken by EURL Groups was labour intensive, extensive and pragmatic
- **Q:** Do we now have evidence that particular species are ‘vector species or reservoirs for that disease, or scientific evidence indicates that such role is likely’, and should therefore, be listed as such in Regulation (EU) 2018/1882 in accordance with Article 8 of the AHL ?
- Proposed lists are based on species for which scientific data partially supports susceptibility and species for which there are only molecular results. **Q:** Does this equate to being vectors?
- Notwithstanding the extensive work and expertise, are the proposed lists sufficiently robust to withstand scrutiny, including that of TCs via SPS procedures?
- **A:** Cautious approach is to be taken which will include input from EFSA

Vector species: Proposed approach

- Prepare a **mandate for EFSA** to produce a scientific opinion concerning the listing of vector species, taking into account Article 8 of Regulation (EU) 2016/429
- Furnish EFSA with **details of the approach which has been taken** and the **reports** produced by the **EURL groups** –very thorough work has already been completed
- Amend vector list in Regulation (EU) 2018/1882 **once EFSA Opinion has been received**
- In the meantime, **keep the current list of vectors (set out in Regulation (EU) 2018/1882)** and amend **ONLY** by deleting a species which has newly been added to the list of susceptible species –i.e. a given **species should not appear on both lists**
- Use only **scientific names** for species

Next steps

- Present to MSs at PAFF when ready
- Further opportunity for written comments from MSs
- Public feedback
- Vote at PAFF
- SPS notification
- In parallel, EFSA examine the question of vectors

Thank you



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