EHDV: summary of the WG of 27 October 2023

point AHW A.07, 23-24 November 2023, PAFF

European Commission, DG SANTE G2

Key messages from the CVOs in early 2023

- Amend CDR (EU) 2020/688 as fast as possible
- Try to use lessons learned, mechanisms and rules for bluetongue
- But do it simpler (category D disease vs. category C disease)
- No vaccine is available
- Individual testing is burdensome and expensive
- Member States will supply data for proper risk assessment later

Amendment to CDR (EU) 2020/688

- CDR (EU) 2023/2515,
- Published on 14 November: OJ L, 2023/2515, 14.11.2023
- https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202302515
- Entry into force: 5 December
- Article 10, 15, 23, 26, 29 amended + Annex IX added
- Baseline/current rule kept and
  - Seasonal freedom added
  - Vector protected establishment added
  - „No conditions” option added

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„No conditions”

- ‘By way of derogation from point (f)(ii), the competent authority of the Member State of origin may authorise movements which do not meet one of the requirements laid down in that point, to another Member State or area thereof if the Member State of destination:
  - (a) has informed the Commission and the other Member States that such movements are authorised; and
  - (b) accepts the animals regardless of the Member State or area thereof of their origin.’;

Interim IT solution in TRACES (since 27 Oct)

(2) [II.2.5. They come from establishments situated in an area of at least 150 km radius around those establishments in which infection with epizootic haemorrhagic disease virus has not been reported in kept animals of listed species for that disease during the last 2 years prior to departure;]

This statement in the certificate

- will remain as a baseline
- or can appear ~~strikethrough~~ too
  - […]
  - (2) Delete if not applicable
- MS were informed by e-mail on 27 Oct

Other issues raised in the past + relevant EU rules

- De-list infection with EHDV
  - Amend Annex II of Regulation (EU) 2016/429 by a delegated act
  - Amend CIR (EU) 2018/1882
- Re-categorise infection with EHDV to Category C disease (as bluetongue)
  - Amend CIR (EU) 2018/1882
  - Amend CDR (EU) 2020/689
- Provide even more flexibility and/or granularity, take into account vaccines
  - Amend CDR (EU) 2020/688
- Differentiate between bovines vs. ovine/caprine vs. other ruminants
  - Amend CDR (EU) 2020/688
- Differentiate between live animals and germinal products
  - Amend CDR (EU) 2020/686 and 2020/688
- Decrease notification obligations
  - Amend CIR (EU) 2020/2002

Participation at the 27 Oct working group

- Most Member States participated
- Presentations
  - France, Spain, Italy, Portugal, Switzerland on situation, observations and needs
  - Commission on EU legal, institutional and scientific risk assessment framework
  - All circulated to participants
- EFSA as observer
- In English

Key elements shared by the participants

- Clinical severity varies
  - Between establishment, areas, species, years, etc.
- Some morbidity, mortality data
  - Confirms EFSA scientific opinion of 2009
- Burdensome for competent authority and operators alike
  - Confirmations, notifications, restrictions, spread, etc.
  - Cost of treatments with anti-inflammatory medicinal products, losses
- Many ongoing national initiatives
  - Surveillance, clinical trials, lab work etc.
- Long viraemia and seroconversation
  - Long viraemia disputed by some, some anomalies in seroconversion: eg. in Sardinia
- Many question marks on disinsectisations
  - Availability, effects on specific vectors, which products, in which quantity, for how long, how often, value of manufacturer's instructions, etc.?
- „False alarm" in Switzerland
  - Importance of lab expertise

Initial impressions

- Picture is far from clear
- Slight variations between national measures
- Slight variations as time progresses in a MS
- Affected MS doing their best but EHD is spreading
- Second year seems to be milder, i.e., affects animals less
- Non-affected MS worry and monitor incoming consignments
- Affected MS are generating a wealth of data but:
  - Their scope, nature, quantity and quality is likely to vary
  - Timeframe for their collection and submission remains unclear
- EFSA opinion of 2009 is still valid

Since the WG

- One set of questions from one MS
- No other inputs by others
- No information from any MS on acceptance of „no conditions”
- Discussion with stakeholders at Animal Health Advisory Commitee
  - Claims that in France co-infection with EHDV and BTV-8 might complicate matters
- *(Some MS embark on working on BTV-3 vaccine together, with EMA etc.)*
  - *Possible for EHD too?*
  - *Vaccine(s) will be key to solve the situation*
- Commission is open to receive any input

Prerequisites for possible new EU rules

- Available vaccine(s)
  - Member States, veterinary medicinal authorities, veterinary medicinal producers
- Raw data
  - From Member States
- National assessments, practical observations, lessons etc.
  - From Member States
- Scientific publications
- Risk assessment by EFSA
- Time

Thank you

European Commission