



# EU animal health rules on IBR/IPV

DG SANTE/G2

PAFF meeting, Section AHW, point A.07

21 March 2025

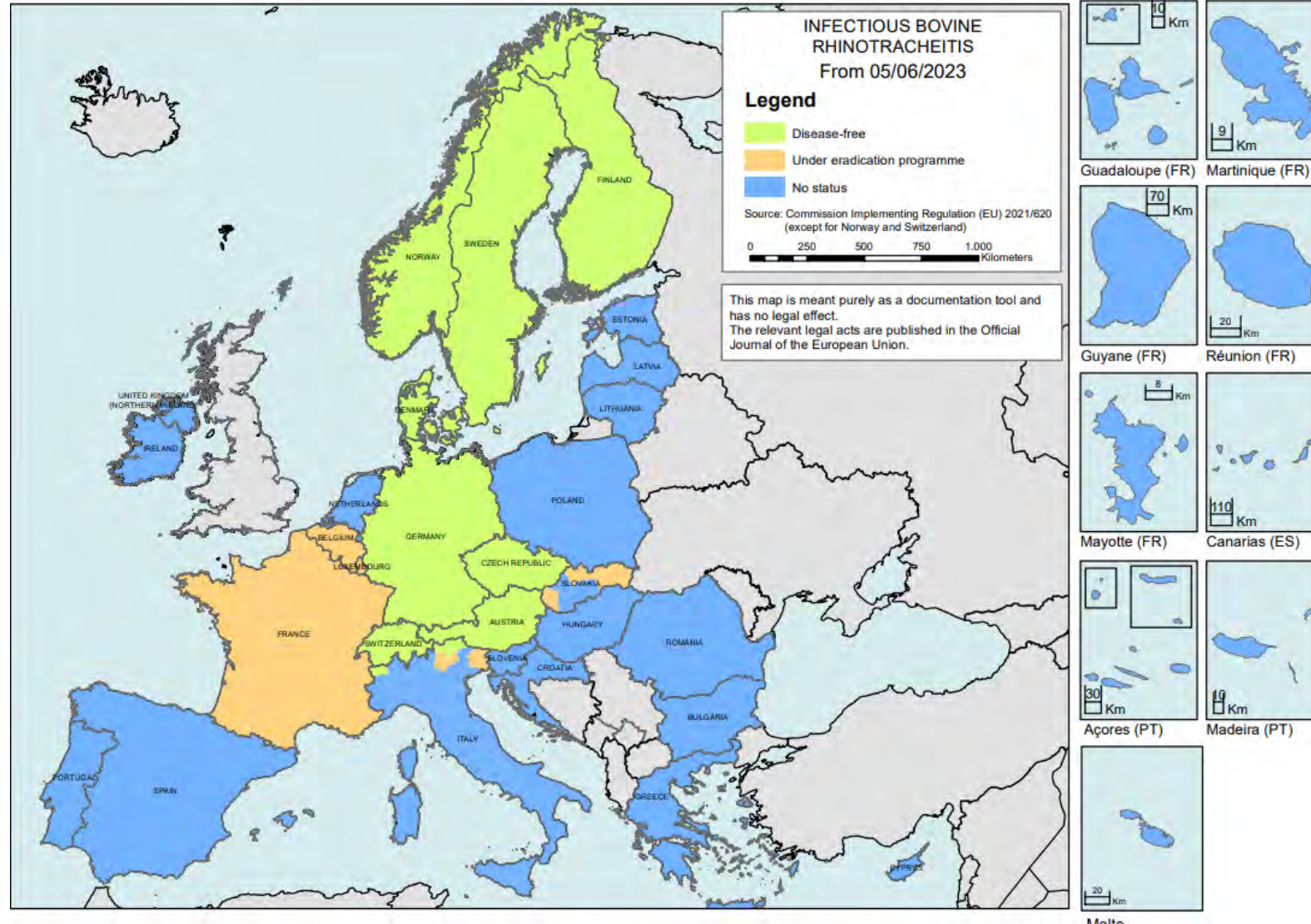
# Higher/wider context

- Sporadic, fragmented criticisms on current EU rules for IBR eradication:
  - ban on vaccination during eradication
  - do not allow use of marker vaccines
  - do not allow the use of vaccines when maintaining free status
- Past fora: AGRI Council AOB, EP, CVO meeting ...
- Claims that „free establishments with non-vaccinated cattle are vulnerable”
- Claims mixed with those on:
  - other diseases (e.g., under the umbrella „vaccination”)
  - other issues (e.g., linked to evaluation of EU AHL)
- Technical input was promised by various actors but never sent to Commission

# Basics and history of the disease

- Listed in the AHL, Category C in CIR (EU) 2018/1882
- Respiratory disease in cattle caused by **Bovine Herpesvirus-1 (BoHV-1)**
  - Complexities!
- Pre-AHL EU rules: „*additional guarantees for intra-Community trade in bovine animals*”
  - CD 2004/558/EC
- Several eradication programmes and free statuses in the EU since decades
- Considerable experience
- WOAHP Regional Reference Laboratory in FLI (DE)
- Current rules in CDR (EU) 2020/689 and 2020/688

# EU MS with freedom or with an approved eradication programme



# EU rules for eradication

- CDR (EU) 2020/689
  - Specific rules in Annex IV, Part IV
1. Status of freedom for establishments is possible
    - No vaccination in the establishment in the last 2 years
    - Previous DIVA vaccination is possible
    - Many possibilities to test, adapted to different farming practises: blood, meat juices, milk, bulk milk, all animals vs. random, etc.
    - Appropriate rules for introduction of bovines into the establishment
  2. Country/zone: prohibition of vaccination, 99,8% of establishments free

# EFSA opinion

2006. Opinion of the Scientific Panel on Animal Health and Welfare related to the  
“Definition of a BoHV-1-free animal and a BoHV-1-free holding, and the procedures to verify and maintain this status” EFSA Journal  
2006;4(2):311, 65 pp, <https://doi.org/10.2903/j.efsa.2006.311>

## Control and eradication

- Page 8 of EFSA: *„If prevalence is moderate to high in a zone or farms that aims to become free, the first steps of eradication should be based on the use of DIVA vaccination to decrease the prevalence of infected animals possibly followed by test and removal procedures.”*

## Diagnosis

- Page 8 of EFSA: *„The BoHV-1 free status of a single animal vaccinated with a gE-deleted BoHV-1 marker vaccine can only be determined using gE-antibody blocking-ELISAs. Due to the sensitivity values of the available gE-antibody tests false negative results do occur more often than with conventional test systems.”*
- Page 8 of EFSA: *„To ascertain the BoHV-1 free status of a marker-vaccinated animal, requirements in addition to a negative serological test result are required (more epidemiological data of the herd, obligatory vaccination of the complete herd, usage of gE ELISAs as a “herd test”). Due to the fact that gE-seroconversion is often late, quarantine intervals of more than 28 days (a minimum of 35 days is recommended) should be considered.”*

## Monitoring and surveillance

- Page 10 EFSA: *“if DIVA vaccines are used the less sensitive gE blocking ELISA need to be to be used for surveillance purposes, which increases the likelihood of false negatives.”*

# Approved erad. programmes vs. eradication

## Approved eradication programmes

- Comply with CDR (EU) 2020/689
- Duration: 6 years
- Official status in CIR (EU) 2021/620
- Supplementary protection from movements between MS
- Normally in later stage of an eradication: low prevalence

## Eradication

- MS have large discretion
- Unlimited duration
- No official status
- No supplementary protection
- Normally in early stage of an eradication: higher prevalence



# EU rules for movements between MS

- CDR (EU) 2020/688
- Article 11(2), into free MS:
  - From free establishments + further granularity
  - no vaccinated animals
- Article 12(2), into MS under approved eradication programmes
  - From free establishment + further granularity
  - Additional possibility for DIVA vaccination; and for bovine for meat production
- Appropriate protection of MS of destination



# The usual approach and progress



# WOAH standards

- WOAH Terrestrial Code, Chapter 11.8
  - Country freedom is possible only after 3 years without vaccination
  - 99,8% of the herds free
  - Testing regime for herd freedom: do not allow for any vaccination
  - Vaccination: relevant only for movements to non-free herds
- WOAH Manual Chapter 3.4.11. (version May 2017)
  - Latent infections. Stress: can turn them into acute and/or clinical ones
  - ELISA: lower sensitivity in milk and bulk milk
  - Vaccines do not prevent infection, they reduce clinical signs and virus shedding

# Past discussions and our current impressions

- All issues were duly discussed in expert groups up to 2019
- Certain comments were raised by several MS
  - Not only on vaccination, also on analytical methods, on matrices, pooling etc.
  - Some were accepted, others were not, all were clarified
  - Initial Commission drafts were „softened”
  - WOAHA Regional Lab was frequently consulted
- EU rules are in line with WOAHA: EU slightly more flexible
- EU rules are in line with past experience
- EU rules are in line with EFSA Scientific Opinions

# Other relevant elements

- A recent F2 audit into one MS under IBR approved eradication programme:
  - „Unconventional farms”, „fattening units”, „mixed origins”, etc.
  - Certain problems with vaccination
- Domestic disagreements between stakeholders cannot be excluded
- EU IBR policy is clear, technical details are key
- These issues have not been raised by MS at tech level
- These issues are not related to evaluation of AHL

# Summary, conclusions, our position

- Commission considers that current EU rules:
  - are proportionate and fit for use
  - have been agreed after due discussions
  - confirm to WOAH standards, to science, to experience
- Issues seem to be limited to certain operators in a few MS
- Operators have obligations in establishments: cattle are not „vulnerable”
- Commission is open to consider further technical input
- Only if necessary (limited resources, priorities etc.)
- Ultimately leading to a new EFSA risk assessment

# Questions, comments?