Netherlands Food and Consumer
Product Safety Authority
Ministry of Agriculture,
Nature and Food Quality

Bluetongue (BTV-3)

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Current Situation

Since the last presentation of September

September

- Onset of the disease
  - 19 infected farms with 13 infected sheep and 3 bovine
  - 18 suspicious cases

- Decrease due to cold weather
  - Currently 5884 BTV positive locations in the Netherlands

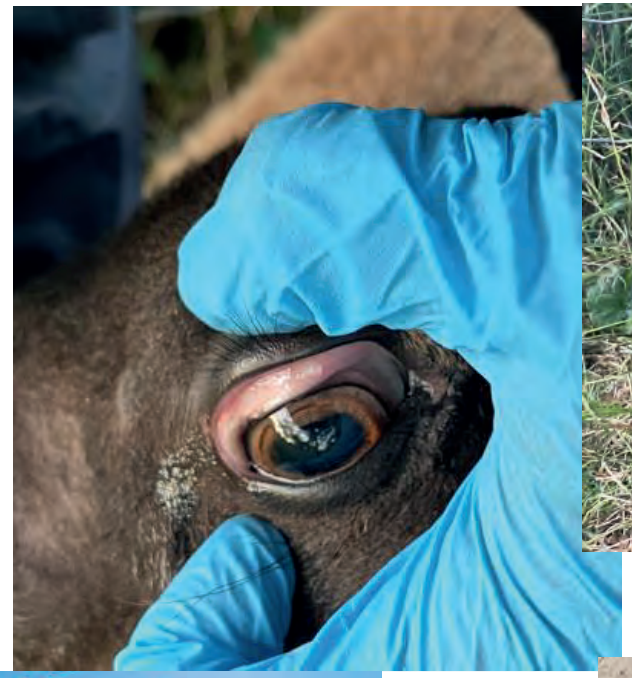
3165	Sheep
2574	Bovine
97	Goats
39	Alpacas
4	Llama
1	Mouflon
1	Water Buffalo
1	Wisent
1	Yak

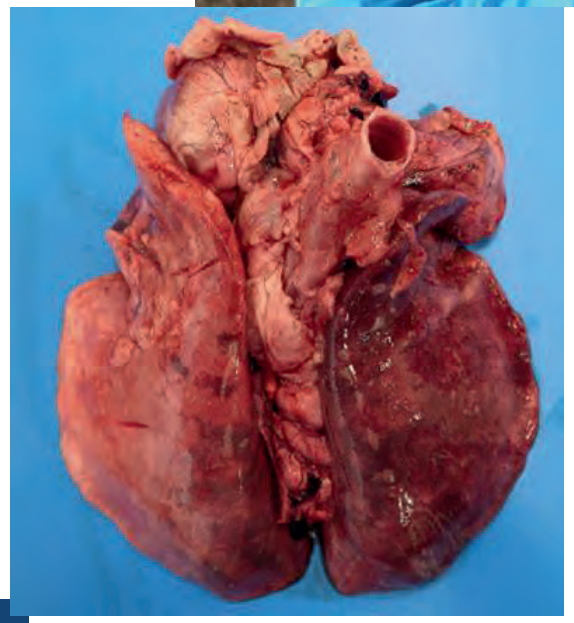
Clinical signs

Clinical signs that were seen:

Sheep

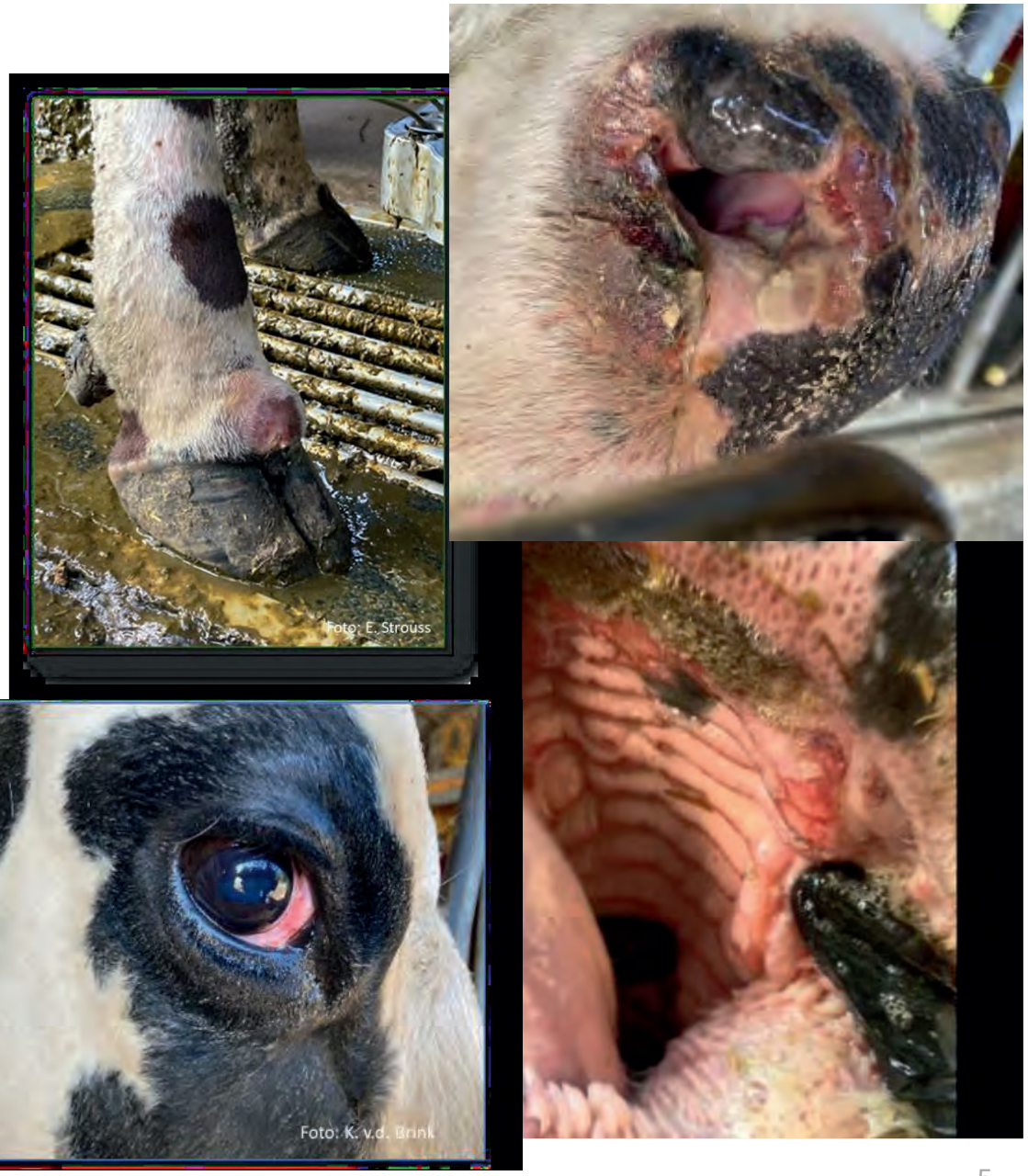
- Fever
- Lesions and/or ulcerations mucous membranes, mouth, tongue/nose/eye
- Excessive salivation and nasal discharge
- Oedema head
- Apathy
- Lameness and tightness
- Pericarditis and detachment hoof
- Vertical transmission
- Lung inflammation and oedema
- Death
- Recovery may take months





Cattle

- Fever
- Milk production drop
- Lesions and/or ulcerations mucous membranes, mouth, tongue/nose/eye
- Excessive salivation and nasal discharge
- Lesions udder and/or teats
- Lameness and tightness
- Red, swollen coronary band
- Swollen legs
- Recovery may take weeks



Vaccination

- Required to control the outbreak
- No vaccine approved for BTV-3

What can we do?

- Facilitate swift approval
- Two routes:
  - Article 25 exceptional circumstances
  - Article 110 allowing use on National level

Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (Text with EEA relevance)

Article 25

Applications in exceptional circumstances

By way of derogation from point (b) of Article 8(1), in exceptional circumstances related to animal or public health, an applicant may submit an application which does not meet all requirements of that point, for which the benefit of the immediate availability on the market of the veterinary medicinal product concerned to the animal or public health outweighs the risk inherent in the fact that certain quality, safety or efficacy documentation has not been provided. In such a case, the applicant shall be required to demonstrate that for objective and verifiable reasons certain quality, safety or efficacy documentation required in accordance with Annex II cannot be provided.

Article 110

Use of immunological veterinary medicinal products

1. The competent authorities may, in accordance with the applicable national law, prohibit the manufacture, import, distribution, possession, sale, supply or use of immunological veterinary medicinal products on their territory or in a part of it if at least one of the following conditions is fulfilled:

(a) the administration of the product to animals may interfere with the implementation of a national programme for the diagnosis, control or eradication of animal disease;

(b) the administration of the product to animals may cause difficulties in certifying the absence of disease in live animals or contamination of foodstuffs or other products obtained from treated animals;

(c) the strains of disease agents to which the product is intended to confer immunity is largely absent in terms of geographic spread from the territory concerned.

2. By way of derogation from Article 106(1) of this Regulation, and in the absence of a veterinary medicinal product as referred to in Article 116 of this Regulation, in the event of an outbreak of a listed disease as referred to in Article 5 of Regulation (EU) 2016/429 or an emerging disease as referred to in Article 6 of that Regulation, a competent authority may allow the use of an immunological veterinary medicinal product not authorised within the Union.

What can we do?

- We facilitated development of an experimental infection model by Wageningen Bioveterinary Research (WBVR)
  BTV-3 in Sheep
- Ready in Q1-2024
- Highly motivated farmers willing to vaccinate


Questions ?