10 years of Bluetongue in the EU

Still Lessons to be learned
And other events

USAHA COMMITTEE ON BLUETONGUE AND RELATED ORBIVIRUSES.
22 October 2013
Outline

- Evolution bluetongue in the EU 2002 – 2013
- Policy and Measures
- Lessons learned
- Vaccine incidents
Bluetongue in the EU

2002 - 2006:
Bluetongue mainly present in Mediterranean area (serotypes 1, 2, 4, 9, 16)

Autumn 2006:
Start of BTV-8 epidemic
Netherlands, Luxembourg, Belgium and Germany
Bluetongue in the EU

2007: BTV-8 spreads southwards towards France

BTV-1 in Spain, Portugal and France

Start of mass vaccination campaign against BTV-1 and BTV-8
Bluetongue in the EU

2009-2012
Due to successful vaccination campaigns:
- BTV8 disappeared
- BTV1 only sporadically in Spain and Portugal

Local circulation of BTV 1, 2, 4, 9 and 16 in Italy, Greece and Cyprus
Bluetongue in the EU

2013
Due to successful vaccination campaigns:

• ONLY BTV1 and BTV4
• ONLY in few areas in the Mediterranean
Which is the EU Policy on BT?

- Movement restrictions
  - Proportionate
  - Sustainable

- Vaccination
  - Mass vaccination
  - Inactivated vaccines

- Surveillance
  - Flexible
  - Fit for purpose
  - Risk based

- Vector control/protection against the vector
  - Feasible (?)
Which are the lessons learnt?

**On vaccination**
- Sometimes is not necessary
- It is an effective for control and even eradication
- Mass vaccination is very expensive (proportionality?, cost-effective?)
- Preventive vaccination in high risk areas can be worthwhile sometimes (cost benefit?)
- It takes time to develop inactivated vaccines (timeliness?)

**On surveillance**
- It is necessary always
- It is complex and expensive (entomological surveillance very expensive)
- Better if informed by risk assessment (risk-based)

**On policy**
- Very difficult disease to handle in the EU context
- Permanent threat
Making the picture more complex

Vaccine incidents
Vaccine incidents: the precedents - 1

BTV 6

- In October 2008, the Netherlands and Germany reported laboratory findings of BTV6 circulation in cattle with very little, if any clinical signs of BT
- The detection was a result of routine surveillance.
- Movement restrictions similar to those applicable in a BT outbreak were applied as a precautionary measure.
- By March 2009, NL and DE presented the results of their investigations:
  - The genetic sequence from the virus isolates indicated high similarity with the BTV6 South African modified live vaccine.
  - This virus might had circulated to a limited extent in the local midge vector population.
  - No BT clinical disease had been observed in the field or under experimental conditions.
- The investigations indicated that no virulent BTV6 virus strain had circulated in NL or DE, while the positive findings were most likely to be ascribed to illegal use of a modified live vaccine.
Vaccine incidents: the precedents - 2

BTV 11

- In November 2008 Belgium reported a similar situation with respect to circulation of bluetongue virus type 11 (BTV11).
- Information on the genetic sequence available indicates a high similarity with the reference strain that was used to produce the South African modified live vaccine for BTV-11.
- No virus was isolated and no clinical signs of bluetongue disease have been observed.
- Precautionary measures with temporary restricted zones were established and lifted as of 5 March 2009,
- After strengthened surveillance was implemented during 2009 no evidence of further virus circulation in the 2009 vector season or if a virulent strain was detected.
Vaccine incidents: the last incident BTV 14

1. Spain detects PCR positive animal from Poland (2011)
   - In December 2011, Spanish authorities detected a PCR positive calf that originated from Poland.
   - The Spanish NRL identified as BTV14 (confirmed by the EU RL, Pirbright)
   - No clinical signs and no indication of circulation of this virus in Spain.
   - Spain informed the Polish authorities of their findings
   - Investigations (both clinical and laboratory) performed in Poland in the region of origin of the calf did not lead to any bluetongue findings and the case was closed as an isolated incident.
Vaccine incidents: the last incident
BTV 14

2. Spain detects PCR positive animal from Lithuania (2012)
- On October 2012, Spain detected again a PCR positive calf that was tested because it was part of a group to be moved from a BT restricted zone to a BT free area
- The calf was born in Lithuania on 1 July 2012 and moved to Spain on 3 August 2012.
- The Spanish NRL confirmed by RT-PCR BTV14
- Spain implemented precautionary measures
- Clinical inspections and sampling did not lead to any other findings.
- Spain concluded that this positive result was a consequence of intra-EU trade from Lithuania and notified findings to Lithuania
Vaccine incidents: the last incident BTV 14

3. Lithuania, Poland, Latvia, Estonia (2012)

-Following notification from Spain, Lithuanian authorities detected 15 bluetongue seropositive animals when they investigated the area of origin of the PCR positive calf.

- In the following days and weeks, also Latvia (16 November), Poland (22 November), and Estonia (22 November) reported the findings of serologically / PCR positive animals

- No clinical signs were observed in any of the 4 countries and although there were many seropositive animals, it was difficult to obtain PCR positive results

- Only Poland and Estonia were able to detect genetic material of BTV by RT-PRC

- The Polish NRL identified BTV14 and the EU RL confirmed the presence of BTV14 in samples from Poland, Latvia and Estonia,
Vaccine incidents: the last incident
BTV 14

4. BTV14 circulating in western regions of Russia (2011-2012)

- In September 2011, BT was circulating in the Smolensk region which is located in the western part of Russia near the Belarus border.
- The Russian NRL (Pokrov) confirmed that there had been a massive outbreak of BTV-14 during last year in the west regions and suggested that BTV14 had been circulating unrecognised already for a long time in cattle and sheep with many seropositive animals that could not be confirmed by PCR or virus isolation.
- No clinical signs typical for BT.
- Characterization of the BTV-RNA showed a very close relationship and a recent common ancestry between the Smolensk isolate and the BTV-14 strain from South Africa (either prototype reference strain or vaccine strain). It is 99.9% similar with the Onderstepoort live vaccine strain.
- There were accusations to the EU's veterinary services of "hiding the discovery of bluetongue serotype 14 for a long time"
5. OUR CONCLUSIONS of the BTV14 vaccine incident

- It is likely that the laboratory findings in the north-eastern part of the EU are related to the circulation of the vaccine like BTV14 strain which is also present in Russia.

- It will be difficult to determine whether this is due to the illegal use of live vaccines in the EU, or vaccinations applied on Russian territory.

- The outcomes of the sequencing performed by the EURL are necessary to confirm if it really a vaccine strain and not the "wild" virus.

- As regards measures to be taken, the precedent set in 2009 for the Netherlands, Germany (both BTV6) and Belgium (BTV11) was considered.

- Initially, as a safeguard measure, all affected Member States apply restrictive measures as described in EU legislation.

- Should the outcome of analyses performed by the EU reference lab show that it is indeed a vaccine related incident, restrictions on movements of animals are no longer necessary and circulation of vaccine strain is expected to gradually disappear.
Vaccine incidents: the lessons learnt

- **It should be considered that:**
  - Live attenuated vaccines could be ordered on line to South Africa (Ondersteport)
  - The formulation of the Ondersteport vaccine:
    - Bottle A: 1, 4, 6, 12 and 14
    - Bottle B: 3, 8, 9, 10 and 11
    - Bottle C: 2, 5, 7, 13 and 19

- **The measures to put in place to manage a "BT-vaccine incident" could be largely based on the rules to control "BT outbreaks" but cannot be the same**
  - Proportionality
  - Sustainability
Conclusions

- *Bluetongue is a problem with many dimensions:*
  
  Veterinary
  Scientific
  Environmental, entomological
  Climatic
  Economic
  Trade
  Political
  **Fraud**
  Agro-terrorism...

- *Bluetongue is a real disease that is there and will continue to be there...*

- *Vaccine incidents and other sources of "background noise" distort even more the blurry picture of BT*
Thanks