Ministero della Salute

**Dipartimento per la Sanità Pubblica Veterinaria,
la Nutrizione e la Sicurezza degli Alimenti**

Direzione Generale della Sanità Animale e del Farmaco Veteriario

The Italian experience on bluetongue vaccination

Dr. Gaetana Ferri

Conference on "Vaccination strategy against bluetongue"

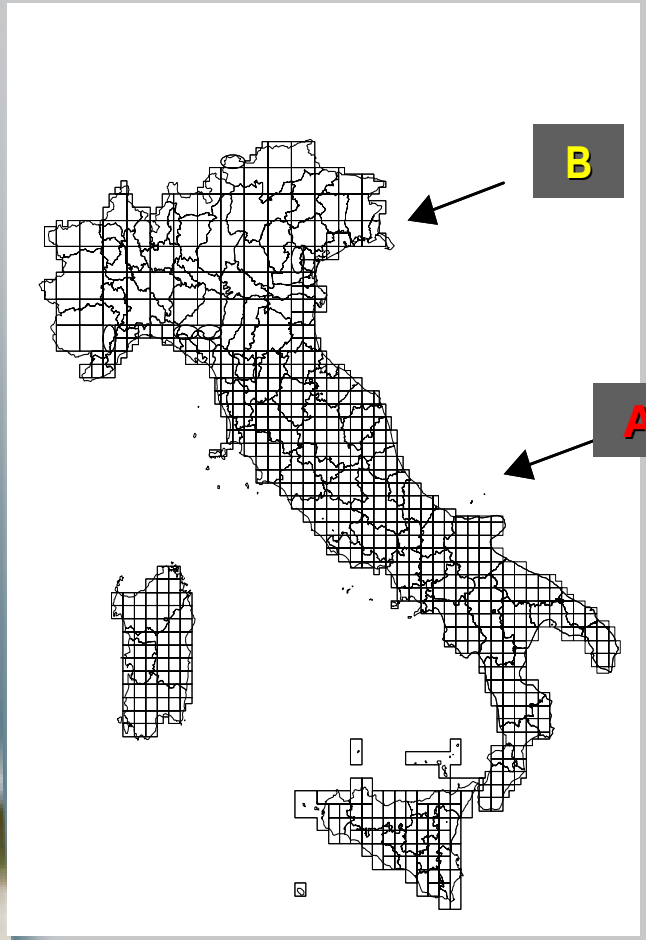
Brussels, Charlemagne building - 16 January 2008

BT Italian surveillance system

- Clinical surveillance
- Serological surveillance
- Entomological surveillance

Serological surveillance

The Italian sentinel network (since 2001)



- **B - LOW RISK**
  - 1600 km² each cell
  - 148 sentinel animals
  - 8-10 herds
  - Period
    - ✓Every 30 dd

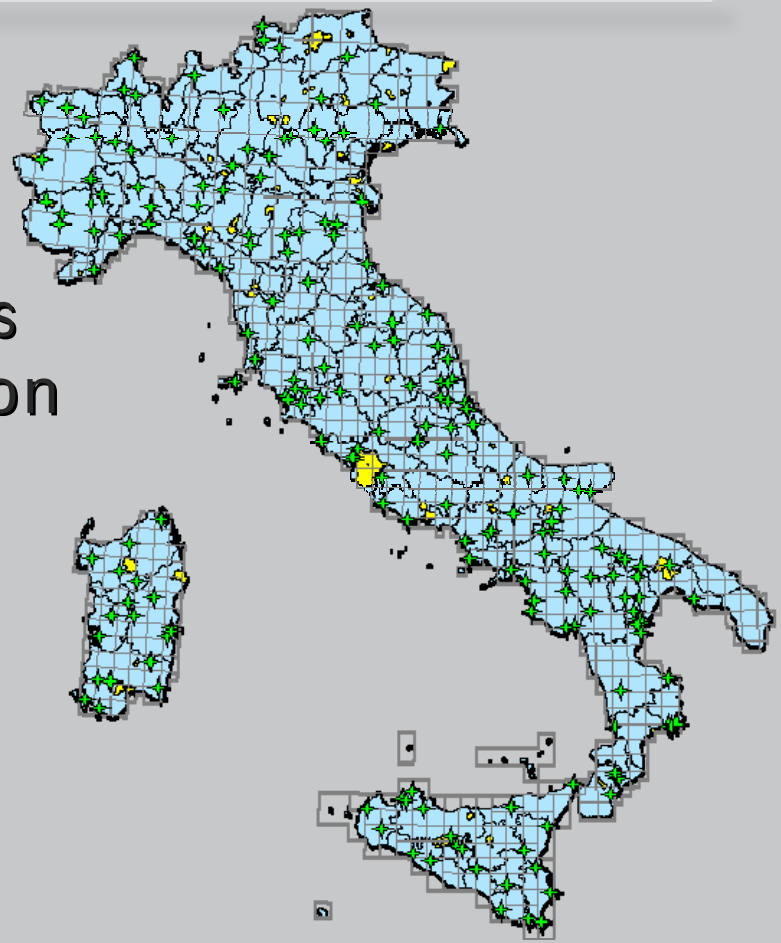
- **A – HIGH RISK**
  - 400 km² each cell
  - 58 sentinel animals
  - 5-8 herds
  - Period
    - ✓Every 30 dd

Entomological surveillance

The Italian entomological network (since 2001)

- Use of black-light traps for *Culicoides* detection

More than 250 black-light traps all over Italy (weekly)



Italian BT epidemiological surveillance system

2 relevant plans:

- **Serological surveillance plan:**
  - To detect or exclude virus circulation in areas where vaccination is carried out, in restricted areas and in those with a high risk of infection and in rest of Italy
  - to verify the vaccination coverage in vaccinated population
- **Entomological plan:**
  - to verify vector's geographical distribution, defining the subsequent risk maps

AIMS:

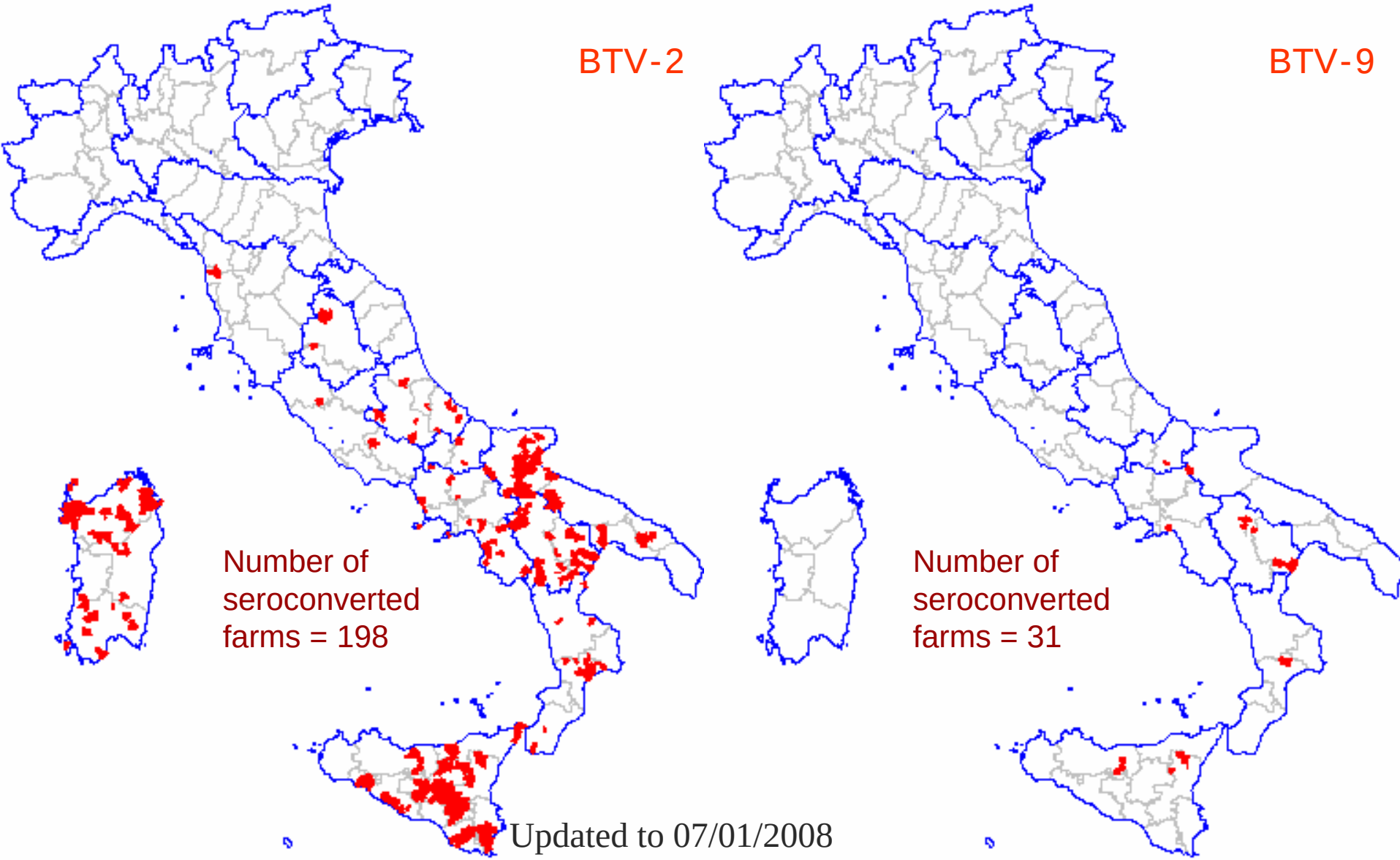
- To monitor animal's health status in areas free from infection
- To identify seasonally free areas
- To evaluate the sanitary status of susceptible population

Brief overview of BT epidemiological situation in 2006 and 2007

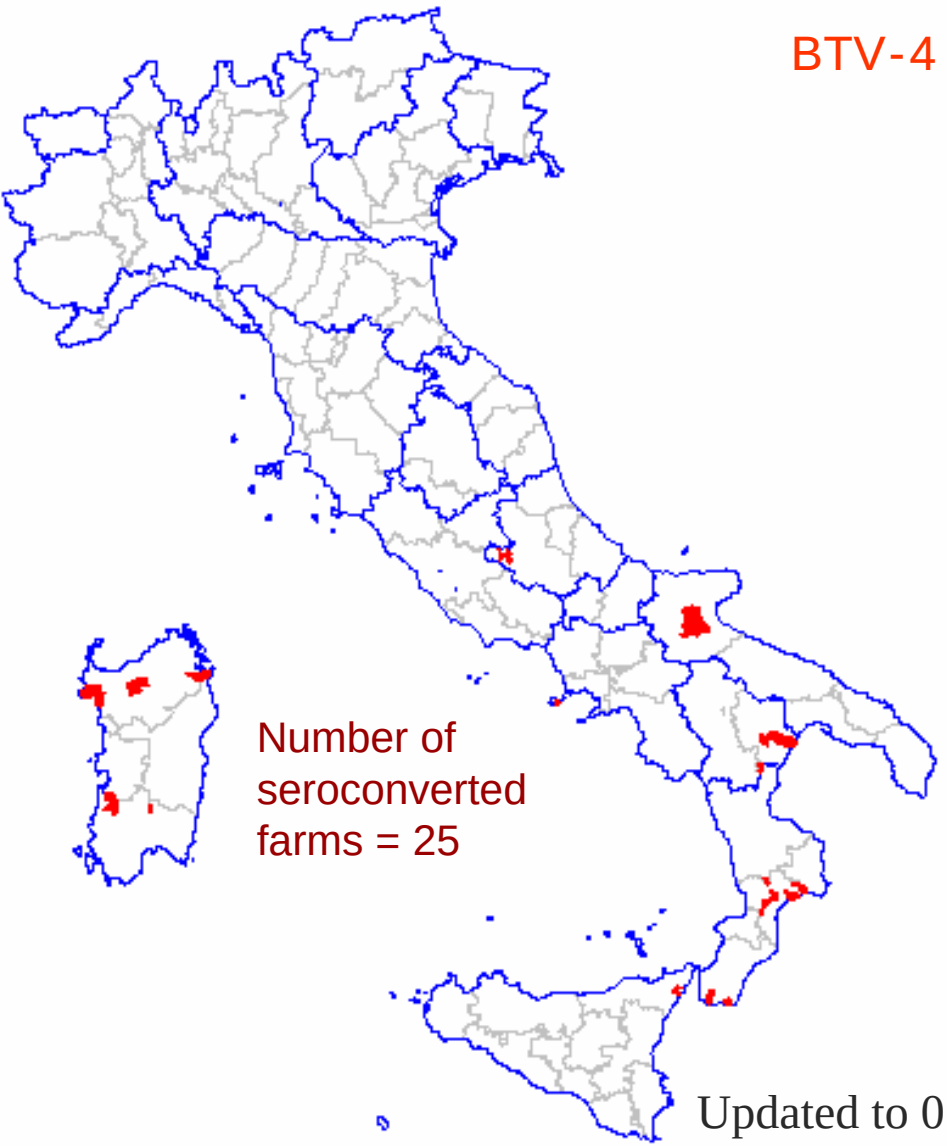
BT virus circulation

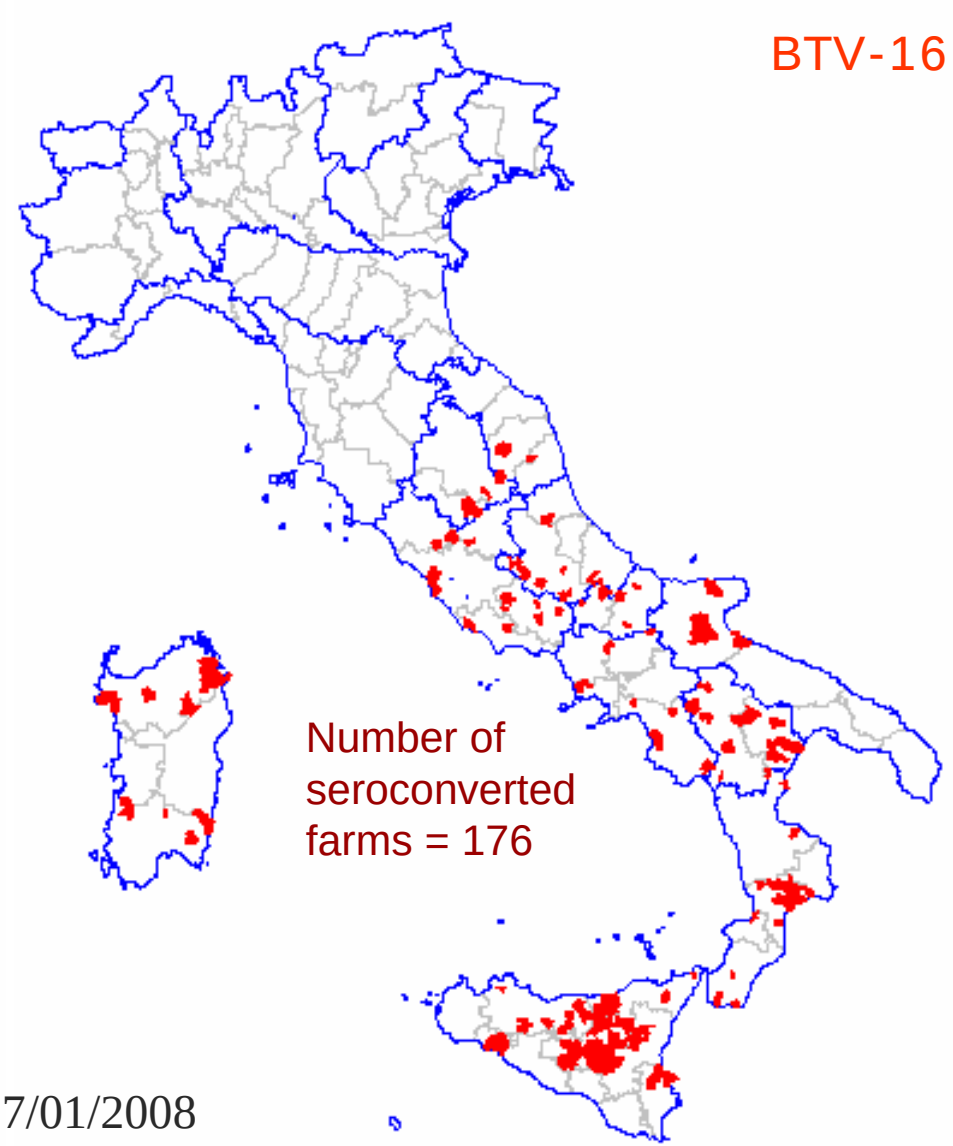
(seroconversion of sentinel animals)

Seroconversion of sentinel animals in 2006



Seroconversion of sentinel animals in 2006





Updated to 07/01/2008

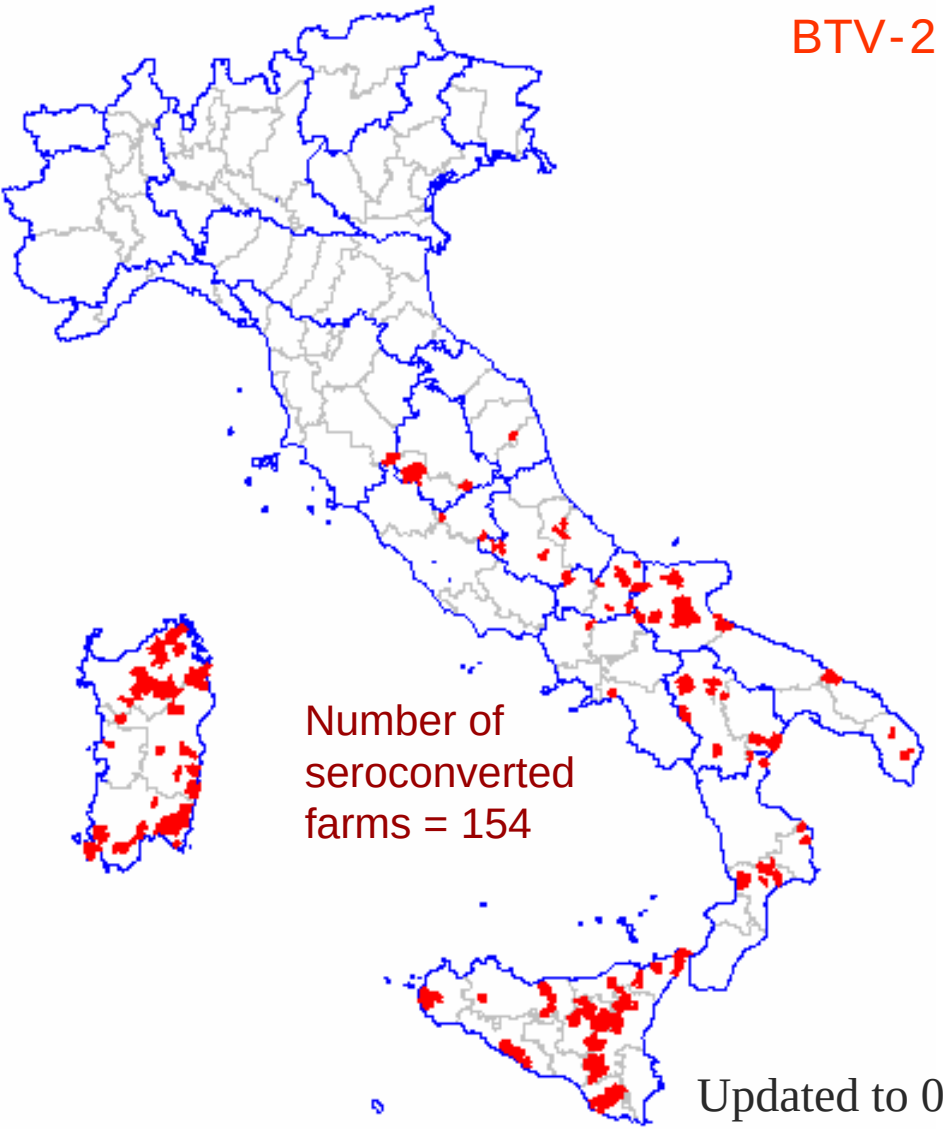
Seroconversion of sentinel animals in 2006

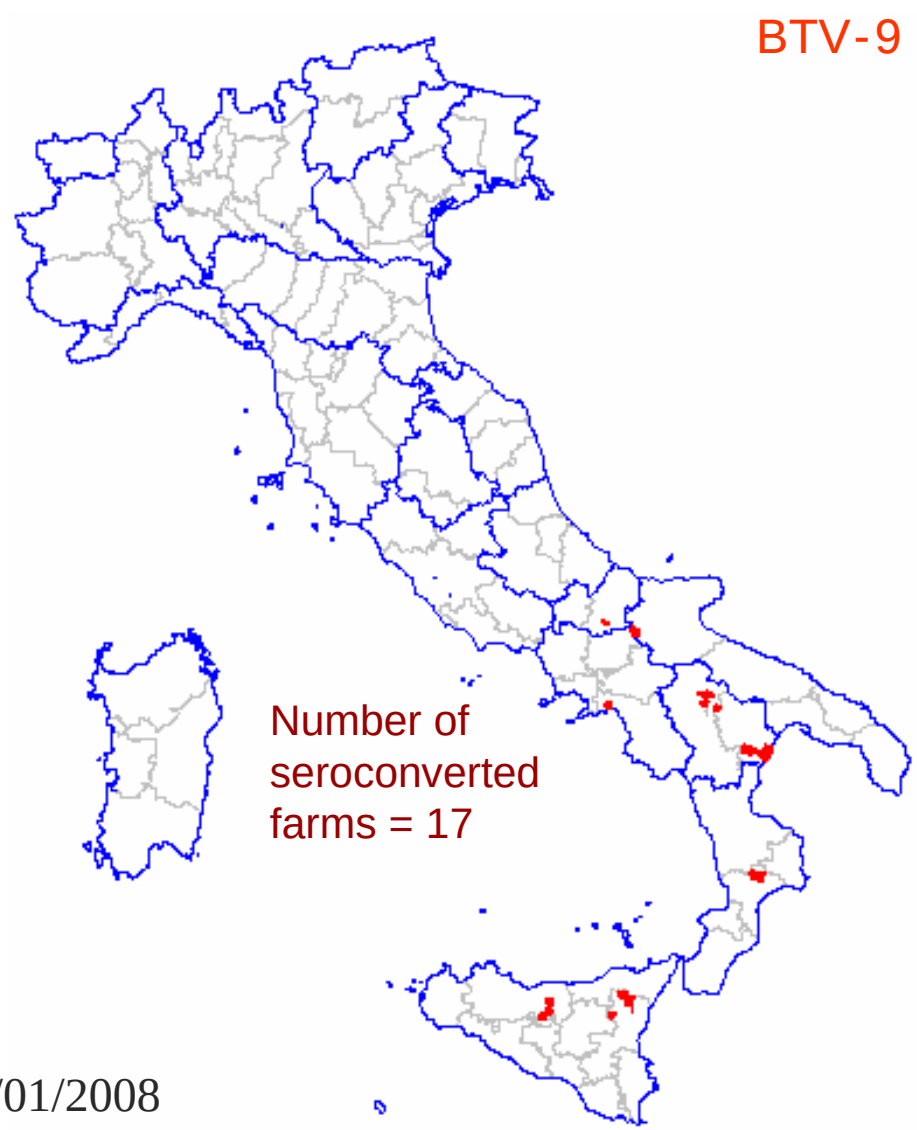
BTV-1

Number of seroconverted farms = 1

Updated to 07/01/2008

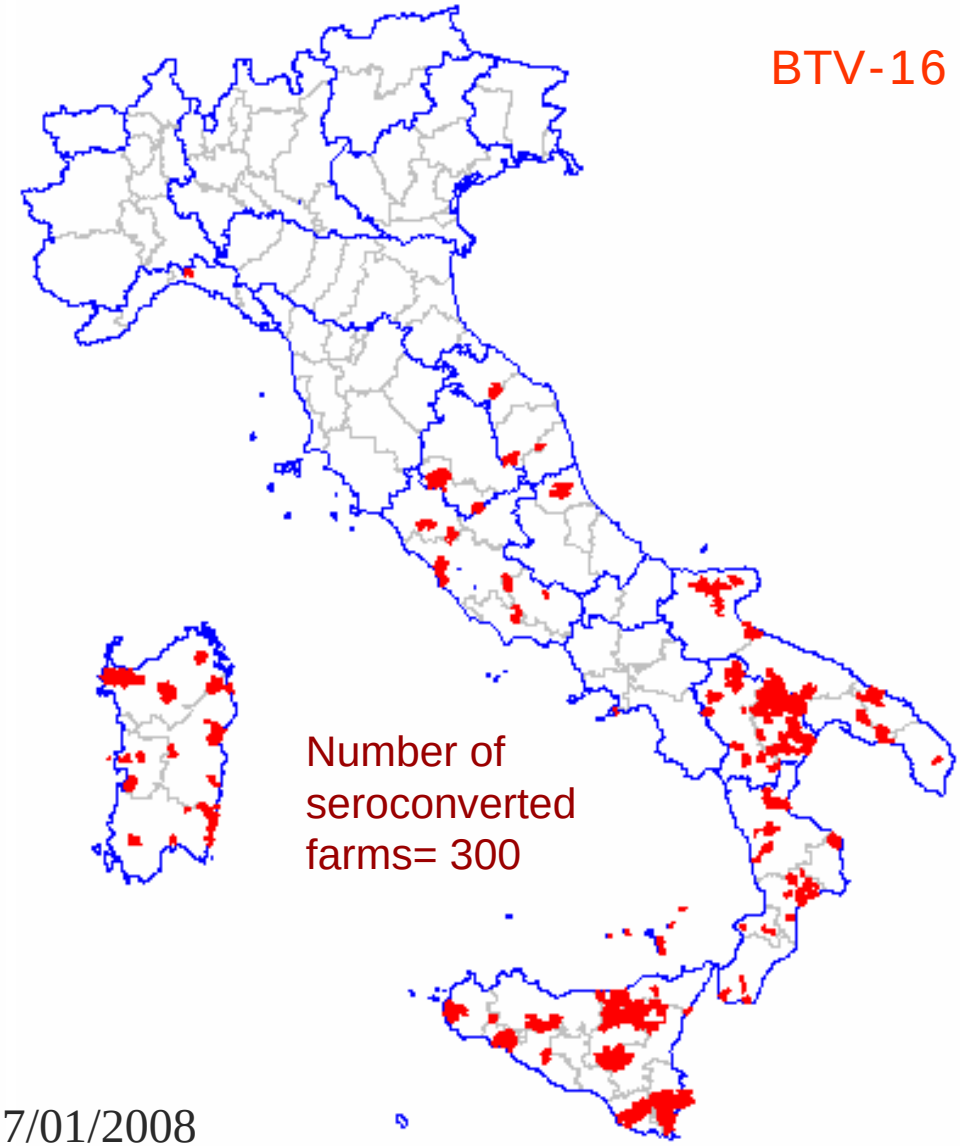
Seroconversion of sentinel animals in 2007





Updated to 07/01/2008

Seroconversion of sentinel animals in 2007



Updated to 07/01/2008

Seroconversion of sentinel animals in 2007

BTV-1

Number of seroconverted farms = 20

Updated to 07/01/2008

The Italian experience on bluetongue vaccination

Bluetongue impact

- The incursion of BTV into the Mediterranean Basin is causing great economic losses, partly due to the disease itself, but mostly linked to the **total ban of ruminant trade** between the infected and non infected areas

Vaccination

- WHY
- WHICH vaccine
- WHEN

Vaccine combinations used in Italy

Years	Modified Live Vaccine			Inactivated Vaccine		
	Serotypes	No. of vaccinated sheep and goats	No. of vaccinated cattle	Serotypes	No. of vaccinated sheep and goats	No. of vaccinated cattle
2002	BTV2 BTV2-BTV9	4 074 574 1 976 397	396 165 896 818			
2003	BTV2 BTV2-BTV9	4 431 356 1 568 895	483 181 848 928			
2004	BTV2 BTV2-BTV9 BTV2-BTV4 BTV2-BTV4-BTV16 BTV2-BTV4-BTV9- BTV16	62 339 60 466 257 899 990 275 329 095	28 207 77 823 47 666 40 571 107 456			
2005	BTV2 BTV2-BTV4 BTV2-BTV4-BTV9	51 896 82 081 274 477	13 373 35 631 62 104	BTV2-BTV4	-	21 627
2006	BTV2 BTV2-BTV4 BTV2-BTV4-BTV9	4 219 44 035 51 107	27 26 227 16 038	BTV2-BTV4	-	36 948
2007	BTV1 BTV2-BTV4 BTV2-BTV4-BTV9	1 181 223 13 911 13 773	3 729 906 2 793	BTV2-BTV4	2 544	151 607

Vaccination WHY

Vaccination strategies were chosen to:

- limit direct losses,
- reduce virus circulation,
- permit safe animal trade.

VACCINATION IS ONE THE MOST EFFECTIVE PROPHYLACTIC MEASURE ABLE TO REDUCE BT IMPACTS

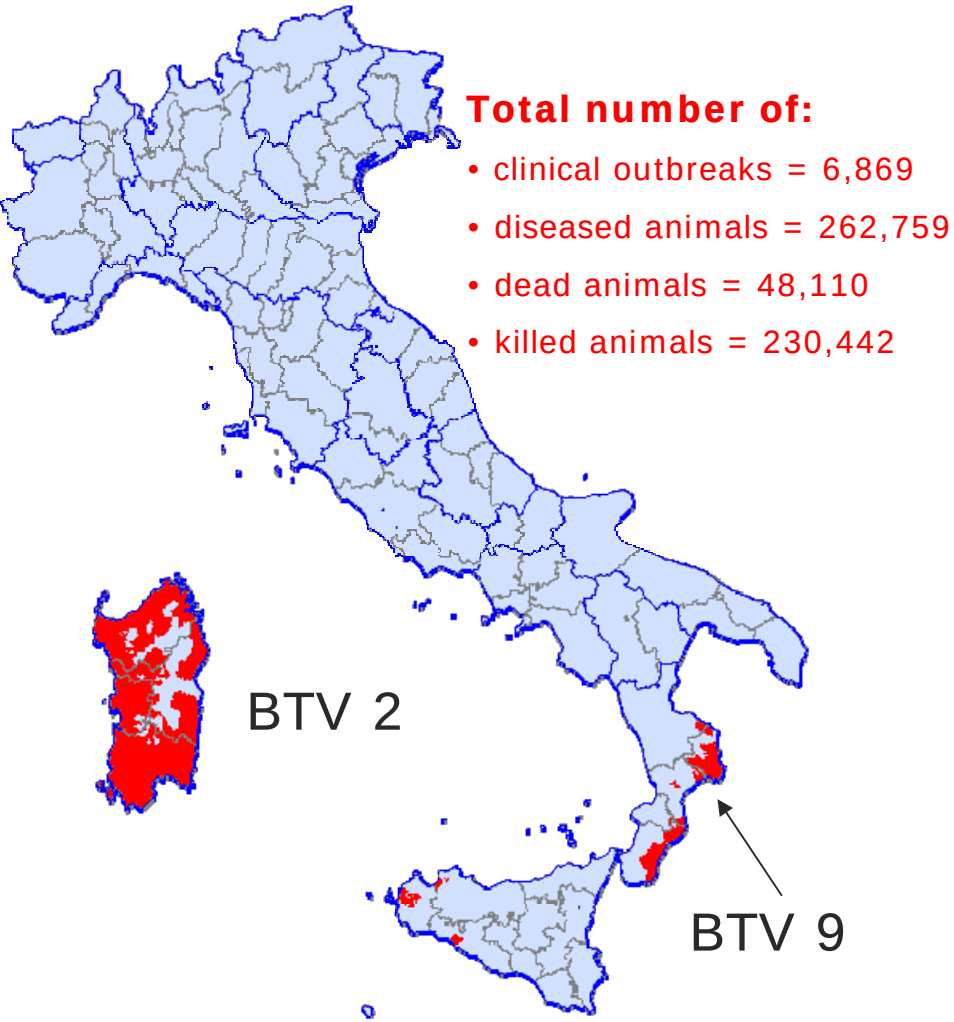
Limitation of direct losses

- Vaccination of susceptible species protects animals from the infection due to the same serotype(s)

CLINICAL OUTBREAKS

2000 – 2001

(15/08/00-14/05/01)

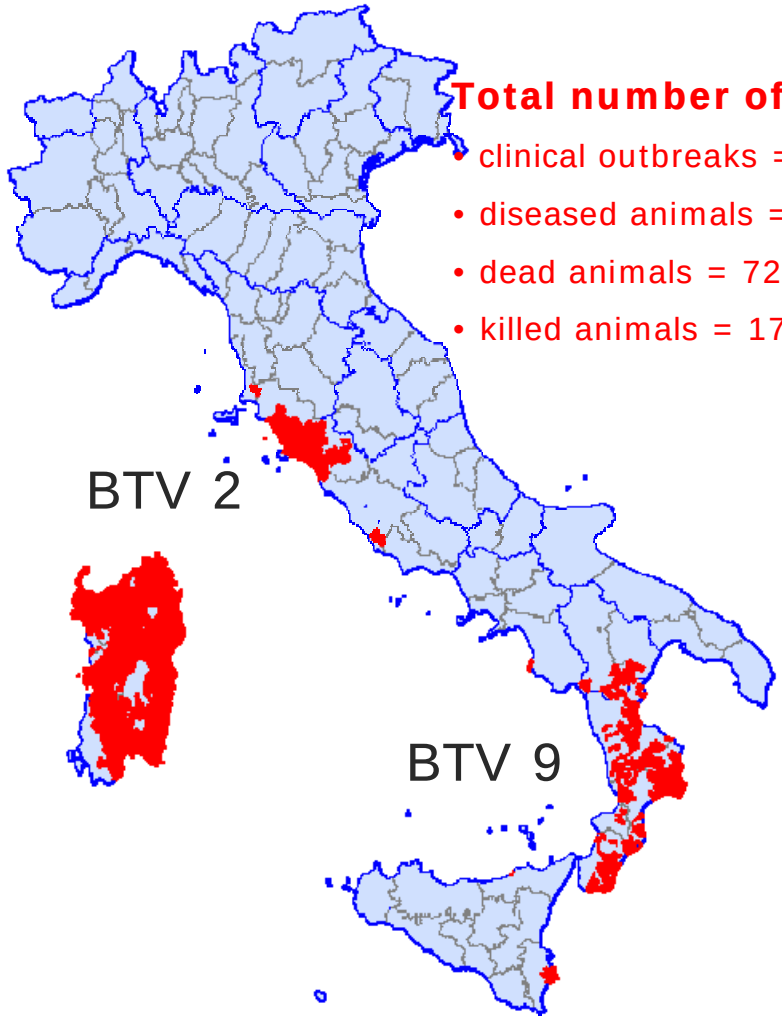


Total number of:

- clinical outbreaks = 6,869
- diseased animals = 262,759
- dead animals = 48,110
- killed animals = 230,442

2001 – 2002

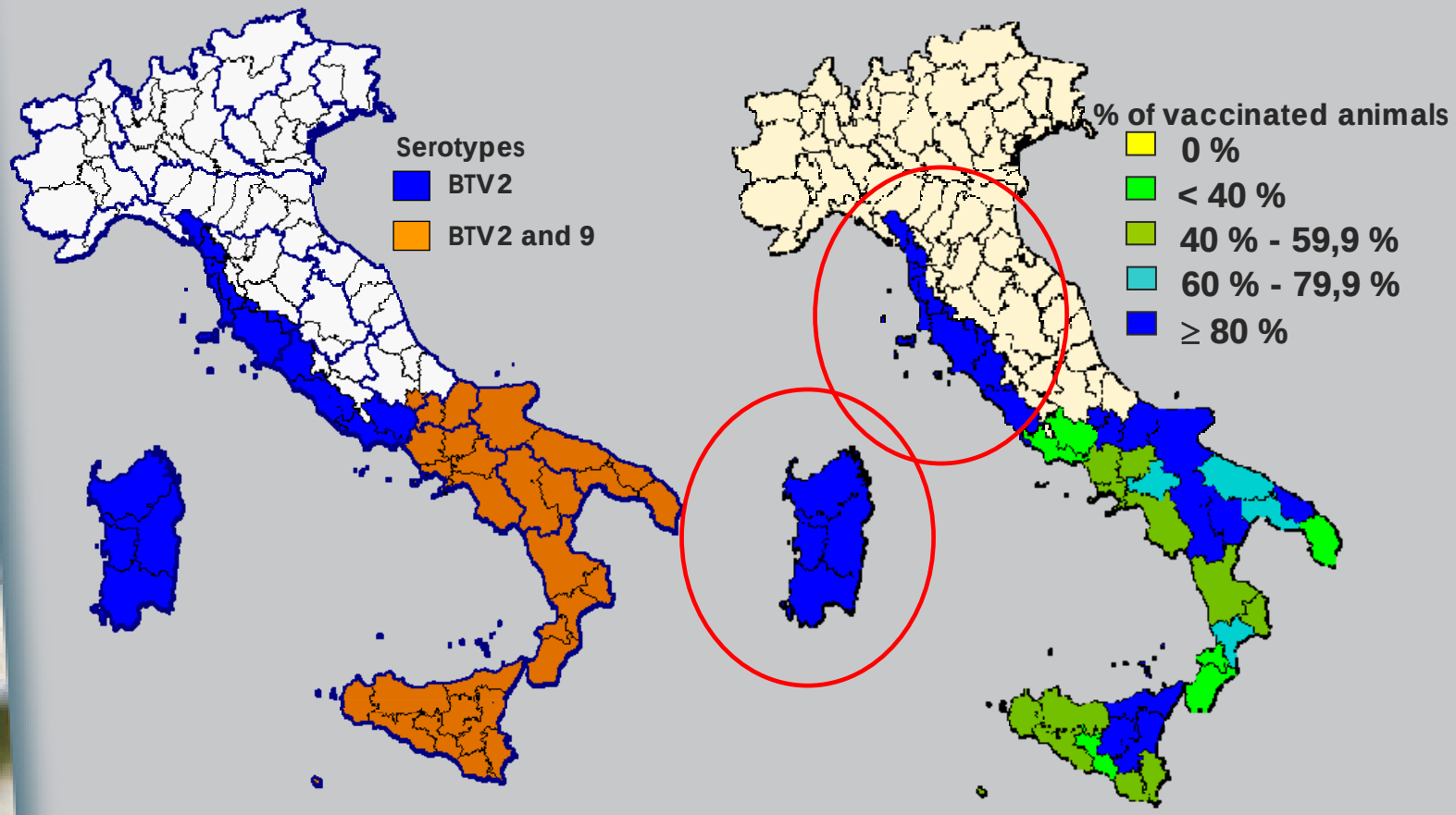
(15/05/01-14/04/02)



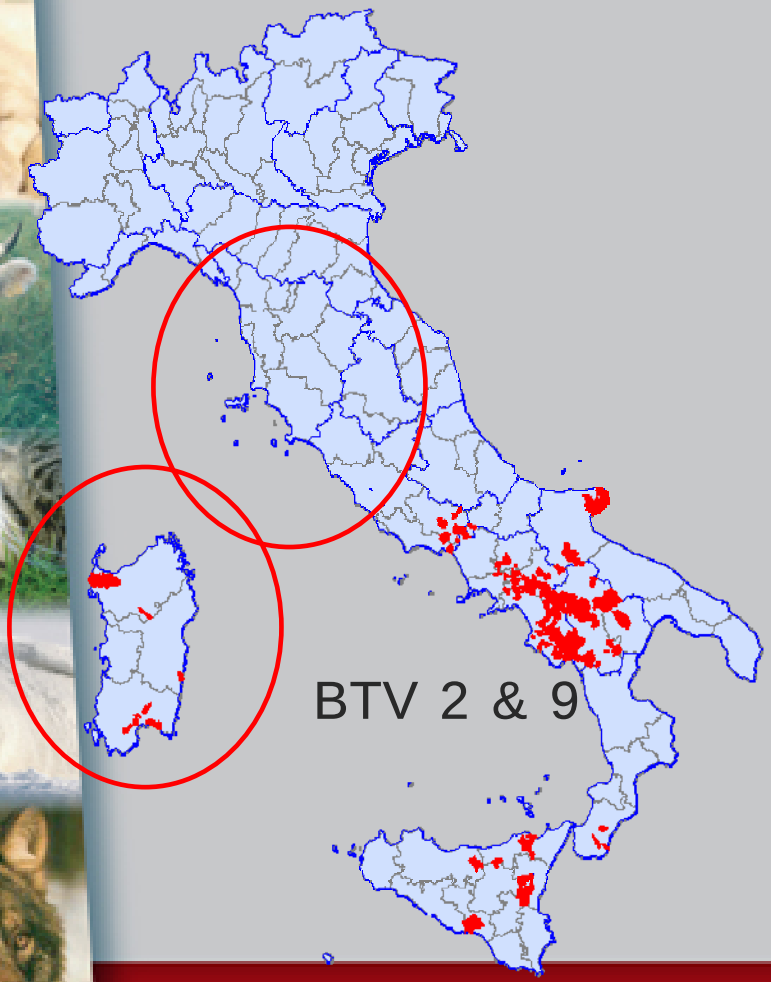
Total number of:

- clinical outbreaks = 6,807
- diseased animals = 250,662
- dead animals = 72,973
- killed animals = 170,429

1st VACCINATION CAMPAIGN (YEAR 2002)



CLINICAL OUTBREAKS



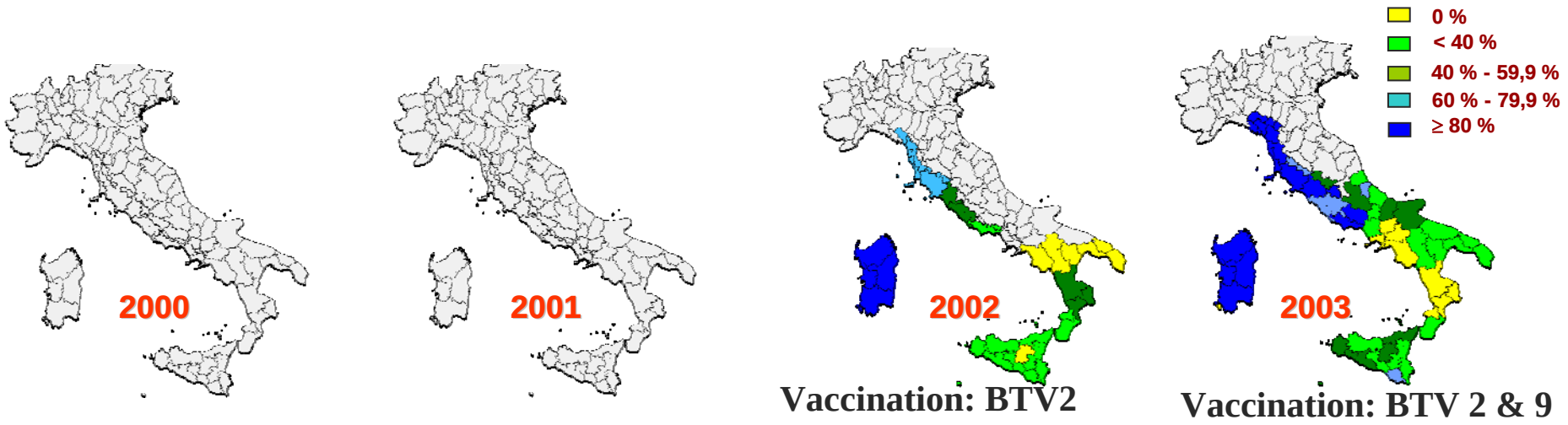
2002 – 2003

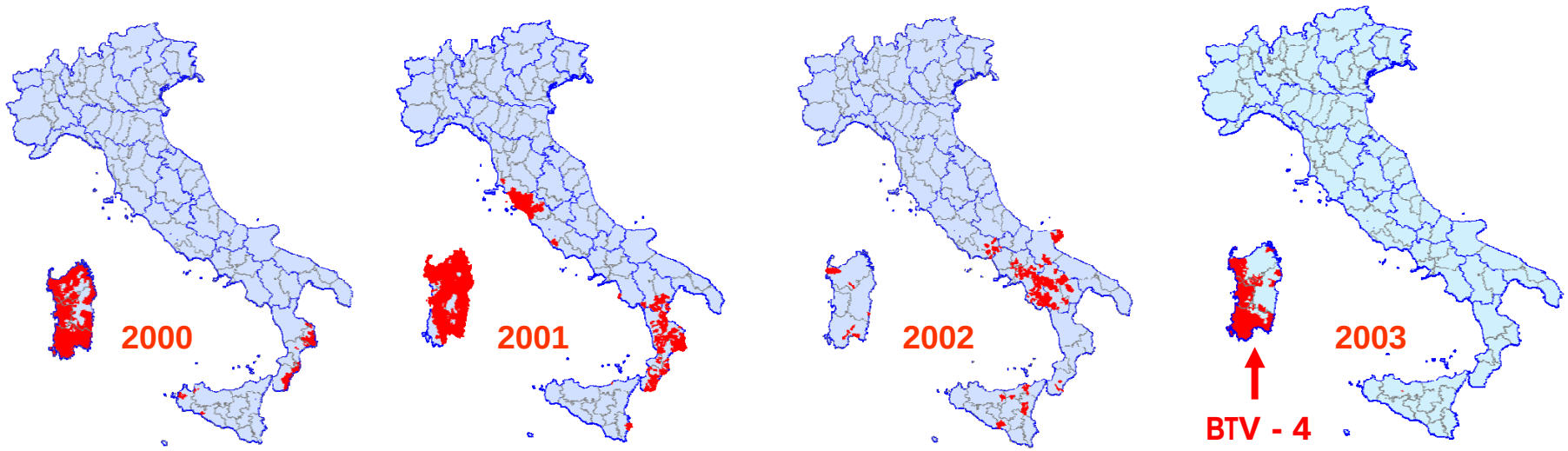
(15/04/02-14/04/03)

Total number of:

- clinical outbreaks = 427
- diseased animals = 3,531
- dead animals = 2,953
- killed animals = 305

Vaccination & outbreaks



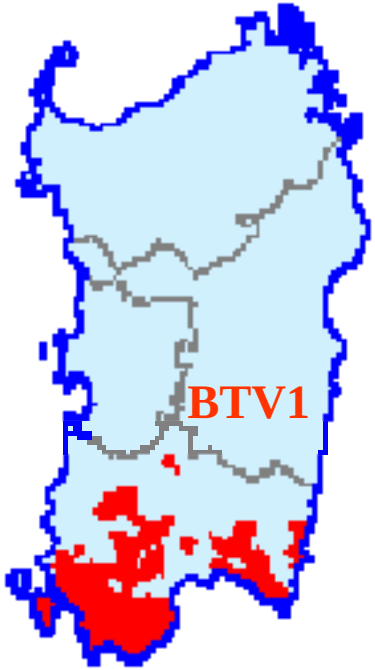


Reduction of virus circulation

- Vaccination prevents the development of viraemia and interrupts the transmission chain
- Mass-vaccination of susceptible animals is able to reduce the probability of infection spread from the infected areas
- Mid-long term objective: reduction of infected areas

Reduction of virus circulation

- To achieve this objective, the vast majority of susceptible animals must be vaccinated
- According to Italian experience, where >80% of susceptible population was vaccinated, the virus circulation decreased significantly



BTV1 clinical outbreaks - 2006

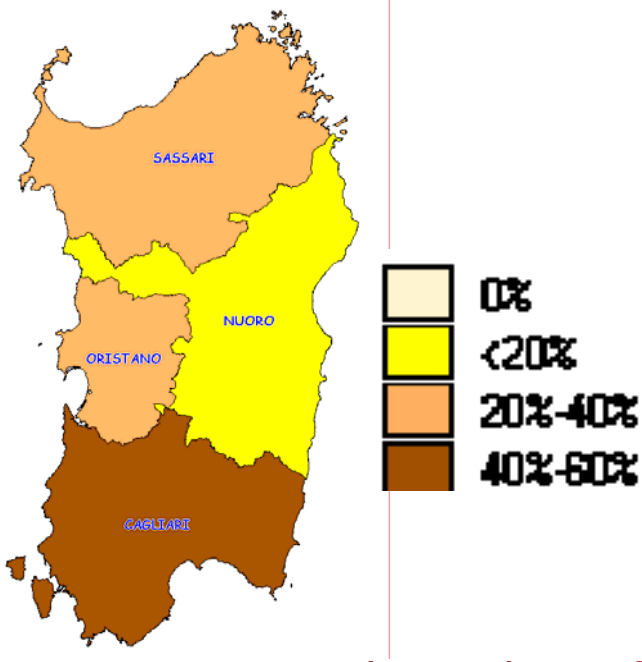
- **No. clinical outbreaks = 237**
- **No. diseased animals = 4855**
- **No. dead animals = 4408**
- **Morbidity rate = 8.3%**
- **Mortality rate = 7.5%**
- **Serotype involved: BTV1**

BTV1 - clinical outbreaks - 2007

No BTV1 clinical outbreaks were recorded during 2007

BTV1 – no vaccination was performed in year 2006

BTV1 - vaccination coverage year 2007



BTV1 – total number of vaccinated animals:

- Sheep and goats = 1,181,223
- Cattle = 3,836

Use of BTV1 live modified vaccine in Italy

- Arrival of a new BTV serotype in Italy (BTV1) in October 2006
- BTV1 caused severe clinical outbreaks in the naive Sardinian population of sheep:
  - 237 clinical outbreaks (since Oct 2006)
  - 4,855 diseased animals
  - 4,408 dead animals
- Italian Ministry of Health, on the basis of Italian (D.Lvo 119 del 27/01/1992) regulation and in order to prevent the spread of BTV1 in Italy, decided to use BTV1 live modified vaccine.
- Therefore, experimental studies were performed and agreed on the use of the vaccine for field vaccination

BTV1 live modified vaccine in Italy – experimental studies

- SHEEP
  - Safety
    - Side effects
    - Viraemia assessment
    - Reversion to virulence
  - Efficacy
    - Immunogenicity
    - Challenge
  - Haematological parameters

BTV1 live modified vaccine in Italy – experimental studies

- BOVINE
  - Safety test
    - Side effects
    - Viraemia assessment
  - Efficacy
    - Immunogenicity
    - Challenge
  - Haematological parameters

Better delimitation of areas at risk

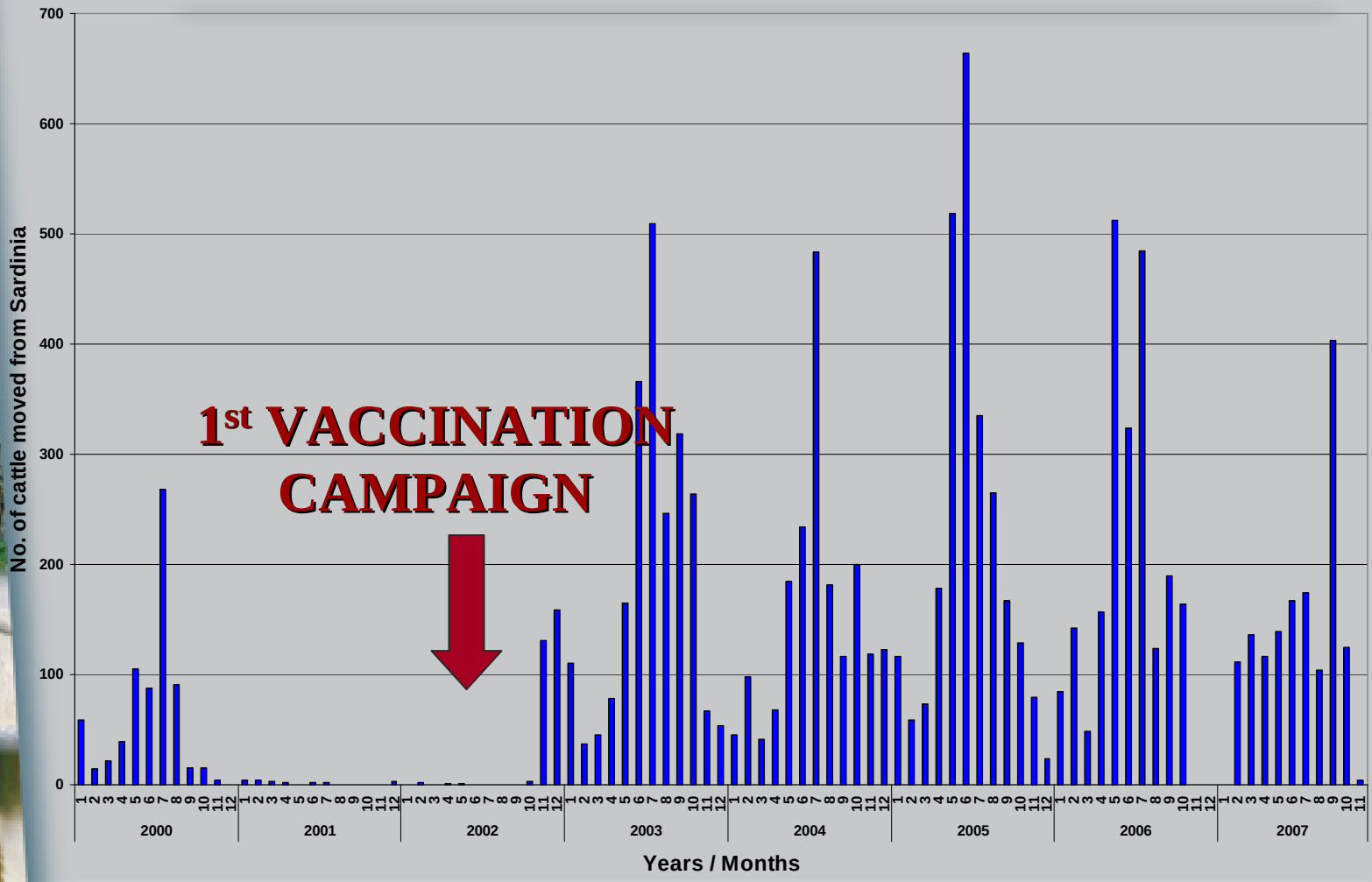
- Vaccination, combined with a very precise and fine surveillance network, permitted to refine the infected and at risk areas in Italy, avoiding the literal application of a 100 km (ZP) and 150 km (ZS) approach

Protection and surveillance zones in Italy

Literal adoption of Directive 2000/75/EC

Areas with viral circulation From 2000 to 2007

Cattle movements from Sardinia



Vaccination - WHICH vaccine

- Inactivated vaccines
  - Actually available for BTV2 and BTV4
  - Development of BTV8
- Modified live vaccines (MLV)
  - Most of the serotypes

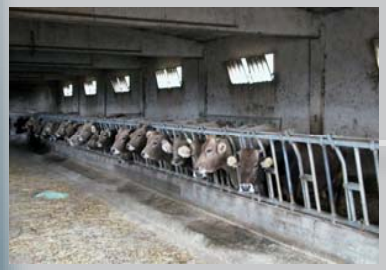
MLV side-effects
EFFECTS ON PREGNANCY

- Experimental studies in cattle with BTV-2 or BTV-2&9 MLV: no adverse effects on pregnancy were observed
- Field data
  - Italy: abortions observed in 0.42% of sheep and 0.18% of cows vaccinated with MLV BTV-2
  - Italy: abortions observed in 0.53 % of sheep and 0.14% of cows vaccinated with MLV BTV-2&9

MLV side-effects
EFFECTS ON MILK PRODUCTION

- BTV-2 or BTV-2&4 MLV
  - Experimental studies (Italy – France): no significant effects on the quantity and quality of milk production in vaccinated animals
  - Field data (Italy): data between 1999-2002 on the quantity and quality of milk of 18,000 cows, demonstrated that the BTV-2 MLV vaccination had no effect on the quality and the quantity of the milk

MLV side-effects
EFFECTS ON MILK PRODUCTION



- BTV-2&9 MLV
  - SHEEP (Italy): transient reduction of 20-30% in milk production. No effects on the quality of milk. This effect is due mainly to the transient perturbation of health induced by vaccination performed in field conditions and not to any direct virus interference on the mammary tissue
  - CATTLE (Italy): no significant effects

Vaccination WHEN

- During WINTER period, to immunize susceptible population before the following epidemic season
- MLV vaccines shall be used during the winter period to avoid the risk of virus dispersal by vectors (usually limited in time and space, due to the limited viraemia)


Thank you for the attention