Vaccination against bluetongue in Spain

June 2014

Blue Tongue (BT) was first detected in Spain among 1956 and 1960, when BT virus (BTV) serotype 10 was detected on the south west of the territory. Once this event was eradicated, no other outbreaks where detected in Spain until October 2000, when a serotype 2 outbreak was detected on the Balearic Islands. Since then, circulation of other BTV serotypes have been detected firstly in Balearic Islands (BTV-4 in 2003) and later in mainland (BTV-1, BTV-4 and BTV-8). Different measures have been adopted during last years to control and eradicate the disease, and currently only two serotypes are still present in the mainland: BTV-1 and BTV-4.

The vaccination against bluetongue has been one of the main tools to control the epidemic waves of different serotypes of the disease in Spain on the last years. The objective of this document is to summarize the evolution of the vaccination policy on the last years and to gather the data available.

The common goals of the consecutive vaccination campaigns were the reduction of the viral circulation, reduction of clinical signs or deaths in ovine, allowing movements to free zone and as final goal, the eradication of the disease.

The scope of the vaccination program has always been all the ovine and bovine population older than 3 months. Vaccination is not compulsory in caprine, nevertheless a big percentage of animals were vaccinated in order to prevent the disease and to facilitate the movements of this species.

The cost of the vaccine was initially supported by the Ministry of Agriculture (co-financed by Commission), and the cost of the vaccination by the Autonomous regions, until July 2011 when vaccination became voluntary where the cost of the vaccine was supported by the owner.

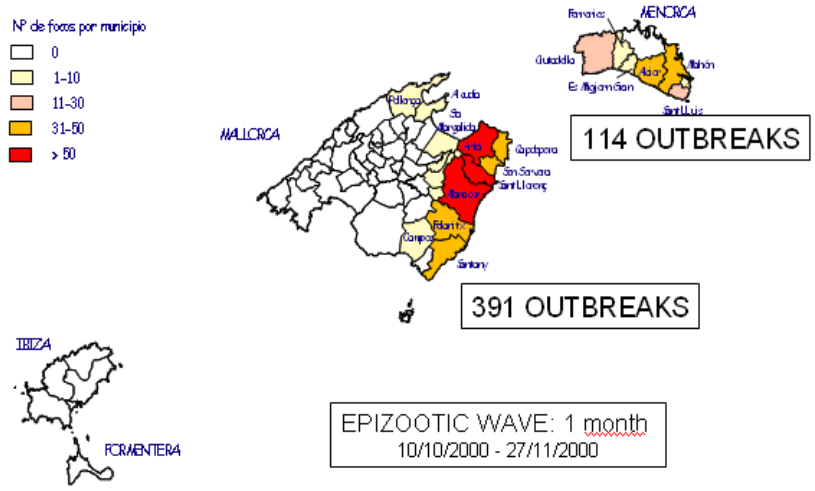
On the compulsory vaccination program, the vaccine could be applied by official veterinary services or by authorised veterinaries, depending on the Autonomous region, but always under official control. Voluntary vaccination programs have been under the control of the private vet of the holding. On this case, the veterinary that has performed the vaccination is obliged to notify the commercial name, serotype and date of vaccination to the competent authority on the following 7 days. These data are recorded on the national database of individual identification of animals, with the exception of ovine that don´t have to be individually identified compulsorily, where the vaccination is recorded on the register book of the holding.

The vaccination policy was adapted to the different epidemiological scenes in Spain on the lasts years.

1-Balearic Islands event

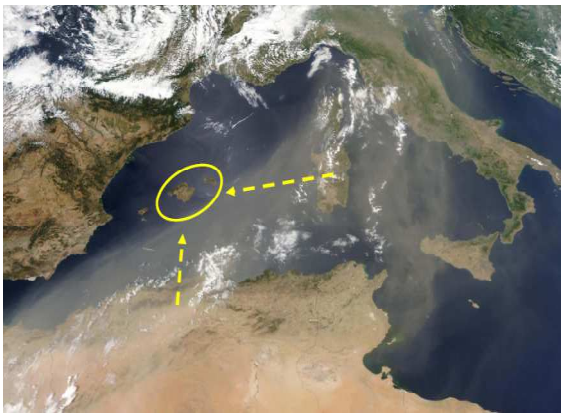
a) Background

Viral circulation of BTV serotype 2 was detected in October 2000 on the Balearic Islands, affecting to Menorca and west area of Mallorca Island.



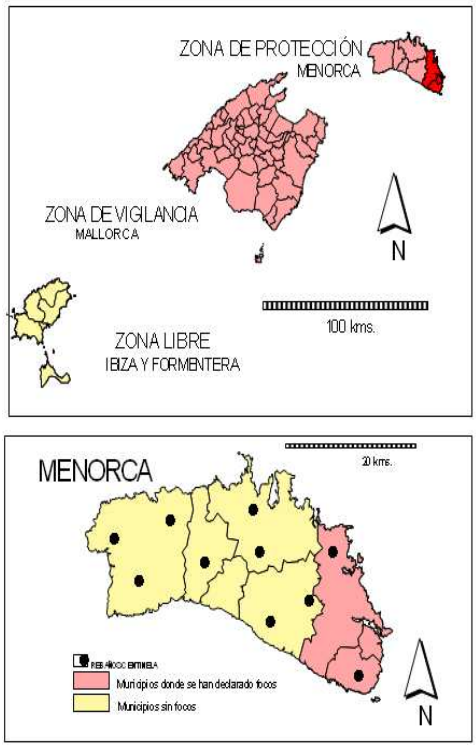
Map 1: Bluetongue in Balearic Islands 2000

These outbreaks were initially epidemiologically linked with virus circulation in Sardinia, Tunis and Algeria had been notified on this territory on the previous months and the origin was likely to be the transport of infected mosquitoes through the wind.



The disease was considered eradicated in 2003, after two years without virus circulation, but in October 2003, a serotype 4 outbreak was confirmed in Menorca (Balearic Islands) once again linked with the transport of infected vectors from the

north of Africa, where this serotype had been confirmed on the previous months. After two months of epidemic wave, 16 outbreaks were confirmed on the southeast of the island. Balearic Islands were again declared officially free at the beginning of 2006.



Map 2: Bluetongue in Balearic Islands 2003

b) Measures taken

- Movement restriction of sensitive species inside the islands and to the peninsula
- Vaccination of ovines
    - 2000 live attenuated vaccines against serotype 2 (Onderstepoort – South Africa). Between November 2000 and May 2001, 320.000 sheep were vaccinated.
    - 2003 live attenuated vaccine against serotype 4 (Onderstepoort – South Africa). Between October 2003 and March 2004, 339.000 animals were vaccinated.
- Thorough epidemiological surveillance not only in Balearic Islands but also on the peninsula.

2- BT SITUATION IN SPAIN 2004 TO 2006: Serotype 4

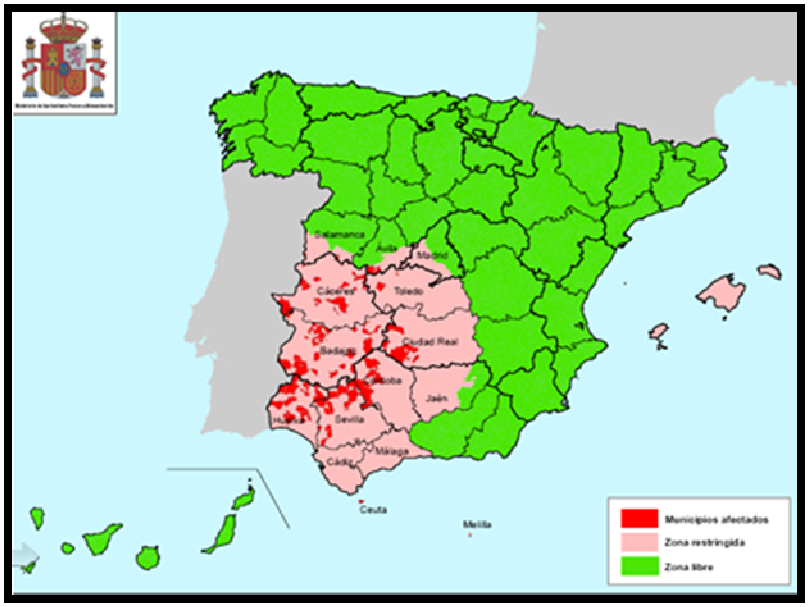
a) Background

Bluetongue was first detected on the mainland in 2004, with a serotype 4 outbreak in Cádiz (South of Spain), whose origin was probably the transport of infected vectors through the wind from the north of Africa.

Map 3: First outbreak of serotype 4 in Cádiz

Onwards, new outbreaks occurred in different provinces, with several autonomous communities affected.

Map 4: Serotype 4 affected territories in 2004.



Map 4: Serotype 4 affected territories in 2005

Map 6: Serotype 4 affected territories in 2006

b) Measures taken

- Control of susceptible species movements by the establishment of two areas, restricted zone and free zone.
- Epidemiological surveillance.
- Vaccination
    - 2004-First semester 2006: Ovine population with attenuated vaccine BTV-4 Onderstepoort – South Africa

- From 2006 bovine and ovine population with inactivated vaccine.

In January 2005, a meeting of Central Veterinary Services with the industry of vaccine production took place. Five laboratories attended the request of development of BTV-4 inactivated vaccine for ovine and bovine: Merial, CZ, Calier, SYVA and Fort Dodge. Efficacy trials were performed in different Spanish BSL-3 animal facilities, and the laboratorial tests in LCV of Algete (Spanish NRL for BT).The vaccine was finally available from the month of may 2006 and live attenuated vaccines were not used any longer.

The main changes brought by inactivated vaccines were the possibility to use it all along the year and the solution to the problems of the movements restrictions on animals vaccinated with live attenuated vaccine, due to the lack of viraemia. The main disadvantages were the increase of the price and the need of two doses to achieve the protective immunity.

Vaccination policy on the previous years had had ovine as its main target. Vaccination in bovine started in 2005, but still, on 2006 the percentage of ovine animals vaccinated in relation to the total amount of vaccinated animals was around 90%.

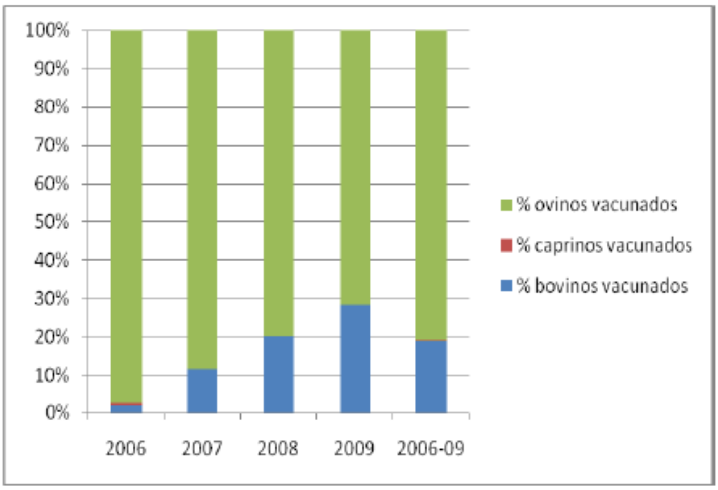


Table 1: Percentage of each species among vaccinated animals

As a result of these measures, viral circulation of serotype 4 ended in October 2006, when it was finally eradicated until its reappearance on 2010.

2004	2005	2006
322	88	0

Table 2: Number of serotype 4 outbreaks per year

3-BT SITUATION IN SPAIN 2007: BTV-4 and 1

a) Background

Serotype 1 was detected for the first time in July 2007, in an ovine holding located in Tarifa (Cadiz). The likely origin was the transport of infected vectors through the wind, concretely from Morocco and Algeria, where this serotype had been detected on the previous months. The virus spread quickly and involved a high level of mortality in ovine holdings.

Some months later, in November, a serotype 1 outbreak was notified in Guipuzcoa, on the North of Spain, nearby the French border. With this new outbreak the involvement of a new vector (C. obsoletus) was proved. This finding, added to the results of the entomological surveillance program, made that the live animals movement restrictions were extended to new provinces.

Map 7: Serotype 1 outbreaks in 2007.

b) Measures applied

- Control of susceptible species movements by the establishment of two restricted zones, Restricted Zone 1-4 and Restricted Zone 1.

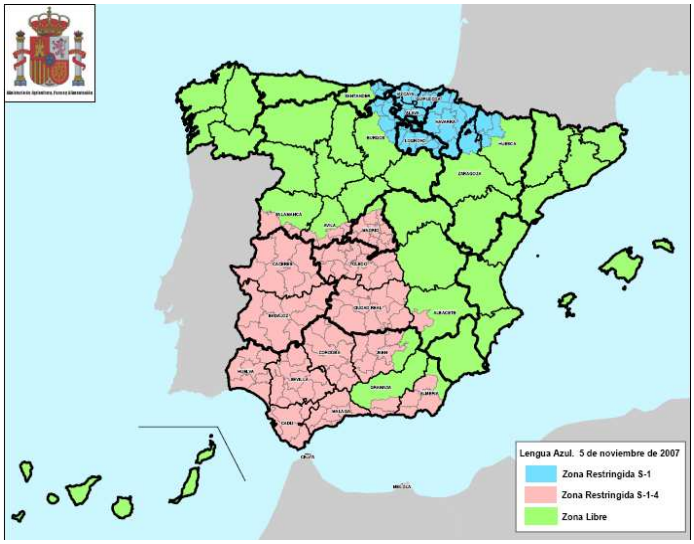
On this year, two restricted zones, Restricted Zone 1-4 and Restricted Zone 1 are established, and several changes are done in national legislation, in order to adapt these restriction zones to the evolution of presence of serotype one.

- Epidemiological surveillance.

From this year on, bovine and caprine started to be used as sentinels instead of bovines samples taken on the frame of sanitary campaings as it was used in previous years, as vaccinated animals or animals coming from areas with viral circulation resulted positive with the respective loss of information, with the exception of free zones.

- Vaccination bovine and ovine population with inactivated vaccines against serotypes 4 and 1.

Four months after the first serotype 1 outbreak, November 2007, inactivated vaccines against serotype 1 began to be available, and vaccination against this serotype started on ovine animals. The vaccination on ovine was prioritized on a first moment due to the lack of vaccine available. Once availability of vaccines allowed it, also bovine was vaccinated. The eradication program against serotype 4 continued on all Restriction Zone 1-4 in ovine and bovine.



Map 8: Restricted zones in November 2007

4-BT SITUATION IN SPAIN 2008: BTV-4, 1 and 8

a) Background

During 2008 serotype 1, spread through the north of the territory, this involved several modifications of the restricted area. As can be observed on table 3 the number of outbreaks of serotype 1 was significantly lower than the year before. No outbreaks of serotype 4 were detected on this year.

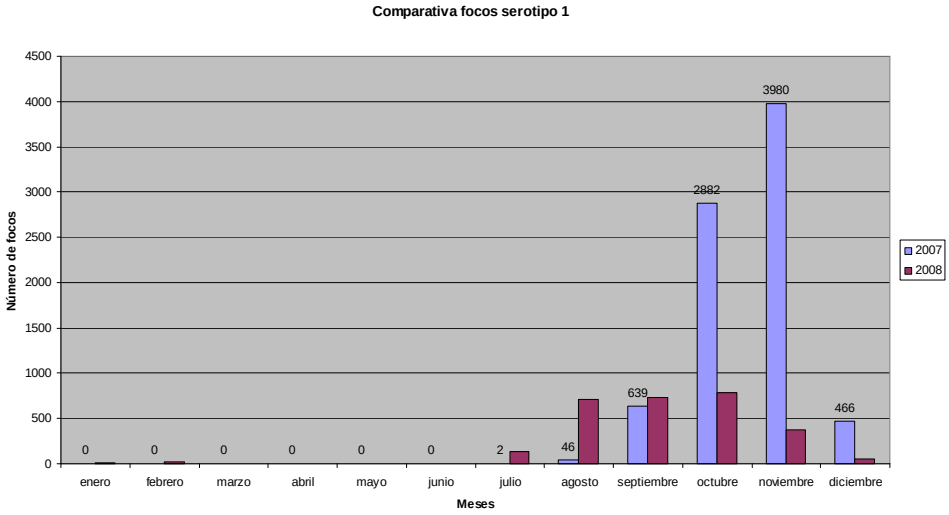


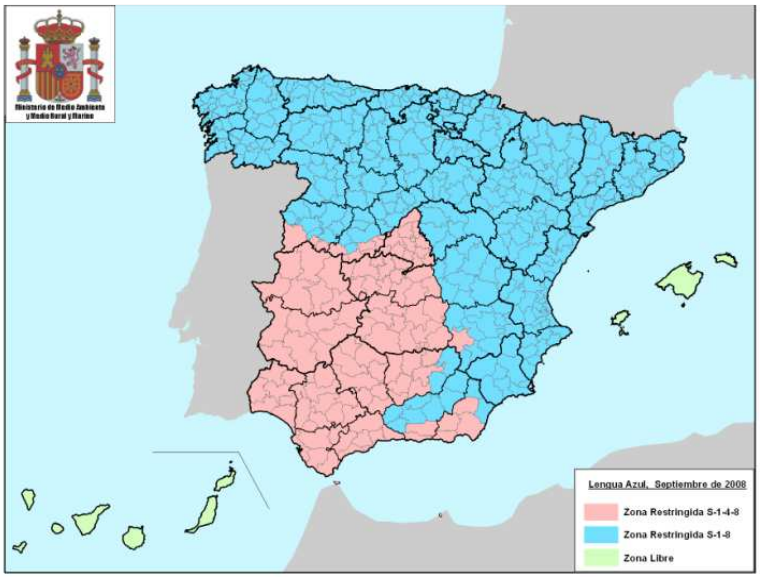
Table 3: Comparison between the number of outbreaks of serotype 1 2007-08

Serotype 8 was registered for the first time on the Spanish territory, in the municipality of Solares (Cantabria),with circulation limited to a small area of 3, 5 km^{2}and no more viral circulation was detected until October 2008, when new outbreaks were notified in Malaga, Cadiz and Lugo. The origin of all this serotype 8 outbreaks was the movement of infected animals from the north of Europe.

Map 9: Outbreaks in 2008

b) Measures taken

- Control of susceptible species movements by the establishment of two restricted zones, Restricted Zone 1-4-8 and Restricted Zone 1-8
- Epidemiological surveillance.
- Vaccination of bovine and ovine population with inactivated vaccines
- Immunization control on vaccinated young animals



Map 10: Restricted zones on 2008

Vaccination against serotype 1 and 4 continued over this year in ovine and bovine until October 2008 when vaccination against serotype 4 ended. In relation to serotype 8, vaccines were available from May 2008, and from then on vaccination against this serotype started. The average vaccine coverage reached on that year was up to 80% against both serotypes.

During this year and the following an immunization control on vaccinated bovine-ovine animals from 3-12 months started. It consisted on an ELISA test for antibody detection, 15 days after vaccination. The conclusion was that immunization rate was high, especially on ovine with a slightly higher rate of immunized animals.

	Ovine			Bovine		
	Samples	Positive	% (IC95%)	Samples	Positive	% (IC95%)
2008	2.115	2.072	97,97% *(97,38:98,36)*	2.121	1.954	92,13% *(91,09:93,02)*
2009	515	462	89,71% *(87,09:92,33)*	1.238	970	78,35% *(75,76:80,94)*

Table 4: Results of the immunization control

5-BT SITUATION IN SPAIN January 2009-December 2010: BTV-1 and 8

a) Background

During these years, a drastic reduction of the number of outbreaks was observed yearly, and viral circulation of serotype 4 remained limited to a region on the south of Cadiz.

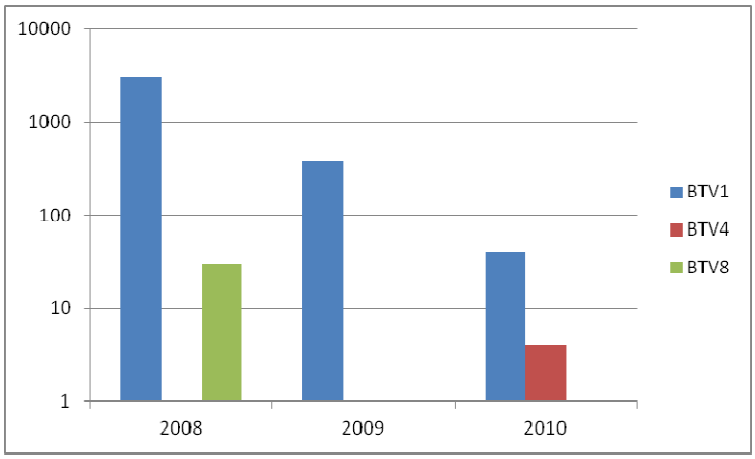
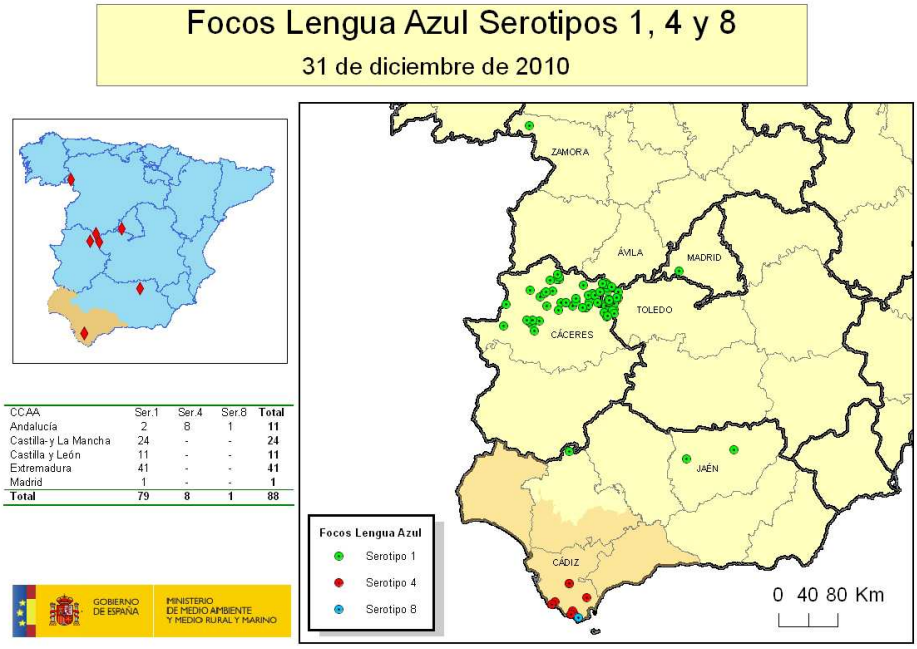


Table 5 bis: Number of outbreaks 2008-10

On March 2009 Spain was declared officially free of serotype 4, after the lack of circulation of this serotype for over two years and after a vaccination campaign that started at the end of 2008.Nevertheless, in October 2010, serotype 4 reappeared in sentinel animals in the province of Cadiz. The virus was linked with the one circulating on the North of Africa.

In relation to serotype 8 the last outbreak notified was on November 2010 on the province of Cádiz.

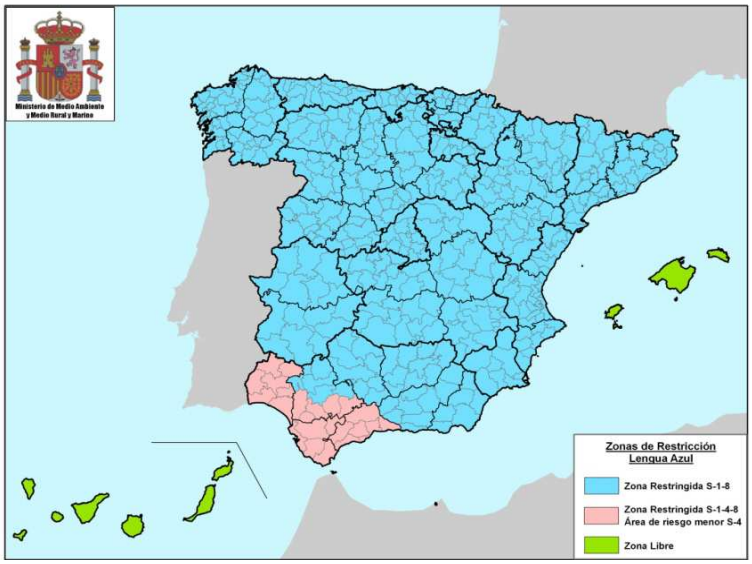


CCAA	Ser.1	Ser.4	Ser.8	Total
Andalucía	2	8	1	11
Castilla-y La Mancha	24	-	-	24
Castilla y León	11	-	-	11
Extremadura	41	-	-	41
Madrid	1	-	-	1
Total	79	8	1	88

Map 11: Location of the serotypes 1 and 4 outbreak. December 2010.

b) Measures taken

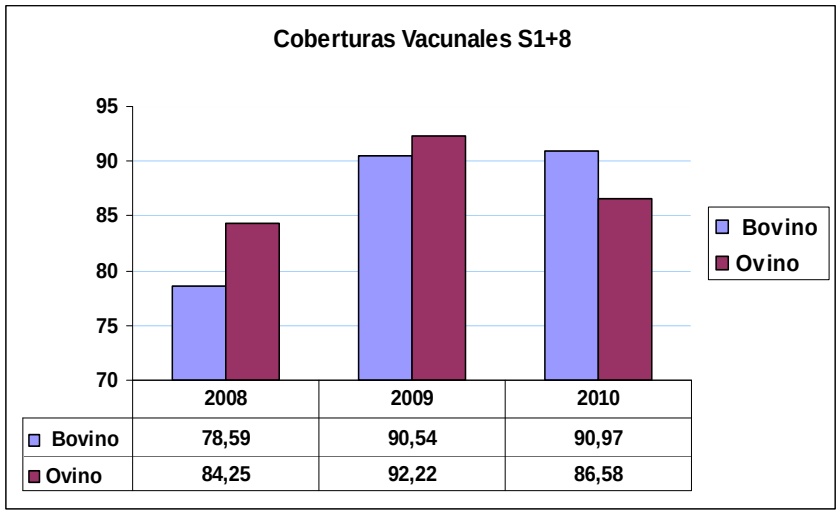
- Establishment of two restricted zones, Restricted Zone 1 and Restricted Zone 1-8
- Establishment of a minor risk area for serotype 4 in March 2010 (Afterwards restricted zone 1-4-8) due to an evaluation of the risk of introduction of this serotype from the north of Africa.
- Epidemiological surveillance.
- Vaccination of bovine and ovine population with inactivated vaccines.
- Immunization control on vaccinated young animal continued along this year.



Map 11: Restriction zones.2009-10

During 2009 and 2010, vaccination against serotypes 1 and 8 continued all along the mainland`s territory for all sensitive species. National legislation changes included the "minor risk area against serotype 4 " on a territory where , even when no viral circulation had been detected up to date, compulsory preventive vaccination against this serotype took place on animals over three months age from the species ovine and bovine. This area was afterwards named "Restriction zone for serotypes 1-4-8", and vaccinations against this last serotype were also performed.

,,. Bivalent vaccines against serotypes 1-8 were available from the month of April 2009.



	2008	2009	2010
Bovino	78,59	90,54	90,97
Ovino	84,25	92,22	86,58

Table 6: Percentage of animals vaccinated by species and serotype.

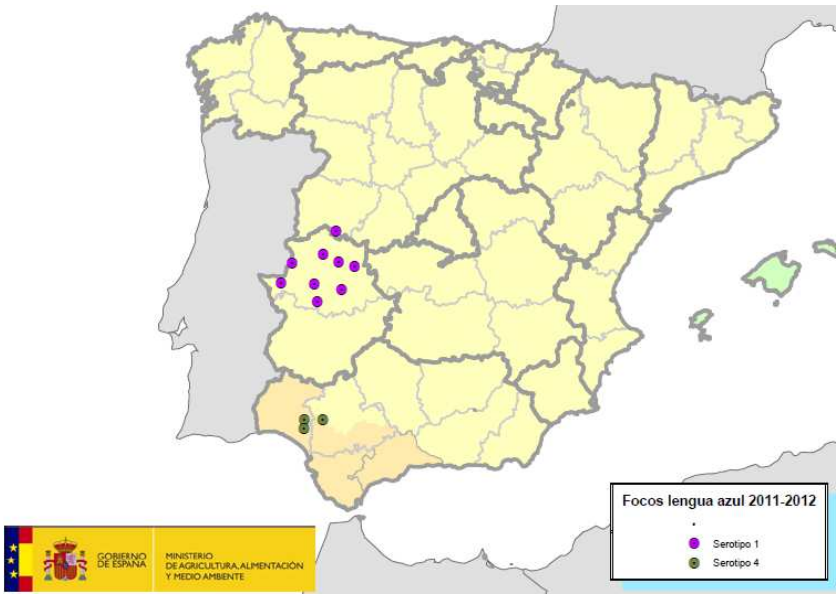
6-BT SITUATION IN SPAIN 2011-2012: BTV-1, 4 and serotype 8 freedom on a part of the territory.

a) Background

As a results of several vaccination campaigns and a high rate of vaccinated animals, the outbreaks of serotype 1 remained restricted to a small area of the north of the province of Caceres, and where most of the outbreaks of this serotype had occurred on 2010. Circulation of serotype 1 was detected for first time on this period in sentinel bovines and sentinel caprine on the south of the province of Salamanca, adjacent to province of Cáceres. During that year 9 outbreaks were confirmed on the same area always in sentinel holdings.

For the same reasons, the behavior of serotype 4, was similar to serotype 1, in the sense that the only three outbreaks notified on that activity season were located, on a very demarcated area on the south.

No viral circulation of any serotype was detected on the rest of the territory.



Map 12: Outbreaks on vector activity season 2011-12

b) Measures taken

Based on the epidemiological situation, on the first of January 2011 serotype 8 vaccination ended and also on 1st July of the same year, vaccination against serotypes 1 and 4 became voluntary

7-BT SITUATION IN SPAIN July 2012-July 2013: BTV-1, 4 and freedom of serotype 8 in all the territory.

a) Background

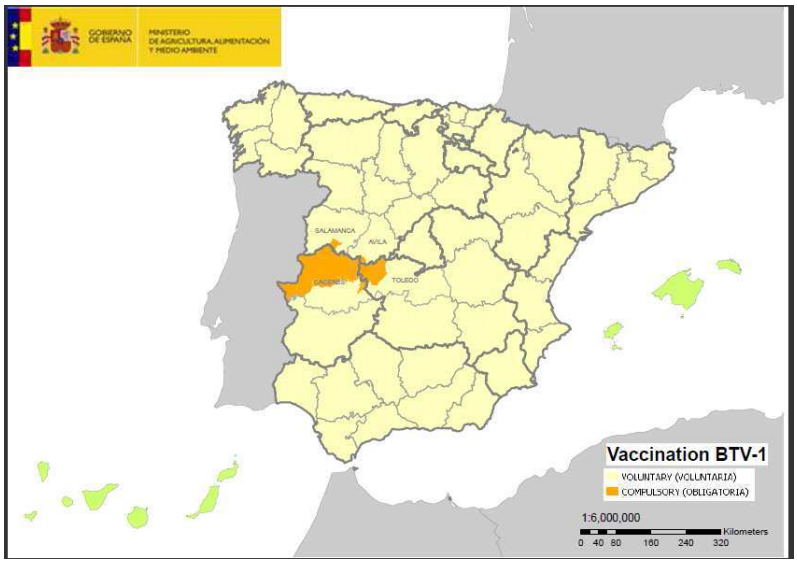
On season 2012-2013 only three outbreaks were notified, two of them of serotype 1 on the month of November 2012 in sentinel holdings on the north of Caceres and one of serotype 4 on the month of March in Cádiz.
As on the previous season viral circulation remained limited to the north of Caceres (serotype 1) and to the south of Cadiz (serotype 4)

Map 14: Outbreaks of bluetongue in vector activity season 2012-2013.

c) Measures taken

- Epidemiological surveillance
- Vaccination against serotype 1 voluntary until March 2013 when became compulsory in an area of the north of the province of Cáceres.
- Vaccination against serotype 4, and vaccination against serotype 1 on the rest of the territory continued to be voluntary

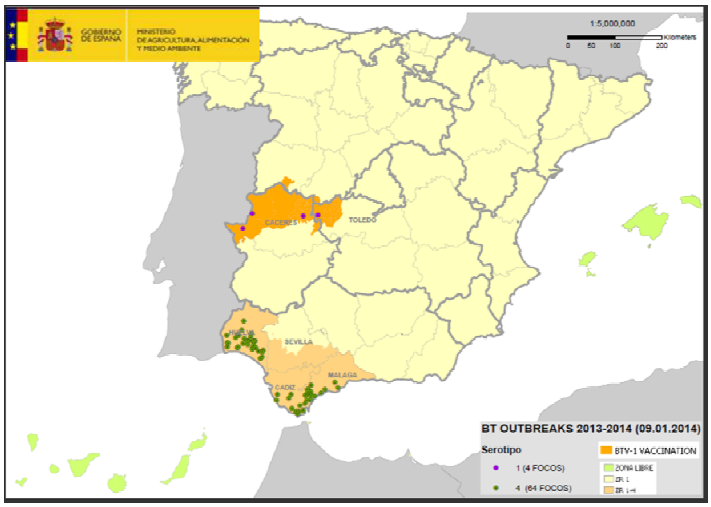
The area of compulsory vaccination against serotype 1 covered the municipalities where viral circulation had been detected and other adjacent municipalities' chosen on the base of a risk analysis, and including part of the provinces of Caceres, Toledo, Salamanca and Ávila. The objective of this compulsory vaccination was to achieve the final eradication of the disease from the country and on the other hand to avoid the dispersion of this serotype to other areas where no viral circulation had been detected on the last years.



Map 15 : Compulsory vaccination against bluetongue serotype 1

7-BT SITUATION IN SPAIN July 2013-July 2014: BTV-1, 4

a) Background



Map 16: Outbreaks in vector activity season 2013-14

In October 2013, the presence of serotype 4 was confirmed in a holding in Andalucía associated to clinical symptomatology. On the same month, serotype 1 was confirmed on a sentinel holding in Toledo.

The number of serotype 4 outbreaks reached 64, all of them inside the RZ 1-4 in ovine holdings and associated to clinical symptomatology. In relation to serotype 1,

4 outbreaks were notified on the following months, all of them inside the compulsory vaccination area.

These events involved a change on the evolution of the disease on the last years.

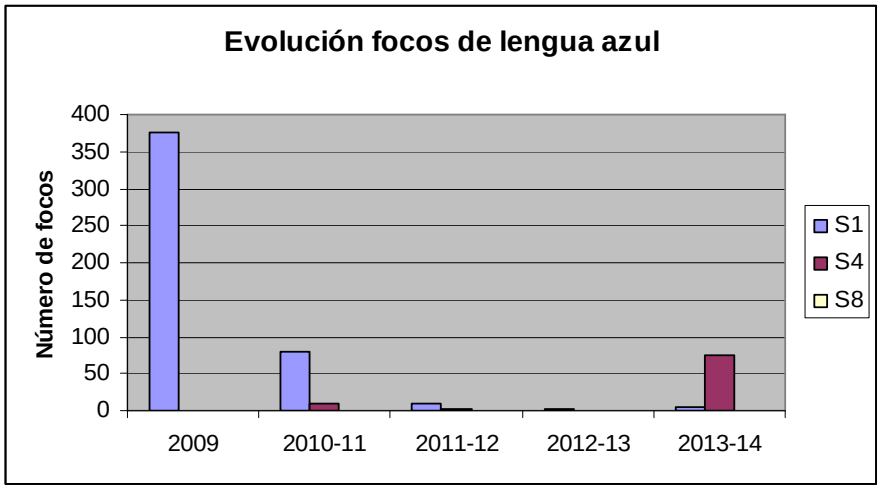
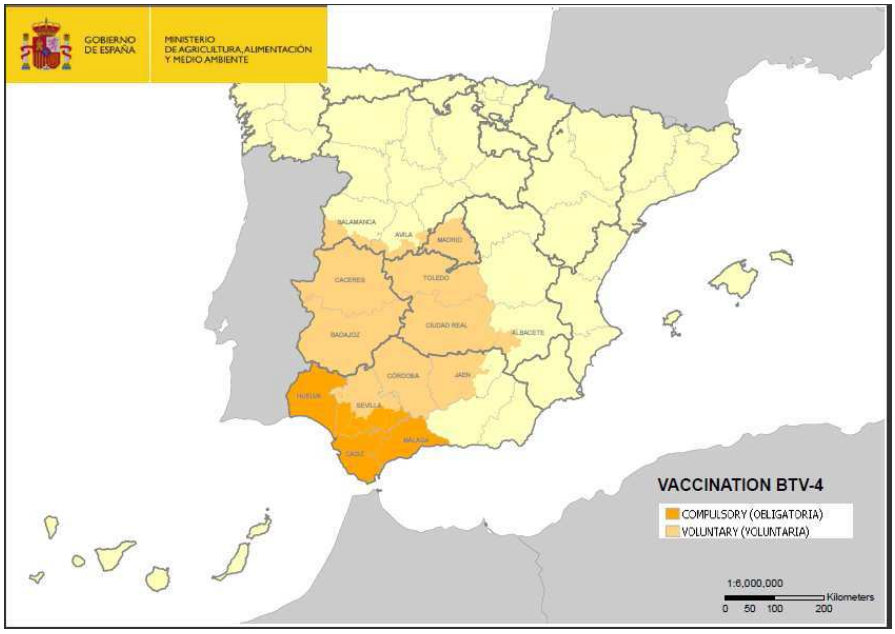


Table 7: Evolution of Bluetongue outbreaks from 2009

b) Measures taken

- Epidemiological surveillance
- Compulsory vaccination area for serotype 4 on the entire RZ 1-4 and for serotype 1 in a limited area on the north of Cáceres and territories nearby (see maps 15 and 16)
- Voluntary vaccination is allowed on the area of historical distribution of serotype 4 and in all the RZ 1 not included in compulsory vaccination area for serotype1.



Map 16: Compulsory and voluntary vaccination area for serotype 4

8-COSTS

The current cost of the purchase of the vaccine, in the case of univalent vaccines can range between 0, 37 to 0, 61€ depending on the species and the serotype. This price, significantly lower that price on free market, was reached as a result of the negotiations of the Ministry of Agriculture with the industry, due to the high number of vaccines to be purchased.

In relation to the cost of the application of the vaccine, the average for all the country in 2009 was 1, 84€ for bovine and 0, 52€ for ovine, but the cost was very variable among regions. The main factors that influenced the final cost of the application of the vaccine were, if it was done through public or private vets and the size of the holdings, smaller holdings involved a higher average cost per animal.

Detailed information on the cost of 2009 vaccination campaign can be found on the annex.

9-CONCLUSIONS

Vaccination has been proved as an effective tool to prevent clinical signs and mortality, by controlling viral circulation and leading to a decrease of outbreaks number. The benefits of it are not only for the vaccination area but also for the rest of the region, by preventing the spread of the virus to other regions.

Moreover it led to eradication of BTV-2 in 2002, BTV-4 in 2005 (Balearic Islands), BTV-4 in 2009 (Spanish Mainland) and BTV-8 in 2013.

In spite of the success of the vaccination these measures have not been enough to achieve the final eradication of the disease, probably due to the persistence of the vector in certain areas of Spain, and for this reason vaccination is compulsory at present on these areas. Another reason of this permanence of the disease in certain areas are the new incursions of the virus from neighbourgh territories, in particular the north of Africa.

It has also facilitated animal movements from restricted zones to free areas, mainly since inactivated vaccines were available on 2006.

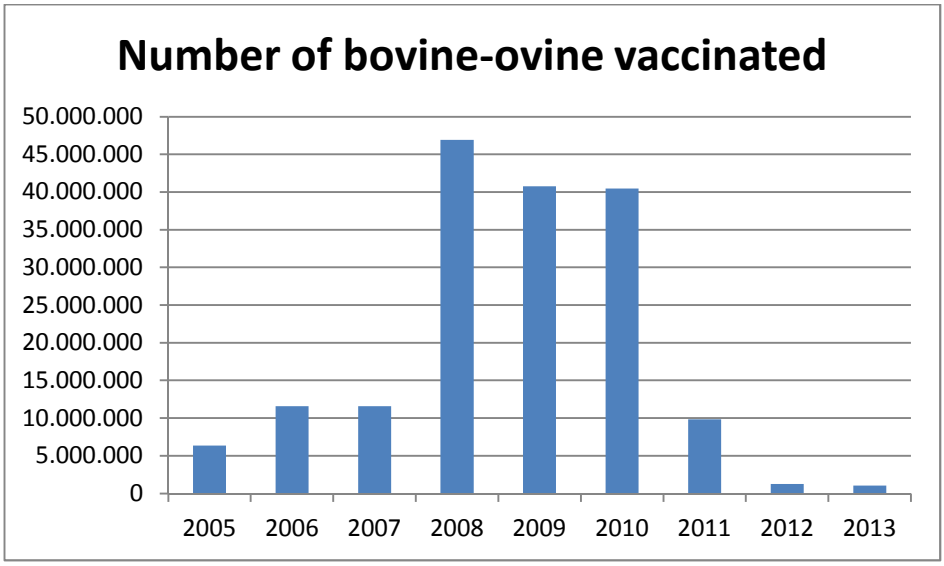


Table 8: Evolution of the number of vaccinated animals 2005-13

ANNEX

Number of animal vaccinated in 2004-2013

		2004	2005	2006	2007	2008
TOTAL BOVINE IN RESTRICTED ZONE			1.424.161	7.723.787	2.351.115	6.327.685
BOVINE VACCINATED	**BTV-1**				1.236.619	4.660.000
	BTV-4		43.497	140.123	1.178.499	1.615.000
	BTV-8					4.200.000
TOTAL OVINE IN RESTRICTED ZONE		3.362 *	6.977.990	6.086.632	11.185.980	16.698.938
OVINE VACCINATED	**BTV-1**				1.170.197	16.000.000
	BTV-4	6.521*	6.287.965	3.409.742	8.014.031	6.460.000
	BTV-8					14.000.000

*Holdings

		2009	2010	2011	2012	2013
RESTRICTED ZONE		5.951.452	5.835.901	6.532.594	5.328.866	5.796.143
BOVINE VACCINATED	**BTV-1**	5.600.947	5.302.145	1.457.952	25.301	367.867
	BTV-4		293.708	141.986		
	BTV-8	5.643.323	5.303.344	340.627	30.873	
RESTRICTED ZONE		16.649.010	16.804.479	17.047.105	14.131.152	16.346.618
OVINE VACCINATED	**BTV-1**	14.592.099	14.544.559	6.925.672	1.180.664	672.278
	BTV-4		483.697	214.091		712
	BTV-8	14.908.306	14.528.249	749.230	2.096	3.196

Costs of vaccination 2009

a) Costs of vaccine purchase

Bovine

S1 univalent	**0,61€ / dose**
S4 univalent	**0,56 € / dose**
S1+8 bivalent	**0,815 € / dose**

Ovine

S1 univalent	**0,38 € / dose**
S4 univalent	**0,37 € / dose**
S1+8 bivalent	**0,5 € / dose**
S8 univalent	**0,37 € / dose**

b) Vaccine application costs:

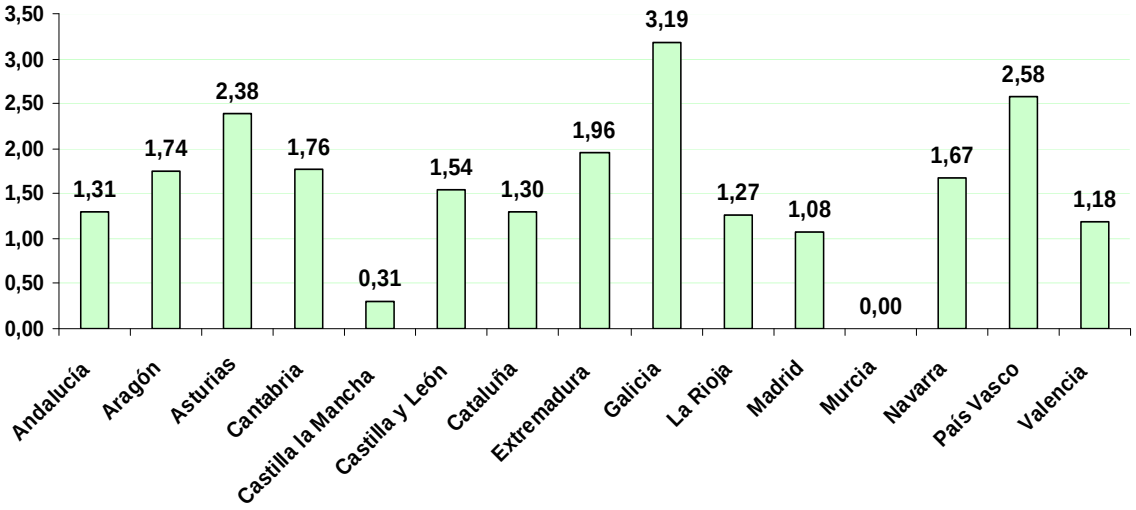


Table X. Costs of application per region in bovine

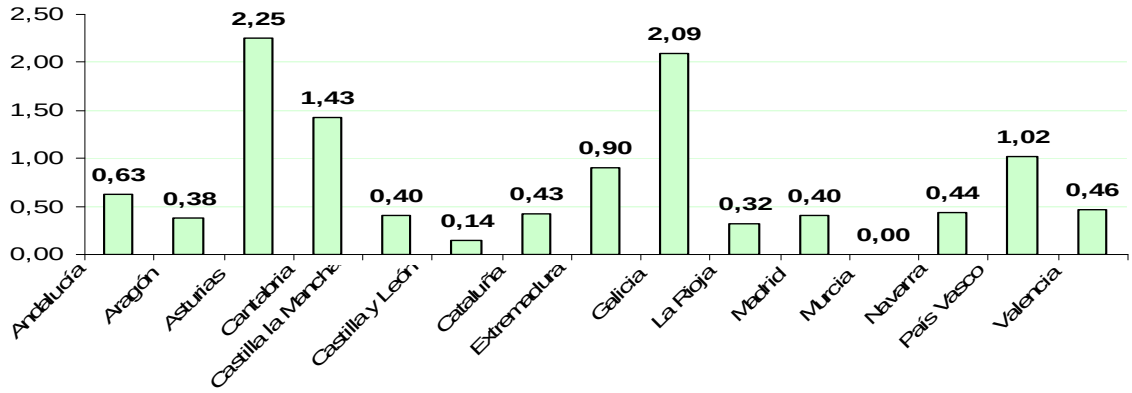


Table X. Costs of application per region in ovine