EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO)/ 2008-8308 - MR - FINAL

# FINAL REPORT OF A MISSION
# CARRIED OUT IN
# SPAIN
# FROM 25 NOVEMBER TO 01 DECEMBER 2008
# IN ORDER TO
# EVALUATE THE EMERGENCY VACCINATION AGAINST BLUETONGUE

***In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected;any clarification appears in the form of an endnote.***

***Executive Summary***

*This report describes the outcome of a mission carried out by the Food and Veterinary Office (FVO) in Spain from 25 November to 1 December 2008.*

*The objective of the mission was to evaluate the implementation of the emergency vaccination against bluetongue (BT) approved and co-financed under Commission Decision 2008/655/EC and to examine, from a veterinary point of view in accordance with Article 9 (1) of Council Decision 90/424/EEC, the arrangements that Spain has put in place to control BT using emergency vaccination.*

*The mission was carried out under the general provisions of Community legislation and, in particular Article 45 of Regulation (EC) No 882/2004 of the European Parliament and the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.*

*The report concludes that national legislation and guidelines are in place for the implementation of the approved vaccination programme at national level and that sufficient staff and resources to carry out the programme were made available. Replacement lambs are not regularly vaccinated when they reach three months of age in the Autonomous Communities (AC) visited, which is not in compliance with the obligation stated in the programme.*

*Despite the fact that every operation is recorded, the lack of organized and updated information at the AC level does not allow a complete appraisal of the degree of implementation of the programme in the field. As a consequence, the tables summarized and organized by the CCA that have been made available to the Commission and to the mission team contained some discrepancies and did not allow, at this stage of implementation, a complete evaluation of the degree of achievement of the objectives of the programme.*

*The report makes a number of recommendations addressed to the Spanish competent authorities, particularly on the need to provide up-to-date, reliable and organized data at national level, in order to allow a proper evaluation of the vaccination programme co-financed by the Commission.*

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## ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

| Abbreviation | Explanation |
|---|---|
| AC | Autonomous Communities |
| ADNS | Animal Diseases Notification System |
| AV | Authorized veterinarians |
| BT | Bluetongue |
| BTV | Bluetongue virus |
| CA | Competent Authorities |
| CCA | Central Competent Authorities |
| CDB | Central Database |
| ELISA | Enzym linked Immuno-Sorbent Assay |
| EMEA | European Medicines Agency |
| FVO | Food and Veterinary Office |
| LVU | Local veterinary Units/ *Unidades Veterinarias Locales o Oficinas Comarcales* |
| PCR | Polymerase Chain Reaction |
| RASVE | National System for Notification of Diseases/*Red de Alerta Sanitaria Veterinaria* |
| RZ | Restricted Zone |
| SCV-AC | *Servicios Centrales Veterinarios* |
| STC-AC | *Servicios Territoriales Veterinarios* |

## 1 INTRODUCTION

The mission took place from 25 November to 1 December 2008. This mission was undertaken as part of a series of missions to certain Member States (MS) and was not part of the Food and Veterinary Office's (FVO) planned mission programme. The mission team comprised two inspectors from the FVO. Representatives from the Central Competent Authority (CCA) accompanied the team during the mission.

## 2 OBJECTIVES OF THE MISSION

The objective of the mission was to evaluate the implementation of the emergency vaccination plan against bluetongue (BT) and to examine, from a veterinary point of view in accordance with Article 9 (1) of Council Decision 90/424/EEC, the arrangements that Spain has put in place to control BT using emergency vaccination.

In pursuit of these objectives, the following sites were visited:

| **Competent authority visits** | | | Comments |
|---|---|---|---|
| Competent Authority | central | | Opening and closing meting |
| | regional | two | |
| | district | two | |
| **other sites visited** | | | |
| Authorized bodies for vaccination | | two | one public and one private association |
| Cattle holdings | | one | fattening |
| Sheep holdings | | one | breeding |
| Vaccine storage facilities | | two | one private laboratory and one public association |
| | | | |

## 3 LEGAL BASIS FOR THE MISSION

The missions was carried out under the general provisions of Community legislation and, in particular Article 45 of Regulation (EC) No 882/2004 of the European Parliament and the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Legal acts quoted in this report are listed in Annex 1 and refer, where applicable, to the last amended version.

## 4 BACKGROUND

Since 2000, outbreaks of BT have occurred in southern Europe and, since 2006, BT cases have been reported in central and northern Europe.

The emergence of this disease represents a serious risk to the Community's livestock population. BT is a vector-borne disease, which cannot be eradicated by culling affected animals. Mass emergency vaccination campaigns are considered the best means to reduce clinical disease and losses.

Council Directive 2000/75/EC has provided the possibility for MS to use vaccination as a complementary measure to control the disease. Certain MS which vaccinate against BT have presented their plans for emergency vaccination for 2007 and 2008 to the Commission. The Commission has assessed these plans and the plans were found to comply with relevant Community veterinary legislation. Commission Decision 2008/655/EC approved the emergency vaccination plans against BT for certain MS, including Spain.

Bluetongue virus 1 (BTV1) was first notified in July 2007 in the south of Spain (Andalusia), where Bluetongue virus 4 (BTV4) was already present. The restricted zone (RZ) was then homologated for the two serotypes, including Extremadura, part of Andalusia, part of Castilla La Mancha and Madrid and some districts in Castilla y Leon.

In October 2007, BTV1 appeared in North of the country (Pais Vasco) and a new RZ was established, including Navarra, a small section of Aragon, La Rioja, part of Cantabria and Castilla y Leon.

Bluetongue virus 8 (BTV8) made its appearance in January 2008 in Cantabria, where a new RZ was created, partly overlapping the area where restrictions were already in place for BTV1. After a new outbreak of BTV1 in Asturias in February 2008 the RZ 1-8 zone further enlarged.

In July 2008, with the new start of viral circulation, the RZ 1-8 has been further extended to include Galicia and Catalonia.

In October 2008 considering the appearance of new outbreaks, the entry of animals from other MS and the borders with countries where BT viruses are circulating, the CCA (Ministerio de Medio Ambiente y Medio Rural y Marino - MMAMRM) took the decision to extend the RZs for BTV1 and 8 to the whole country, excluding the Balearie and Canary islands.

The last outbreaks of BT serotype 4 were notified in October 2006 and vaccination was stopped in October 2008. The co-financed vaccination programme for BT4 is not included in Commission Decision 2008/655/EC.

# 5 MAIN FINDINGS

## 5.1 COMPETENT AUTHORITIES PERFORMANCE

### *5.1.1 Designation of Competent Authorities, coordination and operational criteria*

The CCA is responsible for elaboration and establishment of the vaccination programmes and for collecting and compiling information from the various ACs, in order to provide data summarizing the implementation of the programme at national level and to send periodical reports to the Commission.

The CCA organize and coordinate the purchasing of vaccines from the manufacturers and their delivery to the storage facilities of the 17 Autonomous Communities (ACs).

The ACs are responsible for the organization, implementation and control of the programme in the field. The practical arrangements for carrying out the vaccinations can vary from one AC to another one. In general, the Local Veterinary Units (LVU) rely on authorized veterinarians (AV) employed by public and private associations.

*Observations*

- Responsibilities and competencies have been clearly defined at Central and AC level.

### *5.1.2 Legal power and enforcement*

The vaccination for Bluetongue in Spain is compulsory and sanctions can be imposed in case of non compliance.

*Observations*

- The AVs carrying out the vaccination are legally entitled to enter the holdings.
- No problems or opposition from the owners during the vaccination campaign has been reported to the Competent authorities of the ACs (*Servicios Centrales Veterinarios*/SCV-AC).

### *5.1.3 Staff performing controls and resources*

The staff employed by public and private associations to carry out the vaccination are all qualified veterinarians, authorized by the LVUs. In general, no extra staff have been employed for the vaccination campaign with the exception of a few ACs where the need

for vaccination has been exceptionally high.

The allocation of holdings to each of the AVs is done on the base of existing schedules, since, in the vast majority of the cases, the AV involved in vaccination is already responsible for carrying out other routine operations in the holdings (tuberculosis and brucellosis tests, deworming etc.).

*Observations*

- In general staff were competent and resources for carrying out ihe vaccination campaign were adequate.
- The AVs reponsible for vaccination were normally well established in their area of competence and showed good organization skills.

#### *5.1.4 Procedures on tasks, responsibilities and duties of staff*

The vaccination campaign at national level is implemented through Ordinances issued by the CCA that have been regularly amended to adapt to the changing situations.

A "Manual on measures against Bluetongue" has been reviewed and issued by the CCA in October 2008, to be used as guidance at national level.

Manuals on practical implementation of vaccination have been prepared in one AC visited.

In the two ACs visited, a set of documents to be used during all the different phases of the campaign (reception, distribution and delivery of vaccines; allocation of tasks to the AVs; withdraw of vaccines, report of vaccination etc.) was available.

*Observations*

- Evidence was provided that training/information meetings were organized by the LVUs on BT vaccination for AVs and for farmers.
- The documents to be used during the implementation of the programme were generally correctly filled.

#### *5.1.5 Audits of Competent Authorities*

In the two AC visited, internal or external audits within the scope of the mission had not yet been carried out(see Endnote) 1. Audits to verify the effectiveness of the performances of Servicios Territoriales Veterinarios (STV-AC) and the LVUs, has been foreseen for next year, in the frame of the Multi Annual Control Plan, as required by Council Regulation (EC) No 882/2004.

### 5.2 IMPLEMENTATION OF THE VACCINATION PROGRAMME

#### *5.2.1 Duration of the programme and calendar of application*

The first vaccination programme was presented by the CCA to the Commission on 15 February 2008, reflecting the epidemiological situation of the diseases at that time when vaccination against BTV1 had started in the RZ 1-4 (an extended area in the south east of the country) and in a limited part of the north of the country in November 2007. Even though in January 2008 vaccines for BT8 were not available yet, vaccination for this serotype had been already foreseen and it started in May 2008 in the RZ.

Since the presentation of the first programme, given the new epidemiological situation with the appearance of new BTV1 and BTV8, an updated proposal was sent to the Commission on 15 July 2008 including new areas for vaccination.

On 10 September 2008, given the appearance of further outbreaks of BTV1, a new vaccination area has been proposed to the Commission, including all ACs in the north, with the RZ for BTV1 and BTV4 remaining unchanged.

On 23 September 2008, considering the appearance of outbreaks in various ACs the CCA presented an updated programme to the Commission, extending the vaccination against BTV1 and BTV8 to the all territory of Spain, with the exclusion of the Balearie and Canary islands.

The CCA stated that the first two applications of the vaccine (a initial dose and a booster dose at 21/28 days later interval) will take place before spring 2009.

According to the last programme presented to the Commission, the planned amount of doses to carry out at least the initial and the booster doses in the eligible population (including waste of vaccines) is as follows:

| | Animals | BTV1 doses | BTV8 doses |
|---|---|---|---|
| Bovines | 6.925.252 | 16.600.000 | 16.600.000 |
| Ovines | 21.595.171 | 49.000.000 | 49.000.000 |

*Observations*

- Given the extremely rapid evolution of the situations, in terms of serotypes and geographical areas involved, the implementation of the vaccination programme has been very variable between the various ACs and also within some of them, where some LVUs were included in the vaccination area at different times.
- Significant variations in the time period for completing the double vaccination (initial and booster doses) have been observed between the two ACs visited.

### *5.2.2 Geographical delimitation*

The current geographical delimitation of the vaccination campaign is the entire territory of Spain, with the exclusion of the Balearie and Canary islands.

### *5.2.3 Authorization, distribution and storage of vaccines*

Four manufacturers are at the moment marketing inactivated monovalent BTV1 and BTV8 vaccines for sheep and cattle.

The commercialisation of these vaccines has been provisionally authorized by the National Agency for Drugs and Sanitary Products. However, the vaccines have not been authorized yet by the European Medicines Agency (EMEA).

The manufacturers are responsible for carrying out in-process and final controls on each released batch and to inform the CCA of the results. Vaccines are presented in flasks of different capacity, depending on the commercial products.The SCV -ACs stated that some waste in doses of vaccines is inevitable, especially with larger flasks.

The duration of immunity has not been established yet. The CCA has, given their experience with the BT4 vaccines, decided to carry out revaccination after 12 months.

The CCA purchase the vaccines on the base of a note received from the ACs stating the amount and the type of vaccine needed, according to a calculation based on the request they receive from the STV-AC of LVUs. This information is derived from the request of the public or private associations, calculated on the basis of the list of holdings each AV has to vaccinate, according to the central database (CDB). The manufacturers deliver the vaccines directly to the storage locations indicated by the various ACs. Storage centres can be public or private laboratories, refrigerators located in the premises of the LVS or cold stores belonging to the associations.

Once the vaccines have been received, the SCV-AC has to send a confirmation to the CCA. At the same time, the manufacturers must also confirm to the CCA that the vaccines have been delivered.

The AVs need a permit issued by the LVU in order to collect the vaccine doses from the storage centres.

*Observations*

- The storage location and capacity and the organization for delivery and distribution of the vaccines are extremely variable in the various ACs. The storage facilities visited by the mission teams were well maintained and the vaccines were stored at the required temperature.
- In one of the vaccine storage centre visited, computerized temperature control was in place and corrective actions were taken on one occasion when the cool chamber had a technical problem.
- Register for the reception and delivery of the doses of vaccines were available at the storage facilities visited.

### *5.2.4 Selection of holdings and animals to be vaccinated and movement control*

Cattle and sheep holdings to be vaccinated are those included in the national register of holdings.

The vaccination against serotypes 1 and 8 is compulsory for cattle and sheep over three months of age.

Since the vaccines have not been yet authorized for goats, the CCA decided not to include this species in the compulsory programme. Nevertheless, in several ACs goats are vaccinated.

In the case of cattle, vaccination dates and serotypes are reported in the passport and are also registered individually in the CDB. In the case of sheep, the number of animals and the day of vaccination is entered in the register of Veterinary Medical Products at the holding. The last three vaccinations, with the indication of the serotype and the dates of application, must be recorded in the movement document of the animal.

Vaccinated animals can be moved 70 days after onset of immunity (according to the specification of the producer), or with a negative result to an agent identification test 25 days later after vaccination, in accordance with paragraph 5 of Annex III of Commission Regulation (EC) No 1266/2007.

Observations

- In one of the ACs visited, an AV stated that replacements lambs that at the time of vaccination are younger than three months are not vaccinated. They will be vaccinated with the following periodical vaccination, one year later. The manual for vaccinators prepared by the AC did not specify that the AV has to return to the holding in order to vaccinate the replacement animals. Instead, in another AC visited, catch-up vaccinations of replacement lambs were carried out on a regular basis.
- Slaughter lambs are excluded from the compulsory vaccination programme because in Spain they are sent to slaughter before the age of three months.
- In the two holdings visited (bovine and ovine) the information entered by the AV in the vaccination report matched the data available in the register.
- In one transport document, it was indicated that bovine animals were moved before having received the booster vaccination for BT1. The animals were actually correctly vaccinated but the vaccination dates were wrongly recorded in the CDB.

#### *5.2.5 Control of immunization (efficacy of vaccination)*

A national plan to assess the efficacy of vaccination based on serological testing by ELISA (Enzyme Linked Immuno-Sorbent Assay) in vaccinated animals has not been established yet. The CCA stated that this campaign will start next spring, at the end of the first round of vaccination period.

*Observations*

One of the AC visited had started its own programme for control of immune status of animals.

### 5.3 SUPERVISION OF THE VACCINATION PROGRAMME , NOTIFICATION AND

### *5.3.1 Supervision of the vaccination programme*

A legal basis is in place for the LVUs to inspect the the public and private associations carrying out the vaccination.

Evidence that on-the-spot control on AVs are in place has been shown in the ACs visited. These controls may include cross checks on the number of animals vaccinated against the number of eligible animals in the CDB, cold chain and conservation of the vaccine, sites of application of the vaccine, biosecurity etc.

The control of equipment and consumables is managed by the public and private associations, which have to send periodical reports to the SCV-AC.

*Observations*

- Leftovers and unused flasks of vaccines are left at the holding in special containers that are periodically collected by a specialized company.

### *5.3.2 Notification and reporting procedures*

Once the vaccination has been completed in a given holding, the AV will prepare a report that is sent to the LVU which is responsible for loading the information into the database.

The CCA has the responsibility for collecting and using the flow of information in order to provide an overview of the current situation with respect to number of bovine and ovine animals to be vaccinated and the number of doses of serotype 1 and 8 vaccines to be applied as foreseen in the programme sent to the Commission.

In October 2008, the CCA has sent to the Commission a report about the number of animals vaccinated and number of doses already applied between 1 November 2007 and 31 August 2008, and another report stating the doses foreseen to be applied from 1 September to 31 December 2008.

During the mission, the inspection team received: a table summarizing to the number of doses of serotype 1 and 8 vaccines that have been distributed to the 17 ACs from the CCA and a table detailing, for each AC, the coverage of vaccination (first and second doses) at national level for cattle and sheep for each serotype .

*Observations*

- In one AC, where the vaccination started in different dates in its various LVUs, it was not possible to find out how many doses of vaccines have been already applied, for which serotype in which species. In another AC, these data were available(see Endnote).2
- At AC level, it was not easy to calculate the difference between the numberof doses sent from manufacturers to the storing centres and the number of doses actually taken by the AVs. In one AC, a significant difference in number was not noticed by the Official Veterinarian (OV), until the mission team identified it (see Endnote) 3.

- Following a comparative analysis, inconsistencies and discrepancies have been identified in the information/data provided with the various sets of available information. As an example, the following discrepancies are listed:

- The number of vaccines used for sheep at 31/08/08 in one AC was 8.237.000 whilst the table related to coverage (first and second application) indicated that 6.800.000 doses were applied;(see Endnote) 4

- The percentage of sheep that had received the booster vaccination (76%) in one AC was higher than percentage of animals that had received the first vaccination (67%);(see Endnote) 5

- In the tables related to vaccine coverage, for one AC, 0% of coverage was reported for first vaccination and 49% for the booster vaccination; (see Endnote) 6

- The number of cattle to be vaccinated in one AC in the programme sent to the Commission was 16.234 whilst in the table related to the number of vaccines distributed, the total number reported was 55.209.(see Endnote) 7

### 5.4 MONITORING AND SURVEILLANCE AND NOTIFICATION OF OUTBREAKS

**Monitoring and surveillance**

Before the last extension of the RZ to the entire territory, Spain was divided to:

- restricted areas;

- unrestricted areas, specified as:

-a free area

-areas with no outbreaks bordering the restricted area

-high risk area in the Balearies and around the Mediterranean coast

In the "Technical report on the implementation of surveillance measures for BT in Spain", sent to the Commission in October 2008, the term "surveillance" is used, to mean both "monitoring" activities carried out in the RZ and "surveillance" activities to carried out outside the RZ .

The same activities were carried out inside and outside the RZ, namely:

- Serological monitoring with sentinel animals (bovine). For this purpose, the province was used as "geographical unit of reference", as foreseen by Article 2 of Council Directive 64/432/EEC. 149 animals were selected for each province and they were sampled in order to detect a monthly incidence of seroconversion of 2% with 95% of confidence. Tests were carried out at monthly intervals, whilst in the period of the year with higher vector activities the frequency was fortnightly, in accordance with paragraph 1.1 of Annex II of Commission Regulation (EC) No. 1266/2007. In the high risk area, the sample size of sentinel animals was increased to 300 for the geographical unit of reference in order to detect an index of seroconversion of 1% with 95% of confidence.

- passive clinical surveillance.

- entomological surveillance. Trapping and identification of *Culicoides* were carried out. The main vectors of BT in Spain are *Culicoudes imicola and Culicoides obsoletus complex.*

According to the information provided, the new programmes for monitoring and surveillance, adapted to the new situation of the whole territory of Spain as a RZ, will be presented to the Commission at the beginning of next year.

Observations

- Programmes for monitoring and surveillance of BT have been implemented inside and outside the RZ, albeit with some confusion in the use of terms required by Annex 1 of Commission Regulation (EC) No 1266/2007 .
- Even though in the high risk areas outside the RZ the sample size of animals to be tested was increased, the sample size of 598 animals per geographical unit of reference necessary to detect a prevalence of 0,5% with a confidence of 95% was not respected.
- The epidemiological information is sent periodically to the European BT database (BT-Net system), as required by Article 5 of Commission Regulation(EC) No 1266/2007.

**Notification of outbreaks and follow-up**

Blue tongue is a notifiable diseases in Spain according to the Royal Decree 1228/2001. The system for notification and follow-up of outbreaks has been described in the report of the mission DG(SANCO)/2008/7787.

Samples are first tested with ELISA for the detection of antibodies. In case of positive results PCR (Polymerase Chain Reaction) for the confirmation of virus circulation and seroneutralization for virus identification are carried out in the National Reference Laboratory (NRL) of Algete

Outbreaks are notified to RASVE (Red de Alerta Sanitaria Veterinaria) , the national system for notification of diseases that transfers the information to the Animal Disease Notification System (ADNS). In 2008 (until 30 November) 2,120 outbreaks of serotype 1 and 36 of serotype 8 were notified to RASVE. In 2007, 7 713 outbreaks of serotype 1 were notified.

Observations

- Notification to the CA of suspicion or confirmation of BTV circulation is in compliance with Article 3 of Council Directive 2000/75/EC.
- The number of outbreaks of BTV1 has declined in 2008, in comparison with the previous year.

## 6 CONCLUSIONS

### 6.1 COMPETENT AUTHORITIES PERFORMANCE

National legislation and guidelines are in place for the implementation of the approved vaccination programme.

Despite some variation in the practical arrangements of the programme, the basic principles and conditions are uniformly applied at national level with the exception of vaccination of replacement lambs (see paragraph 6.2).

Sufficient staff and resources to carry out the programme were made available in the AC visited.

### 6.2 IMPLEMENTATION OF THE APPROVED EMERGENCY VACCINATION PROGRAMME

The vaccination programmes have been adapted to the changing epidemiological situation.

The variations observed in the time period completing the double vaccination (initial and booster doses) might prolong the duration of the vaccination campaign over the deadline set by the CCA.

The storage condition for the vaccines were adequate.

Despite the fact that documents to be used at all stages of the campaign were available and that they were generally filled correctly, a general overview of the flow of vaccines sent to the storage centres and the number of doses actually withdrawn by the AVs and applied in the field was not available in the ACs visited.

The lack of uniform approach in the vaccination of replacement lambs does not guarantee that all eligible animals are vaccinated and it is not in compliance with the obligation stated in the programme.

### 6.3 SUPERVISION OF THE VACCINATION PROGRAMME , NOTIFICATION AND REPORTING PROCEDURES

A system for supervision from the LVUs to the public and private associations delegated for the implementation of the programme and of their AVs is in place.

Considering that the implementation of the programme has been not uniform and that in the various zones the onset of the vaccination for the serotypes 1 and 8 did not take place at the same time, it is difficult to analyse the information provided

Despite the fact that every single operation is recorded, the lack of organized, updated, well presented information at the AC level does not allow a proper and detailed appraisal of the degree of implementation of the programme in the field. As a consequence, the tables organized by the CCA that have been made available to the Commission and to the mission team contained some discrepancies and were not fully auditable.

The lack of organized, consistent and auditable data at national level does not allow, at this stage of implementation, a complete evaluation of the degree of achievement of the

objectives foreseen in the programme presented to the Commission.

### 6.4 MONITORING AND SURVEILLANCE AND NOTIFICATION OF OUTBREAKS

The activities related to passive clinical surveillance, serological and entomological surveys have been carried out as required by Article 4 of Commission Regulation (EC) No. 1266/2007. However, no distinction between activities to be carried out in the RZ (monitoring) and outside the RZ (surveillance) has been made, as required by Annex I of Commission Regulation (EC) No 1266/2007.

The sample size of animals to be tested outside the RZ is not in compliance with Paragraph 2.2 of Annex I to Commission Regulation (EC) No 1266/2007.

### 6.5 OVERALL CONCLUSION

National legislation and guidelines are in place for the implementation of the approved vaccination programme at national level . Staff and resources to carry out the programme were made available. Replacement lambs are not regularly vaccinated when they reach three months of age in the ACs visited, which is not in compliance with the obligation stated in the programme.

The lack of organized, updated, well presented information at the AC level does not allow a proper and detailed appraisal of the degree of implementation of the programme in the field. As a consequence, the tables summarized and organized by the CCA than have been made available to the Commission and to the mission team did not allow, at this stage of implementation, a complete evaluation of the degree of achievement of the objectives foreseen in the programme presented to the Commission.

## 7 CLOSING MEETING

A closing meeting was held on 1 December 2008 in Madrid with representatives of the CCA. At this meeting, the main findings and conclusions of the mission were presented by the FVO team. The representatives of the CA took note of the findings and provided the mission team with some additional information

## 8 RECOMMENDATIONS

| No. | Recommendation |
|---|---|
| 1 | To guarantee that the double vaccination (initial and booster doses) will be completed within the given timeframe in all ACs(see Endnote) 8. |
| 2 | To ensure that the information related to the delivery of vaccines, to the vaccinated animals and the doses applied by the AVs will be collected, revised and compiled by the SCV-AC, in order to provide updated, organized, reliable and auditable data at national level to allow a proper evaluation of the degree of achievement of the objectives foreseen in the programme presented to |

| No. | Recommendation |
|---|---|
| | the Commission.(see Endnote) 9 |
| 3 | To guarantee that all eligible animals over three months of age will be vaccinated, as stated in the programme presented to the Commission.(see Endnote) 10 |
| 4 | To guarantee that the programme for monitoring and surveillance activities that will be presented to the Commission will be in accordance with Annex I to Commission Regulation (EC) No.1766/2007. |

The competent authority's response to the recommendations can be found at:

http://ec.europa.eu/food/fvo/ap/ap_spain_8308_2008.pdf

## 9 ENDNOTES

| Concerning | Detail |
|---|---|
| Section 5.1.5 | 1 In their response to the draft report, the Spanish CCA stated that an internal audit, within the scope examined by the mission, as provided for in Council Regulation (EC) No 882/2004, is currently being carried out in the autonomous community of Castile-La Mancha. |
| Section 5.3.2 | 2 In their response to the draft report, the Spanish CCA commented that vaccination in the different LVUs of the autonomous community mentioned was carried out at different times due to its changing epidemiological situation. In the time between the publication of the order and the community inspection, updates and amendments were being made to IT systems that may have given rise to discrepancies in some of the data provided and may have made it impossible to obtain specific information. |
| Section 5.3.2 | 3 In their response to the draft report, the Spanish CCA stated that the difference between the doses delivered by the ministry, those used by the authorised veterinarians and those kept in the vaccine stores corresponded to the doses in the possession of those veterinarians for use the following week. |
| Section 5.3.2 | 4 In their response to the draft report, the Spanish CCA made the following comment: The difference is due to the fact that the first figure, 8 237 000, refers to the doses of vaccine used. The second figure, 6 800 000, is the number of doses applied to animals. The difference of 1 437 000 doses refers to losses during the vaccination campaign, in this case the equivalent of 17%. |
| Section 5.3.2 | 5 In their response to the draft report, the Spanish CCA commented that this stems from the use of different criteria in the interpretation of the data requested in this autonomous aommunity: When this Autonomous Community records animals receiving the second dose, the figure includes those which have completed their vaccination cycle, i.e. those |

| Concerning | Detail |
|---|---|
| | receiving both doses in 2008 and those which received only one dose that year because it is a booster, in that the animals had already been vaccinated the previous year. |
| Section 5.3.2 | 6 In their response to the draft report, the Spanish CCA commented that the autonomous community made a different interpretation when the data were requested. They presented the figures in such a way that animals that received a second dose of vaccine were not entered in the column for the first dose. |
| Section 5.3.2 | 7 In their response to the draft report, the Spanish CCA made the following comments: The difference between the plan and the number of vaccines distributed is due to the fact that, at first, when this autonomous community was asked for its plan, they only had the census of herd numbers for the region, but no account was taken of the fact that this is an autonomous community which takes many animals into its fattening houses and that the doses used to vaccinate those incoming animals would also have to be taken into account. |
| Section 8 | 8 In their response to the draft report, the Spanish CCA explains that a document sent to all the autonomous communities recalls that it is compulsory to comply with the vaccination protocol. |
| Section 8 | 9 In their response to the draft report, the Spanish CCA added that communication from the CCA to the autonomous communities reminds all of these of the need to send in the vaccine coverage data every month. |
| Section 8 | 10 In their response to the draft report, the Spanish CCA observed that the vaccination programme lays down the obligation to vaccinate animals over 3 months of age, but it does not set any deadline for vaccinating them. |

## ANNEX 1 - LIST OF LEGISLATION REFERENCED IN THE REPORT

| Reference | OJ Ref. | Detail |
|---|---|---|
| Directive 2000/75/EC | OJ L 327, 22.12.2000, p. 74–83 | Council Directive 2000/75/EC of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue |
| Decision 2008/655/EC | OJ L 214, 9.8.2008, p. 66–69 | 2008/655/EC: Commission Decision of 24 July 2008 approving the emergency vaccination plans against bluetongue of certain Member States and fixing the level of the Community's financial contribution for 2007 and 2008 |
| Regulation (EC) No 1266/2007 | OJ L 283, 27.10.2007, p. 37–52 | Commission Regulation (EC) No 1266/2007 of 26 October 2007 on implementing rules for Council Directive 2000/75/EC as regards the control, monitoring, surveillance and restrictions on movements of certain animals of susceptible species in relation to bluetongue |
| Directive 64/432/EEC | OJ 121, 29.7.1964, p. 1977–2012 | Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine |
| Directive 82/894/EEC | OJ L 378, 31.12.1982, p. 58–62 | Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community |
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| Regulation (EC) No 1760/2000 | OJ L 204, 11.8.2000, p. 1–10 | Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97 |
| Regulation (EC) No 21/2004 | OJ L 5, 9.1.2004, p. 8–17 | Council Regulation (EC) No 21/2004 of 17 December 2003 establishing a system for the identification and registration of ovine and caprine animals and amending Regulation (EC) No 1782/2003 and Directives 92/102/EEC and 64/432/EEC |
| Regulation (EC) No 1082/2003 | OJ L 156, 25.6.2003, p. 9–12 | Commission Regulation (EC) No 1082/2003 of 23 June 2003 laying down detailed rules for the implementation of Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards the minimum level of controls to be carried |

| Reference | OJ Ref. | Detail |
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