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EXTRACT FROM THE REPORT ON THE FOOD AND VETERINARY OFFICE MISSION

TO FRANCE

FROM 24 TO 28 NOVEMBER 2008

TO EVALUATE THE IMPLEMENTATION

OF THE EMERGENCY VACCINATION PROGRAMME

AGAINST BLUETONGUE

NB. This is a summary translation of part of the original mission report (ref. No: DG(SANCO)/2008-8309). It is intended to assist visitors to this site, but has no official status. Please refer to the full text of the original mission report.

1. Conclusions

1.1. Competent authorities

The roles and responsibilities of the competent authorities and other operators in the vaccination programme are established. The coordination measures needed for the programme to run smoothly are in place. However, given the lack of monitoring procedures, it is not possible to determine whether the programme is proceeding as anticipated.

1.2. Implementation of the vaccination programme

The shortage of vaccines during the vaccination campaign significantly impeded the smooth running of the vaccination programme in France. It is not possible to make an assessment of vaccine supply planning or to determine the role of structural and operational factors in the shortage.
The vaccines are authorised in accordance with Article 8 of Council Directive 2001/82/EC, which allows the use of immunological veterinary medicinal products without an authorisation for placing on the market as a provisional measure in the event of a serious disease epidemic and in the absence of a suitable medicinal product. Nonetheless, the lack of information on the efficacy of the authorised vaccines makes it impossible to assess the level and duration of protection they offer to cows and sheep. Compulsory vaccination of goats is not possible as there is no authorised vaccine for this important species.
The vaccine distribution system was effective in practice.
In view of vaccine availability, the BTV-8 vaccination programme was applied according to detailed procedures. At present there is no clear picture of the programme's degree and precision of application because of limited checks and the length of time required to collect information.
The BTV-1 vaccination programme has neither achieved its aim nor been applied on the basis of this aim, for various reasons:

- delays in delimiting vaccination zones;
- synchronisation with BTV-8 vaccination (a limiting factor);
- exclusion of certain categories of livestock;
- absence of application checks.

The accuracy of checks on the number of animals realistically vaccinated is limited because ONIEP recorded the number of animals and not their identity.

1.3. Follow-up and monitoring programmes

During the period covered by this evaluation, the monitoring system did not comply with either the provisions of Article 4 of Commission Regulation (EC) No 1266/2007 nor with the 2008 bluetongue monitoring and eradication programme approved by Commission Decision 2007/782/EC. Nor did it comply with the emergency vaccination programme approved by Commission Decision 2008/655/EC. The system was not capable of ensuring early detection of new cases of BTV-1 outside of the restriction zones for this serotype and adjacent departments. It did not ensure that the vaccination and movement restriction

measures needed to effectively combat the geographic spread of this serotype were adequately applied.

2. Recommendations

1) To establish procedures to assess the efficacy of official activities carried out as part of the national vaccination programme approved by Commission Decision 2008/655/EC, including making vaccination compulsory, in order to validate correct application of the programme and to establish a final technical report on the technical execution of the monitoring measures, including the results attained during the period from 1 November 2007 to 31 December 2008, in accordance with Article 4(1c) of Commission Decision 2008/655/EC.

2) To ensure that the decision-making procedures for approving manufacturers and identifying vaccine needs and estimated ordering schedules are documented and transparent, allowing Commission experts to access the relevant information and documentation needed to evaluate these aspects, in accordance with Article 6(1) of Commission Decision 1998/139/EC.

3) To establish a marketing authorisation approval schedule for each bluetongue vaccine in consultation with manufacturers, in accordance with Article 5 of Council Directive 2001/82/EC, in order to retain the provisional nature of the temporary authorisations currently in force. To consider the possibility of including all relevant susceptible domestic species under pre-authorisation access, in particular goats.

4) To ensure that recent and detailed information is collected on the numbers and types of animal vaccinated at every stage of the vaccination campaign, and that relevant information is inputted into EU databases (ADNS and BT-NET) in accordance with Articles 3 and 5 of Commission Regulation (EC) No 1266/2007.

5) To put in place a monitoring system, in accordance with both Article 4 of Commission Regulation (EC) No 1266/2007 and the vaccination programme approved by Commission Decision 2008/655/EC.

The competent authority's response to the recommendations can be found at:
http://ec.europa.eu/food/fvo/ap/ap_france_8309_2008.pdf