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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

FRANCE

FROM 20 TO 29 SEPTEMBER 2011

IN ORDER TO EVALUATE THE IMPLEMENTATION OF ANIMAL HEALTH RULES IN RESPECT OF INTRA-UNION TRADE IN CATTLE

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 a footnote.

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) audit in France, which took place between 20 and 29 September 2011.

The purpose of the audit was to evaluate the measures and control systems put in place to give effect to EU animal health requirements concerning intra-Union trade (IUT) in live animals of the bovine species in the framework of Council Directive 64/432/EEC.

Overall, the central competent authority (CCA) has put in place mechanisms aimed at ensuring compliance with EU requirements on IUT of cattle, which are likely to be further reinforced by: a) the complete enactment and enforcement of additional legislation in respect of approval and operation of assembly centres (ACs), and b) the impending roll-out of a new certification system for IUT of live animals. However, in the meantime, significant weaknesses still prevent this system from being fully in accordance with provisions laid down in Directive 64/432/EEC, in particular as regards:

- *Insufficient enforcement of requirements currently in force applicable to ACs involved in IUT of live animals, with a consequent weakening in the application of biosecurity measures and prevention of transmission and spread of endemic diseases, that may remain undetected, and of an exotic disease, in the event of an outbreak;*
- *Current certification arrangements for IUT which rely on the pre-certification carried out by authorised practitioners and on herd health status data whose accuracy, cannot be sufficiently ascertained by certifying officers before issuing the relevant health certificate, and*
- *The significant diversion from and non-compliance with requirements laid down in Annexes A and B to Directive 64/432/EEC in relation to diagnosis of bovine tuberculosis and qualification of the health status in that respect of bovine herds.*

As a consequence, the certification system in place for animals involved in IUT can not sufficiently guarantee that all those animals are always certified in compliance with all requirements laid down in the model certificate included in Annex F to Directive 64/432/EEC.

The report makes a number of recommendations to the French competent authorities (CAs) aimed at rectifying the shortcomings identified and enhancing the implementing and control measures in place.

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Abbreviations and definitions used in this report

Abbreviation	Explanation
AC	Assembly centre
ADAS	Pre-movement health attestation - *Attestation sanitaire à delivrance anticipée*
ANSES	French Agency for Food, Environmental and Occupational Health & Safety – *Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail*
AV	Authorised veterinarian
BDNI	National database for identification and movement data - *base de données nationale d'identification*
BICMA	Department for animal identification and movement control (in SDSPA) - *Bureau de l'identification et du contrôle des mouvements des animaux*
Bovine PPD	Purified protein derivative of *Mycobacterium bovis* Tuberculin
BSA	Department for animal health (in SDSPA) - *Bureau de la santé animale*
CA	Competent authority
CCA	Central competent authority
CIT	Comparative intra-dermal tuberculin test
DDCSPP	Departmental Directorate for social cohesion and protection of the population - *Direction départementale de la cohésion sociale et de la protection des populations*
DGAL	Directorate General for Food - *Direction générale de l'alimentation*
EU	European Union
FVO	Food and Veterinary Office
IFN-γ	Gamma-Interferon assay
IUT	Intra-Union trade
MS	Member States of the EU
OV	Official veterinarian
SDSPA	Sub-Directorate for Animal Health and Welfare (in DGAL) - *Sous-direction de la santé et de la protection animales*
SIGAL	Information system of the DGAL - *Système d´Information de la DGAL*
SIT	Single intra-dermal tuberculin test
TRACES system	Trade control and expert system - integrated computerised veterinary system introduced by Commission Decision 2004/292/EC
VS	Authorised veterinarian – *Vétérinaire sanitaire*

1 Introduction

This audit took place in France from 20 to 29 September 2011, as part of the FVO planned programme for 2011. The audit team comprised two FVO auditors.

The team was accompanied throughout the audit by representatives of the Central Competent Authority (CCA), the Directorate General for Food (*Direction générale de l'alimentation* - DGAL), in particular by representatives of the departments involved in the controls covered by this audit, namely, the Department for animal identification and movement control (*Bureau de l'identification et du contrôle des mouvements des animaux* - BICMA) and the Department for animal health (*Bureau de la santé animale* – BSA) of the Sub-Directorate for Animal Health and Welfare (*Sous-direction de la santé et de la protection animales* - SDSPA).

An opening meeting was held on 20 September 2011, with the CCA. At this meeting, the objectives and itinerary were confirmed, and additional information required for the satisfactory completion of the audit was requested.

2 Objectives

The objective of the audit was to evaluate the measures and control systems put in place to give effect to EU animal health requirements concerning IUT in live cattle in the framework of Council Directive 64/432/EEC.

In terms of scope, the audit focused on the control systems in place for IUT in live cattle and their capability to ensure that only eligible animals are consigned to other Member States (MS); particular attention was paid to verify certification assurances in relation to the official health status of their herds of origin.

Insofar as appropriate within the objectives and scope above mentioned, the audit also verified the measures taken to address relevant recommendations of previous audits concerning IUT of live animals (mission DG(SANCO)/8152/2006) and traceability of bovine fresh meat and products derived thereof (mission DG(SANCO) 2010-8506).

In pursuit of those objectives, the following sites were visited and meetings held:

Meetings/visits			**Comments**
Competent authorities	National	**8**	Opening and closing meetings with the CCA. Meetings with representatives of the DDCSPP in the six *départements* visited (Rhône, Saône-et-Loire, Côte d'Or, Aveyron, Dordogne and Haute-Vienne).
	Regional		
Assembly centres		**7**	ACs in five of the six *départements* visited (none in Dordogne)
Holdings		**3**	Three cattle herds (in Rhône, Côte d'Or and Dordogne)
Slaughterhouses		**3**	Three slaughterhouses in two of the *départements* visited (Dordogne and Haute-Vienne)

3 Legal Basis

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

Full legal references are provided in Annex 1. Legal acts quoted in this report refer, where applicable, to the latest amended version.

4 BACKGROUND

A description of the organisation and functioning of the French competent authorities (CAs) in the context of the scope of this audit can be found in the country profile for France published at the following address:

http://ec.europa.eu/food/fvo/country_profiles_en.cfm

More specific details on the CAs responsible for official controls in relation to the system for cattle identification and registration can be found in the previous FVO audit report on traceability of bovine fresh meat and products derived thereof (mission DG(SANCO) 2010-8506). A copy of the report of that audit, together with the response of the CAs to the report recommendations, is accessible at:

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=2546

Additional information that is worth highlighting within the scope of this audit is:

- The French national database for identification and movement data of bovine animals (*Base de données nationale d'identification* - BDNI), that was created in 2000, was considered fully operational from 2 September 2001 according to Commission Decision 2001/399/EC.
- According to Commission Decision 2003/467/EC, the cattle herd in France has a status of officially free of bovine tuberculosis, bovine brucellosis and enzootic bovine leukosis.
- Commission Decision 2004/315/EC approves the French surveillance network system for bovine holdings implemented in accordance with Article 14 of Directive 64/432/EEC.

France is a significant player in the area of IUT of live cattle as during 2010 more than 1.3 million cattle were consigned to other MS, mainly Italy (74%) and Spain (20%); data for the first half of 2011 indicate a similar level of trade. According to representatives of the DGAL, during 2010 they received very few notifications from other MS in relation to anomalies found in consignments of cattle dispatched from France (112, mostly from Italy).

5 FINDINGS AND CONCLUSIONS

5.1 ASSEMBLY CENTRES

5.1.1 Legal requirements

Article 2 (2)(o) of Directive 64/432/EEC defines ACs and indicates that they must be approved for trading purposes and meet the requirements laid down in Article 11 therein.

Article 11 of Directive 64/432/EEC lays down conditions and requirements:

- to be fulfilled by ACs in order to be approved by the CA;
- to be complied with by the owner or person in charge of the AC concerning the type of information to record on a register or a data base and retain for a minimum period of three years;
- that determine that the CA shall issue an approval number to each approved AC and keep up to date a list of approved ACs and their approval numbers and make it available to the other MS and to the public;
- that determine that the CA shall ensure that, when operating, ACs have sufficient approved

veterinarians to carry out all duties, and

- that determine that the CA may suspend or withdraw approval of an AC in the event of failure to comply with this Article or other appropriate provisions of the said Directive, or of Regulation (EC) No 1/2005 or other EU veterinary legislation listed in Chapter I of Annex A to Directive 90/425/EEC.

5.1.2 Findings

According to representatives of the BICMA, they were in the process of introducing new measures in relation to approval and control of ACs involved in IUT of live animals. This can be considered as a satisfactory response to address one of the recommendations contained in the audit report of mission DG(SANCO) 2010-8506; however, the following points are worth highlighting in this respect:

- The above mentioned measures include a new legal framework (including a *décret* and an *arrêté*) in relation to approval of ACs involved in IUT of live animals; however, pending introduction of the remaining implementing pieces of that legislation (the *arrêté*), the system still operates on the basis of previous legislation, which does not fully transpose all the requirements laid down in Article 11 of Directive 64/432/EEC[1]. This limits the enforcement powers of the local veterinary services (*Direction départementale de la cohésion sociale et de la protection des populations* – DDCSPP). According to several representatives of the DDCSPPs met, the new legislation will allow them to take more effective enforcement measures easier and quicker than before.
- Approval of most ACs dates back to many years ago but despite their re-approval and regular official control, the following problems were still present in many of them:
    - Facilities were difficult to clean and disinfect and there were no procedures for this or they had only recently been introduced as a result of inspections carried out by the DDCSPP. As a consequence, in most ACs visited, biosecurity conditions such as accumulation of bedding and manure for weeks and even months, could not be considered adequate to prevent transmission of contagious diseases between groups of animals kept in the AC at consecutive times as part of different consignments. Moreover, in many ACs visited there were no appropriate isolation facilities for sick animals and in one of them, sick animals (with leg injuries) had been kept for more than three months in pens next to those used for animals ready to be dispatched.
    - Animals were kept in the ACs in many cases longer than the maximum six days required by Directive 64/432/EEC[2].
    - In most cases, facilities of the ACs were used both for IUT and the national market[3]. Sometimes they were used as dealers' premises and in some cases there were even animals from a cattle herd not sufficiently separated from animals intended for IUT. This has already been underlined as a problem in the audit report of mission DG(SANCO) 2010-8506.

1 *In their comments to the draft report, the CA note that this legislation, which was further modified to take on board the observations and comments of the audit team, entered into force before the end of 2011 and the reception of the draft audit report by the French authorities.*

2 *In their comments to the draft report, the CA note that they have always been transparent with the Commission on this issue and have repeatedly indicated the difficulties encountered with a recurrent percentage of animals (approximately 5%) exceeding the maximum limit of six days by a few days. They added that several letters have been sent to the European Commission (DG SANCO) proposing that this rule be changed.*

3 *In their comments to the draft report, the CA note that a new legal requirement has been introduced to approve ACs operating for the national market so that they will have to comply with the same requirements necessary for IUT.*

- According to representatives of the BICMA, the BSA and the DDCSPPs met, all cattle arriving at an AC must be accompanied by the same pre-movement health attestation attached on their passports (*Attestation sanitaire à delivrance anticipée* - ASDA). ASDAs must certify the highest health status of the holdings of origin; i.e. officially free of tuberculosis, brucellosis and enzootic bovine leukosis, regardless of the final destination of the animals being in France or in other MS. Therefore, they stressed that all animals present at one AC at a certain time would always comply with the required health status for IUT. However, the following was noted by the FVO audit team:
    - as described in section 5.2.2 below, there are occasions where attestations contained in the ASDA concerning bovine tuberculosis are not in compliance with EU requirements in respect of maintenance of the officially free status of the holdings of origin;
    - animals destined for the national market can be kept at the ACs for up to 30 days, whereas those intended for IUT must be there only for a maximum of six days. As a consequence, while at the AC, cattle destined for IUT can be mixed with many different animals (including small ruminants) belonging to many different batches destined for the national market, whose respective 30 days stays may overlap to each other's and thereby, increase the risk of transmission of diseases to the animals destined for IUT. This is in contravention to preventative measures embedded in the Articles of Directive 64/432/EEC that are aimed at reducing as much as possible those risks of disease transmission, such as:
        - the limited period of time (six days) for the animals destined for IUT to stay in ACs;
        - the requirement that animals destined for IUT must at no time between leaving the holding of origin and arriving at destination come into contact with cloven-hoofed animals other than animals that have the same health status, and
        - the requirement to clean and disinfect the facilities of ACs before they are used for IUT.
    - the above mentioned was even less in compliance with those requirements in those cases where facilities of ACs were used as dealers' premises, and even as a cattle herd, where:
        - in some cases no consideration had been given to dedicate any of those facilities exclusively for IUT;
        - when this had been done, proper separation arrangements where not in place and,
        - in general, little if any cleaning and disinfection were ensured before any of the ACs were used for IUT.
- For some of the ACs visited, it was common practice that animals pass through more than one AC before being dispatched to another MS. According to representatives of the BICMA, implementation of the requirement limiting the pass of animals through only one AC sometimes met with difficulties in the field and they added that the DGAL had sent several letters to the European Commission proposing changes to this rule;

- ACs do not keep adequate records of means of transport passing through their facilities, whether bringing animals or collecting animals for the national market, which significantly undermines traceability of these operators in case of necessity[4].
- In the majority of the ACs visited, many of the shortcomings described here above had been recently found by staff of the DDCSPPs during their latest inspections; recommendations to increase compliance of those ACs had been provided to their operators and in a few cases action plans had already been submitted and even implemented. In other few cases, the FVO audit team could see correspondence sent by operators where they expressed their reluctance to abide by the rules; as mentioned above, some representatives of the DDCSPPs stressed the fact that only now when the new set of upcoming rules finally enter into force, they will be in a position to fully enforce EU requirements on ACs involved in IUT.

5.1.3 Conclusions

The CCA have recently introduced measures to improve the approval system of ACs involved in IUT of bovine animals in accordance with Article 2 (2)(o) of Directive 64/432/EEC; however, pending its full and effective implementation[5], the system currently in place can not yet ensure that all ACs always meet the conditions and requirements laid down in Article 11 of the said Directive, in particular that they:

- have adequate facilities dedicated exclusively for this purpose when used as an AC;
- are cleaned and disinfected before use for IUT and have appropriate equipment for cleaning and disinfecting of their facilities and appropriate storage area for litter and manure;
- have appropriate isolation facilities for sick animals;
- are regularly inspected in order to ascertain that the requirements for approval continue to be fulfilled, and
- are subject by the CA to effective and dissuasive enforcement procedures in the event of failure to comply with requirements laid down in the above mentioned Article.

5.2 HEALTH STATUS OF THE HERDS OF ORIGIN

5.2.1 Legal requirements

Article 6(2) and (3) of Directive 64/432/EEC lays down conditions and requirements in relation to the health status of the herds of origin that bovine animals involved in IUT must comply with. Notwithstanding specific derogations indicated in the said Article, those animals must come from bovine herds that are considered officially free for bovine tuberculosis, bovine brucellosis and enzootic bovine leukosis.

Annex A to Directive 64/432/EEC lays down conditions for cattle herds and MS to achieve and maintain free health status with respect to bovine tuberculosis and bovine brucellosis. Chapter 1 of Annex D thereto lays down equivalent conditions concerning enzootic bovine leukosis.

Annexes B, C and D (chapter 2) to Directive 64/432/EEC lay down provisions in accordance with which tests must be carried out on bovine animals and herds in order to ascertain their health status

4 *In their comments to the draft report, the CA note that requirements for AC to keep records on means of transportation passing through their facilities are now included in the new legislation applicable to all ACs.*

5 *In their comments to the draft report, the CA note that the new legal framework for ACs has been implemented and covers all the requirements referred to in Article 11 of Directive 64/432/EEC, and that they will concentrate their efforts in the coming months in guaranteeing implementation and compliance with those new national requirements.*

for bovine tuberculosis, bovine brucellosis and enzootic bovine leukosis.

5.2.2 Findings

Within the limitations of the scope of the audit, the audit team did not find any shortcoming in relation to official controls and surveillance of bovine brucellosis, enzootic bovine leukosis, bluetongue and infectious bovine rhinotracheitis that would bear any important risk to IUT of live cattle.

In addition and even if the present audit did not have as one of its objectives the thorough assessment of the official controls and surveillance of bovine tuberculosis in the whole territory of France, the FVO audit team visited the two *départements* with the highest incidence of bovine tuberculosis over the recent years, Côte-d'Or and Dordogne (hereafter referred to as high risk areas), where several issues have been found which are worth being underlined since they involve non-compliances with EU requirements in this respect and in the context of IUT. These discrepancies include:

- The CCA have agreed to allow the subjective reading of the single intra-dermal tuberculin test (SIT) in most cases; i.e. there is no measuring of the skin fold at the time of injecting the tuberculin and the reading of the test is based on palpation. Measuring is only done if authorised veterinarians (*vétérinaire sanitaire* - VS), who are practitioners who have been delegated this task by the DDCSPP and who have been selected for carrying out these official controls by the operator, consider it necessary (clear signs of reaction). As a sign of the scant attention given by VSs to the practice of properly measuring the results of the SIT, the FVO audit team found cases of positive SIT where there was no proof or record that any measuring had taken place. Unlike the SIT, when the comparative intra-dermal tuberculin test (CIT) is used, measuring is obligatory at both the time of injection and when reading the test 72 hours later; the FVO audit team found that this practice had been followed in the cases checked during this audit.
- According to representatives of the BSA, a reflection on that matter was at the time of this audit ongoing within their services as:
    - preliminary results of a study promoted by the consultative risk analysis body for the DGAL, the French Agency for Food, Environmental and Occupational Health & Safety (*Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail* - ANSES) on the sensitivity of this system, appeared to indicate that a significant number of inconclusive cases were being misinterpreted as negative and, as a consequence, no further testing to verify the possible presence of the disease is carried out in the relevant animals or the involved cattle herds[6];
    - evidence gathered all over France, as underlined on reports of the ANSES, indicate that in many cases there is a common practice, well known amongst practitioners, of not even using palpation to test the possible reaction to the SIT, and only doing a visual check from the distance of the possible reaction in the animals;
    - representatives of the DDCSPPs in the high risk areas above mentioned added the following point; before they took strong action due to the obvious worsening of the

6 *In their comments to the draft report, the CA note that the study will be further complemented by another one covering additional issues in the same context and that some of the results obtained so far indicate that there is a non-negligible risk of misclassification for negative cases into inconclusive ones, and vice versa, but a negligible one for misclassifying positive cases into negative or inconclusive ones. The CA stress the fact that this level of uncertainty is not taken into account in EU legislation and that inconclusive results may always lead to losing of the herd health status when this uncertainty might well be solved resorting to a test such as the IFN-γ.*

situation around 2006, they confirmed that practitioners were not reporting weak positive or inconclusive results with the SIT and they were not measuring it, i.e. no objective proof of those checks was recorded anywhere, so that they avoided the serious disruption that a suspicion would have on farmers' businesses. Once the new systems described below were introduced, since disruption was 'shortened' significantly with the new procedures for reinstating the free herd status, notifications increased rapidly, and

- analysis carried out by experts consulted by the DGAL on the epidemiological situation in geographical areas neighbouring high risk areas in Dordogne has raised concerns over the likely widespread practice of not notifying inconclusive or positive results with the SIT, as in the same areas tuberculosis cases had been detected by slaughterhouse surveillance, i.e. the disease has been present in the area as these are normally animals that have been infected for a long time. These experts drew the attention of the DGAL to the importance of not underestimating the risks associated with the transmission of tuberculosis and the need to raise awareness and provide additional training to ensure that surveillance of the disease, both concerning performance of the SIT and in slaughterhouses, was carried out properly.

- The gamma-interferon assay (IFN-γ) is used as a tool to decide on the official status of a herd and not only as a complementary test to detect latent tuberculosis in more animals in a suspected or confirmed case. Its use is authorised by the DGAL in the high risk areas and some other *départements* with a similar epidemiological situation to re-qualify herds as free in case of animals with unresolved status. For doing that, the BSA and the DDCSPP have decided to use two IFN-γ, the standard one with the bovine purified protein derivative of *Mycobacterium bovis* Tuberculin (so called, bovine PPD) and another one using two recombinant antigens (ESAT-6 and CFP-10).
- The combination of the SIT and the IFN-γ is interpreted in series, i.e. both must give positive results to consider the animal a real reactor; therefore, the objective is to increase the specificity of the diagnosis to the detriment of its sensitivity because, according to representatives of the CAs, the specificity of the SIT is too low in the epidemiological context they face in the high risk areas[7]. In addition, in the large majority of cases if one of the two types of IFN-γ is negative, mainly the recombinant one, the presence of tuberculosis is excluded and the officially free status reinstated.
- In cases when there had been a positive reactor in the herd or a suspicion at an slaughterhouse, the audit team found that sometimes the free herd status had not been suspended at all and, if suspended, it had been reinstated shortly afterwards (some even after 72-96 hours and the majority after seven days) once: a) negative results were obtained on tests with the IFN-γ on blood samples taken from reactors at the time of reading of the SIT, or b) negative PCR results were obtained on samples of ganglia taken in the slaughterhouse at time of suspicion or after slaughtering a reactor animal.
- In some cases, even after both IFN-γ had given positive results, if the PCR, as explained above, gave negative results; the free status of the herd had been reinstated immediately. These approaches concerning reinstatement of the herd status are in contradiction with provisions laid down in Directive 64/432/EEC requiring that the suspension of the officially tuberculosis-free status may only be lifted following a test of all animals over six weeks of

7 *In their comments to the draft report, the CA note that the arrangements with the IFN-γ were implemented in order to increase overall sensitivity to detect outbreaks on farms rather than at the slaughterhouse, an objective that was achieved. They add that the aim of this strategy was to take into account the co-existence of specific minority tuberculin reactions and non-specific majority tuberculin reactions.*

age with negative results at least 42 days after the removal of the reactor animal.

- In some relevant cases, in particular in the areas in Côte-d'Or with high incidence of the disease, controls on tuberculosis are only applied on animals over 12 months of age. Likewise, in Dordogne, when an infection is confirmed, steps to follow for re-qualifying herds only check animals over 6 months of age. Both approaches are also in contradiction with provisions laid down in Directive 64/432/EEC requiring that: a) qualification of officially tuberculosis-free herds requires testing of all animals older than six weeks of age, and b) the officially tuberculosis-free status of a herd is to remain withdrawn until all animals over six weeks of age have reacted negatively to at least two consecutive tuberculin tests, the first no less than 60 days and the second no less than four months and no more than 12 months after the removal of the last positive reactor.
- In general, data provided on the number of suspicious lesions found in slaughterhouses all over France show that the contribution of this surveillance to the detection of new cases of bovine tuberculosis varies significantly depending on the level of awareness among technicians and the official veterinarian (OV) responsible for *post-mortem* inspection. For instance, in the areas heavily infected above mentioned, there has been a significant improvement over the last two years, simultaneously to the increase of detection of outbreaks in these areas. This does not mean that the infection is more widespread now than five years ago, but that surveillance at both herd level (intensification and better quality of the SIT or use of the CIT) and at slaughterhouses, has improved dramatically as a consequence of the initiatives to raise awareness and levels of training promoted by the BSA and the relevant DDCSPPs.
- According to representatives of the BSA, this intensified training initiatives had not yet been widespread throughout France, even if plans in that respect had been discussed and were foreseen to be widely implemented in the short term. Moreover, no specific audit initiative had been carried out by the CCA to verify whether this fundamental component of bovine tuberculosis surveillance is being effectively implemented all over France. It is worth mentioning in this respect that in many areas of France slaughterhouse surveillance is the only kind of bovine tuberculosis surveillance carried out, because no SIT at all is carried out on the bovine population or the interval between SIT varies from two to four years in most *départements* where it is still used (see also the second indent above).
- As a consequence of the shortening of the period to reinstate the free status in previously suspected herds, animals can enter IUT from herds which had not kept their status in accordance with provisions laid down in Directive 64/432/EEC. The FVO audit team found evidence that this had actually happened.
- The CCA defended their decision to approach the problems found with bovine tuberculosis, as described above, because of the different epidemiological situations encountered in the affected areas, which according to them could not be addressed with the diagnostic tools and protocols prescribed by Directive 64/432/EEC, and on the basis of a risk analysis done at local level on a case by case basis in consultation with representatives of the ANSES.
- However, the use of the combination of diagnostic tools explained above and the decision making pathways followed by the DDCSPPs depending on the results of these tests was already the basis to take official decisions on the health status of herds without having been yet fully validated for the specific epidemiological context in which they are used. Moreover, despite the obvious impact that this methodology has both on certification of live animals for IUT (see 5.3) and the possible spread of bovine tuberculosis to other regions of France; this diversion from requirements laid down in Directive 64/432/EEC had, at the time of the audit, not been shared with the European Food Safety Authority, the Commission or

the other MS.

5.2.3 Conclusions

The CCA can largely ensure that official controls and surveillance of bovine brucellosis, enzootic bovine leukosis, bluetongue, as far as cattle are concerned, and infectious bovine rhinotracheitis are carried out, whenever appropriate and required, in accordance with provisions laid down in EU legislation on IUT of cattle. However, the CCA are not in a position to ensure that:

- all herds of origin of cattle involved in IUT are officially free of bovine tuberculosis as required by Article 6(2)(a) and (3) of Directive 64/432/EEC;
- all cattle herds achieve and maintain their free health status with respect to bovine tuberculosis always in accordance with conditions laid down in Annex A to Directive 64/432/EEC, and
- tests in order to ascertain herd health status for bovine tuberculosis are carried out on cattle and herds always in accordance with provisions laid down in Annex B to Directive 64/432/EEC.

Within the limitations of the geographical coverage and scope of this audit, weaknesses have also been identified with regard to: a) attention given by the CCA to ensure adequate levels of training and awareness amongst those responsible for performing SIT and bovine tuberculosis surveillance at slaughterhouses in areas of France other than those where the disease has been identified as a significant problem, and b) verification of effectiveness of both pillars of this surveillance all over France in the context of the recrudescence of the disease in those specific areas. This casts doubts on the overall sensitivity of the surveillance system for bovine tuberculosis nationwide and its capability to detect a possibly low incidence of the disease in some regions of the country other than those where the disease has already been identified as a problem in recent years.

5.3 Certification for intra-Union trade

5.3.1 Legal requirements

Article 3 of Directive 64/432/EEC requires that each MS shall ensure that only animals that fulfil the relevant conditions laid down in this Directive are sent from its territory to that of another MS. This article also lays down the following requirements for bovine animals covered by this Directive:

- they must be subjected to an identity check, and to a clinical inspection within 24 hours of departure by an OV and show no clinical sign of disease, and
- they must be identified in accordance with the provisions of Regulation (EC) No 1760/2000.

Article 4 of Directive 64/432/EEC requires that bovine animals covered by this Directive must at no time between leaving the holding of origin and arriving at destination come into contact with cloven-hoofed animals other than animals that have the same health status.

Article 5 of Directive 64/432/EEC requires that:

- bovine animals covered by this Directive must be accompanied during transportation to destination by a health certificate conforming to model 1 set out in Annex F to this Directive;
- the CA shall ensure that the health certificate is drawn up by the OV after inspections, visits and controls as provided by this Directive, and
- the OV for the AC shall carry out all necessary checks on animals arriving there.

Council Directive 96/93/EC describes the general principles for certification.

5.3.2 Findings

In relation to the certification process for consignments of live animals sent to other MS, the audit team observed the following:

- At the moment, consignments sent from ACs are pre-certified by a VS. Responsibilities of the VS include verification of the identification of the animals and of documentation indicating their residence in a single holding of origin for at least 30 days and the health status of their holdings of origin. They must also verify that animals have not been at the AC for more than six days and carry out the physical checks before the animals are loaded.
- This pre-certification follows an administrative verification carried out by an OV of the DDCSPP, including checks to ensure that the health status indicated on the ASDA is still applicable, who will eventually sign the certificate accompanying the animals and introduce the relevant data in the TRACES system.

Some of the weaknesses observed in relation to the above mentioned tasks are that:

- The VS responsible for physical checks on animals intended for IUT do not verify the health status of other animals kept in the same facilities at the AC (see 5.1.2). Likewise, the VS is not responsible for verification of compliance by the AC with requirements on cleaning and disinfection or exclusive use of facilities for IUT;
- Verification of the residence at the holding of origin and of their health status is based on information included in the ASDA accompanying the animals on their arrival at the AC. This is based both on the notification of movements to the BDNI, and on the health status recorded for the holding of origin in the information system of the DGAL keeping animal health data on the animal populations (*Système d'Information de la DGAL* - SIGAL). The statements as incorporated in the up-to-date ASDA include sanitary information on the holding of origin that is valid for 30 days after it has been signed by the keeper of the animal. On occasion, it can happen that not all movements of the animals are included in the BDNI, because the reporting period for a recent one has not expired yet, or that the health status of a herd has been granted not in accordance with EU requirements (see 5.2.2); neither of these cases can be verified by the VS or the OV of the DDCSPP;
- In several cases, VSs had issued pre-certificates without ensuring that the animals had been for a maximum of six days at the AC (see 5.1.2);
- On-the-spot verification of the VS is responsibility of the DDCSPP; this is done usually once a year and in most cases no problem had been found.
- According to the CCA, the certification system will change shortly as new legislation and implementing tools had just been approved and entered into force. In the new system, the current figure of the VS will change and appointed certifying officers will get the official mandate to carry out the whole process of certification, including access and responsibilities in relation to the TRACES system. This will become an official task for the appointed veterinarians and they will be paid directly by the State in accordance with pre-fixed amounts depending on the time dedicated to it.
- Initial trials with the new system have already started and, as witnessed by the FVO audit team, show promising results; however, the operation of the system could not be verified in its definitive format as it still needs further refinement and adaptation to the realities of the ACs and the new role of the veterinarians. According to veterinarians met who had started to operate according to the new procedures as part of the trials or who could shortly be granted

this task, and as confirmed by representatives of the CCA and the DDCSPP visited met, introduction of the new system will require intensive additional training in relation to their new tasks before the system can be fully operational. According to the CCA, they foresee a gradual implementation of the new system so that it can be fully operational in the whole of France before the end of 2012.

5.3.3 Conclusions

The CCA can largely ensure that cattle involved in IUT are:

- subject to an identity check, and to a clinical inspection within 24 hours of departure by a VS who has been delegated these tasks by the CAs and show no clinical sign of disease;
- identified in accordance with the provisions of Regulation (EC) No 1760/2000, and
- accompanied during transportation to destination by a health certificate conforming to model 1 set out in Annex F to Directive 64/432/EEC.

However, some shortcomings have been identified in relation to the chain of IUT certification, in particular as regards drawing of health pre-certificates by the VSs and the final issuing of the IUT certificates by OVs, namely:

- all inspections, visits and controls provided for by Articles 4 and 5 of Directive 64/432/EEC are not always fulfilled completely by the VSs before pre-certifying consignments of cattle for IUT, as non-compliances such as those described in section 5.1 regarding operation of ACs are often not considered relevant from the disease prevention point of view so as to prevent risks of transmission of diseases through IUT, and
- OVs responsible for issuing of IUT health certificates on the basis of pre-certificates made by VSs and herd health status data contained in the SIGAL database can not ascertain the accuracy of that information so as to ensure that only animals that fulfil the relevant conditions laid down in Directive 64/432/EEC are sent from France to another MS, as required both by Article 3 of the said Directive and by certifying rules laid down in Directive 96/93/EC.

6 Overall Conclusions

The CCA has put in place mechanisms aimed at ensuring compliance with EU requirements on IUT of cattle, which are likely to be further reinforced by: a) the complete enactment and enforcement of additional legislation in respect of approval and operation of AC, and b) the impending roll-out of a new certification system for IUT of live animals. However, in the meantime, significant weaknesses still prevent this system from being fully in accordance with provisions laid down in Directive 64/432/EEC, in particular as regards:

- Insufficient enforcement of requirements currently applicable to ACs involved in IUT of live animals, with a consequent weakening in the application of biosecurity measures and prevention of transmission and spread of endemic diseases, that may remain undetected, and of an exotic disease, in the event of an outbreak;
- Current certification arrangements for IUT which rely on the pre-certification carried out by authorised practitioners and on herd health status data whose accuracy cannot be sufficiently ascertained by certifying officers before issuing the relevant health certificate, and
- The significant diversion from and non-compliance with requirements laid down in Annexes A and B to Directive 64/432/EEC in relation to diagnosis of bovine tuberculosis and qualification of the health status in that respect of bovine herds.

As a consequence, the certification system in place for animals involved in IUT can not sufficiently guarantee that all those animals are always certified in compliance with all requirements laid down in the model certificate included in Annex F to Directive 64/432/EEC.

7 Closing Meeting

A closing meeting was held on 29 September 2011 with the CCA. At this meeting, the main findings and preliminary conclusions of the audit were presented by the audit team. The representatives of the CCA did not express disagreement with the findings and conclusions presented.

The CCA expressed their undertaking to both take action to improve the level of compliance of ACs with EU requirements, and to inform within the shortest possible deadline the Commission services in detail of the current approach taken to address the problems encountered with the management of bovine tuberculosis in certain areas of France.

8 Recommendations

The CCA is invited to provide details of the actions taken and planned, including deadlines for their completion ('action plan'), within 25 working days after receipt of the report, aimed at addressing the recommendations set out below:

N°.	**Recommendation**
1.	To ensure that approval of ACs involved in IUT of bovine animals and official controls thereon are fully and effectively implemented so that the system in place can provide sufficient guarantees that those establishments always meet the conditions and requirements laid down in Article 11 of Directive 64/432/EEC.
2.	To ensure that in the event of failure to comply with requirements laid down in Article 11 of Directive 64/432/EEC, ACs are subject to effective and dissuasive enforcement procedures in accordance with Articles 54 and 55 of Regulation (EC) No 882/2004.
3.	To ensure that all herds of origin of cattle involved in IUT are officially free of bovine tuberculosis as required by Article 6(2)(a) and (3) of Directive 64/432/EEC.
4.	To ensure that all cattle herds achieve and maintain their free health status with respect to bovine tuberculosis always in accordance with conditions laid down in Annex A to Directive 64/432/EEC and, in particular, that for those areas of France where bovine herds are dispensed with tuberculin testing or the interval between routine testing is not annual, adequate consideration is given to guarantee that all bovine animals slaughtered are examined for lesions of tuberculosis and any such lesions are submitted to a histopathological and bacteriological examination for evidence of tuberculosis.
5.	To ensure that tests in order to ascertain herd health status for bovine tuberculosis are carried out on cattle and herds always in accordance with provisions laid down in Annex B to Directive 64/432/EEC.

N°.	Recommendation
6.	To ensure that all inspections, visits and controls provided for by Articles 4 and 5 of Directive 64/432/EEC are always fulfilled completely by authorised veterinarians before pre-certifying consignments of cattle for IUT, so as to prevent risks of transmission of diseases through IUT.
7.	To ensure that OVs responsible for issuing of IUT health certificates can always ascertain the accuracy of all attestations contained therein so as to ensure that only animals that fulfil the relevant conditions laid down in Directive 64/432/EEC are sent from France to another MS, as required both by Article 3 of the said Directive and by certifying rules laid down in Directive 96/93/EC.

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2011-6043

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of 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
Reg. 1/2005	OJ L 3, 5.1.2005, p. 1-44	Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97
Reg. 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
Dir. 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
Dir. 90/425/EEC	OJ L 224, 18.8.1990, p. 29-41	Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra- Community trade in certain live animals and products with a view to the completion of the internal market
Dir. 96/93/EC	OJ L 13, 16.1.1997, p. 28-30	Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products
Dec. 2003/467/EC	OJ L 156, 25.6.2003, p. 74-78	2003/467/EC: Commission Decision of 23 June 2003 establishing the official tuberculosis, brucellosis, and enzootic-bovine-leukosis-free status of certain Member States and regions of Member States as regards bovine herds

Legal Reference	Official Journal	Title
Dec. 2004/292/EC	OJ L 94, 31.3.2004, p. 63-64	2004/292/EC: Commission Decision of 30 March 2004 on the introduction of the Traces system and amending Decision 92/486/EEC
Dec. 2001/399/EC	OJ L 140, 24.5.2001, p. 69-69	2001/399/EC: Commission Decision of 7 May 2001 recognising the fully operational character of the French database for bovine animals
Dec. 2004/315/EC	OJ L 100, 6.4.2004, p. 43-44	2004/315/EC: Commission Decision of 26 March 2004 recognising the system of surveillance networks for bovine holdings implemented in Member States or regions of Member States under Directive 64/432/EEC