Ref. Ares(2015)5635291 - 07/12/2015

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate F - Food and Veterinary Office

DG(SANTE) 2015-7565 - MR

FINAL REPORT OF AN AUDIT CARRIED OUT IN GERMANY FROM 20 APRIL 2015 TO 28 APRIL 2015 IN ORDER TO EVALUATE THE ANIMAL HEALTH CONTROL SYSTEM IN PLACE FOR BODIES, INSTITUTES OR CENTRES APPROVED IN ACCORDANCE WITH ANNEX C OF COUNCIL DIRECTIVE 92/65/EEC

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

The report describes the outcome of an audit carried out by the Food and Veterinary Office in Germany from 20 to 28 April 2015.

The objective of the audit was to evaluate the effectiveness of the animal health controls in place in relation to bodies, institutes or centres (ABICs) approved in accordance with Annex C to Council Directive 92/65/EEC. Overall, the report concludes that for the German Federal States visited, hereafter, the Länder :

Germany has a system to control animal health in ABICs. There is a variation in the quality and consistency of these official controls in different Länder, mainly due to the absence of documented procedures and limited supervision.

The CAs have limited capacity to demonstrate that they carry out systematic and adequate checks on ABICs, as in many cases they do not have written procedures and officials do not issue reports for the controls done. There is limited assurance that approved ABICs fully meet legal requirements.

Despite weaknesses in the surveillance plans, extensive post mortem investigations together with official controls on animal movements give confidence that suspicion of notifiable diseases will be detected quickly. The ability to trace animals and the professional approach to outbreaks of notifiable animal disease give assurance of the CA capacity to contain the diseases listed in Annex A of Directive 92/65/EEC.

The system in place to import ungulates from ABICs in third countries is robust and a good basis to prevent the entrance of animal diseases through imported animals.

The report makes recommendations to the German authorities to strengthen the official controls in this area.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
ABIC	Approved body, institute or centre: establishment where animal species are kept or bred, either for the display of animals and education of the public, or for conservation of the species, or for basic or applied scientific research or breeding of such animals for such research, and approved according to Directive 92/65/EEC
CA	Competent Authority
EU	European Union
FVO	Food and Veterinary Office
HI-Tier	Identification and Information System for Animals
MV	Federal State of Mecklenburg-Western Pomerania (*Mecklenburg-Vorpommern*)
TRACES	TRAde Control Expert System, a trans-European network for veterinary health notification and certification.

1 INTRODUCTION

This audit took place in Germany from 20 to 28 April 2015, as part of the planned audit programme of the Food and Veterinary Office (FVO). The audit team comprised two FVO auditors and a trainee. At the opening meeting on 20 April the FVO audit team confirmed the objectives and scope of the audit as well as the itinerary.

The FVO audit team was accompanied by representatives from the Federal Office of Consumer Protection and Food Safety, which is the coordinating department for FVO audits taking place in Germany, throughout the mission. Representatives of the CAs of the Länder visited accompanied the audit team during their time in their respective territories.

2 OBJECTIVES AND SCOPE

The objective of the audit was to evaluate the effectiveness of the animal health controls in place in relation to bodies, institutes or centres approved in accordance with Annex C to Council Directive 92/65/EEC and in particular:

• The assurances given by the official controls regarding the compliance of approved bodies, institutes and centres with applicable requirements;

• The standards of animal health surveillance and control measures applied in these establishments in relation to the objectives of applicable legislation;

• The conditions for movements of animals to and from these establishments, and their traceability;

• The specific arrangements in place for the introduction of animals from third countries to approved bodies, institutes or centres.

The operational criteria and performance of the competent authorities in this sector was assessed against the standards laid down in Regulation (EC) No 882/2004.

In view of this objective, the following sites were visited:

Visits	**Number**	**Comments**
Central Competent Authority	2	Opening and closing meetings
Regional and local Competent Authorities	5	Berlin, Hessen and Mecklenburg-Western Pomerania
Approved bodies, institutes or centres	5	
Laboratory carrying out post mortem examinations	1	

3 LEGAL BASIS

The audit was carried out under the general provisions of European Union (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.

A full list of the EU legal instruments referred to in this report is provided in Annex I. EU legal acts quoted in this report refer, where applicable, to the latest amended version.

4 BACKGROUND

This audit is one of a series from the European Commission on this topic. It was selected on the basis that animals traded to and from approved bodies, institutes or centres (ABICs) can carry animal diseases which, transmitted via direct or indirect contact, can have serious consequences for livestock farming, zoo populations and human health (zoonoses).

Article 2 of Directive 92/65/EEC defines ABICs as establishments where animal species are kept or bred for one or more of the following purposes: display of animals and education of the public, conservation of the species or basic or applied scientific research or breeding of animals for the purposes of such research.

Conditions for approval and official supervision of these ABICs are detailed in Annex C to Directive 92/65/EEC and compliance with these conditions should ensure that ABICs have a high animal health status and biosecurity standard.

In general, the intra-Union trade of animals requires a health certificate issued by the competent authority (CA). However, Article 13 of this Directive permits trade in most animals to and from ABICs if they are accompanied by a transport document completed by the veterinarian responsible for the ABIC of origin. In other words, ABICs can exchange animals between themselves in a relatively unrestricted manner if they comply with the Directive.

5 FINDINGS AND CONCLUSIONS

5.1 LEGISLATION AND COMPETENT AUTHORITIES

Legal requirements

Articles 4 to 8 of Regulation (EC) No 882/2004; Article 291 of the Treaty on the Functioning of the European Union.

Findings

5.1.1 Legislation

1. The Federal Regulation on Internal Movements and Import of Animals and Goods transposes Council Directive 92/65/EEC. The Federal Regulation requires ABICs to meet the requirements of Annex C to Directive 92/65/EEC. CA confirmed that Section 7 of the Federal Regulation required any establishment taking part in intra-community

trade to be approved by CA. This goes beyond the requirements of Directive 92/65/EEC.

2. The Federal Regulation on Notifiable Animal Diseases lists the diseases which are notifiable in Germany. CA confirmed that it is through this Regulation that animal keepers must notify CA of suspicion of Annex A to Directive 92/65/EEC diseases. This list does not include psitacosis which is listed in Annex A to Directive 92/65/EEC as a notifiable disease. The Law for the Prevention and Control of Animal Diseases (Animal Health Law), section 4, requires keepers of an animal suspected of a notifiable disease to immediately inform CA.

3. The CA confirmed:
   - Psittacosis was a reportable disease and any laboratory isolating it had to report finding to CA;
   - Germany has no national programmes for diseases listed at Annex B to Directive 92/65/EEC.

5.1.2 Competent authorities

4. The full structure and organisation of the CA, as well as the control system for animal health is described in the country profile for Germany at:
   http://ec.europa.eu/food/fvo/country_profiles/details.cfm?co_id=DE

   At national level, the Federal Ministry of Food and Agriculture (BMEL) has responsibility for policy and Federal legislation relating to animal health. The Länder are responsible for the implementation of official controls to comply with the animal health legislation and the administration can consist of up to three levels:
   - Ministry level – is the supreme Länd authority.
   - Intermediate Länd level – some Länder e.g. Hessen are subdivided into provinces which have an intermediate administrative level between supreme Länd authority and District authorities.
   - District authorities – constitute third administrative level of the Länder and are responsible for delivery of official controls.

5. Responsibility for approval of ABICs varied between Länder visited. District authorities were responsible for the approval procedure in Berlin (Mitte and Lichtenberg Districts). In Hessen (Frankfurt), Intermediate Länd level was responsible for initial approval while in Mecklenburg Vorpommern (MV), the Ministry was responsible for the approval procedure. Following approval, District authorities were responsible for delivery of official controls in ABICs in all cases.

6. In one Länd visited (MV), documented procedures (instructions / guidance) relating to official controls in ABICs were in place and were part of a quality management system (QMS). CA confirmed no documented procedures, which are required by Article

(8)(1) of Regulation (EC) 882/2004, had been issued for official controls performed in ABICs in Frankfurt, Berlin Liectenberg and Berlin Mitte (see also paragraphs 12 and 13) .

7. There is a working group (LAV) for animal health and animal diseases established to facilitate cooperation between Länder - this is an effective mechanism for coordination in line with Article 4(3) to Regulation 882/2004. The minutes reviewed from 2010 and 2011 confirmed that ABICs are sometimes discussed at these meetings, but not often. These minutes solely made reference to a Q fever outbreak in a zoo and the need to have one official check to zoos per annum.

8. A mechanism does exist for the supervision of work performed at District level but there was little evidence of this supervision covering official controls at ABICs which is not in line with Article 8(3)(a) of Regulation (EC) 882/2004 requiring CA to verify the effectiveness of official controls. In Berlin (Mitte), CA confirmed they could not supervise / audit Districts but did receive quantitative reports recording number of inspections and findings carried out by District[1].

Conclusions on legislation and competent authorities

9. There is a framework for delivering official controls in ABICs which are delivered mainly at District level. The absence of documented procedures and limited supervision, in two out of the three Länd visited, leads to a variation in the quality and consistency of official controls delivered in ABICs. The fact that Districts have responsibility for this area and each District has a relatively small number of ABICs makes it difficult for them to build up expertise in this area.

10. The fact that psittacosis is not a notifiable disease in Germany will likely result in a delay in suspending approval of an ABIC should there be a case because there is no obligation to report a suspicion of the disease, only an obligation by laboratory to report a confirmed case.

[1] In their response to the draft report the competent authority noted that in Berlin, monitoring of the districts' supervisory tasks is not carried out by means of technical supervision, but is implemented through a notification obligation, the power to intervene, administrative provisions (currently not covering the area concerned by Directive 92/65/EEC) and the Länd 's common QMS, including a related audit system (currently not covering the area concerned by Directive 92/65/EEC).The number of controls and their outcome are listed by district in the statistical reports.

5.2 APPROVAL OF BODIES, INSTITUTES AND CENTRES

Legal requirements

Article 13 of Directive 92/65/EEC; Annex C to Directive 92/65/EEC.

5.2.1 Procedures and conditions for approval

11. CA confirmed all ABICs in Germany were allocated a unique approval number in accordance with Article 13(2)(d) of Directive 92/65/EEC. Federal level have responsibility for the allocation of these numbers and updating the publicly available list of ABICs. All ABICs visited were approved and documents were made available to FVO team confirming approval status.

12. In one ABIC visited, the CA (Hessen) confirmed they had not made an on-site visit to assess compliance with requirements of Directive 92/65/EEC prior to issuing approval. Instead, they had reviewed documentation e.g. types of animals to be kept, quarantine facilities and how animal by-products were going to be handled and consulted with veterinary colleagues who visited the establishment for other reasons e.g. good laboratory practice. No report was available to record the extent of documentary checks carried out to fulfil the requirements of Annex C to Directive 92/65/EEC.
    In another ABIC, the CA(MV) confirmed they had approved the establishment for simiae and prosimiae only and the most recent approval document dated 14 May 1997- reviewed by the FVO team- indicated approval for primates only.

13. Approach to maintenance of approval varied:
    - In Berlin (Mitte) there was no specific visit to ensure provisions of Directive 92/65/EEC were met in order to maintain approval as required by point (2) of Annex C to Directive 92/65/EEC. CA stated conditions for approval were checked regularly but no documented records of these official control visits to ABIC were available and no complete audit had been carried out on ABIC to date.
    - CA in Hessen had no documented records of official controls carried out in the ABICs visited.

14. The quality and completeness of procedures and documents used to check compliance with approval conditions varied:
    - MV had a comprehensive, version controlled, checklist specifically for ABICs. Completed forms were seen for 2013 and 2014 which, in case of deficiencies, included recommendations.
    - CA in Berlin (Liectenberg) used a rudimentary checklist for maintenance of approval which was completed annually. FVO team reviewed records for 2013 and 2014 which mainly comprised a yes / no checklist on whether tests for specific Annex A diseases had been performed and PMEs had been completed.

Otherwise, there were no documented records available to confirm the provisions of Directive 92/65/EEC had been met.

Findings

5.2.2 Listing of approved bodies, institutes and centres

15. A list of ABICs is publicly available on the website as required by Article 13, 2(d) of the Directive. For the Länder visited, the publicly available list of ABICs (version 29/01/2015) showed Berlin, Hessen and MV, to have three, nine and three ABICs respectively.

Conclusions on approval of bodies, institutes and centres

16. The procedures in place give limited assurance that the initial approval and maintenance of ABIC approval fully meet the requirements of Directive 92/65/EEC. The absence of documented procedures for the delivery of official controls and of complete records of the controls done, prevent the CAs from demonstrating that these controls are carried out systematically to the required standard. It also makes it difficult for the CAs to audit and improve their own interventions in this area.

5.3 DISEASE SURVEILLANCE AND CONTROL MEASURES

Legal requirements

Annex A and C to Directive 92/65/EEC; Decision 2007/598/EC; Chapter 5.9 of the 2013 World Organisation for Animal Health Code.

Findings

5.3.1 Approved veterinarian

17. All ABICs had at least one veterinarian appointed to provide services as required by Directive 92/65/EEC. The CA had no framework in place (Berlin and Hessen) to approve these veterinarians and confirm they possessed the skills necessary for this particular field of animal health – which is not in line with point (1)(g)(i) of Annex C to Directive 92/65/EEC.

5.3.2 Disease surveillance and prevention

18. All ABICs (zoos) visited had disease surveillance plans. These tended to focus on routine health issues e.g. vaccination plans and faecal examination for parasitology.

19. There was a variation between Länder regarding approval of surveillance plans e.g.

- In one district visited (Frankfurt), a detailed vaccination plan had been drafted in co-operation with ABIC.
- In MV, the CA approved the plans.
- In Berlin, Mitte, CA confirmed they had drafted disease surveillance plan in co-operation with ABIC. In Berlin, Lichtenberg, the surveillance plan held by CA was different to that held by ABIC – in the CA copy, the reference to Annex A and B diseases was missing.

20. The majority of plans reviewed by the FVO audit team did reference Annex A diseases and copies of plans were available in district offices visited.

21. In all ABICs visited, animals which died in the establishment were subjected to post mortem examination (PME) as required by Annex C(1)(d)(v) to Directive 92/65/EEC – the main exception being when an obvious trauma was involved. Extensive post mortem reports were available in all ABICs visited (e.g. one ABIC had 331 post mortem examinations performed by external laboratory in 2014) which also confirmed the use of extensive microbiology in an attempt to reach a final diagnosis. For the majority of ABICs, virology was used for exclusion diagnosis e.g. avian influenza and Newcastle disease. In all ABICs visited, these post mortem examinations were undertaken at off- site independent laboratories.

22. One laboratory performing PME on animals from ABICs was then treating their animal-by-products (ABPs) as category 1 and category 2.This is not in compliance with Article 8(a)(iii) of Regulation (EC) 1069/2009 which requires zoo animals to be treated as category 1 animal by-product[2].

23. Active surveillance on exotic species was performed in ABICs visited for some of the Annex A to Directive 92/65/EEC diseases. This included tuberculosis, brucellosis and avian influenza and in many cases was related to animal movements or routine handling of animals.

24. The majority of ABICs considered the threat of avian influenza and adapted surveillance plans to the risk which included the testing of all wild birds found dead. Examples of laboratory reports (Hessen) were available showing negative real-time PCR results for wild birds tested for Influenza A virus. One ABIC (Berlin, Liectenberg) had a contingency plan for avian influenza which included a combination of housing birds or covering open bird cages when housing was not possible.

25. Vaccination against bluetongue had been carried out by some of ABICs visited using inactivated vaccine in line with point (1)(g)(ii) of Annex C to Directive 92/65/EEC. Such vaccines were supplied by CA.

[2] In their response to the draft report the competent authority noted that the animal-by-products of both categories are finally disposed of as if they were category 1 material.

26. One ABIC (Hessen) visited was a laboratory keeping pigs. Its disease surveillance plan was based on the recommendations of the Federation of European Laboratory Animal Science Association. The recommendations are risk based for each species and include lists of diseases where routine monitoring is recommended and other diseases to be monitored on request or when associated with lesions or clinical signs. This included some of the Annex A to Directive 92/65/EEC diseases e.g. classical swine fever, swine vesicular disease and foot and mouth disease.

27. For the two ABIC's visited in Berlin, the CA confirmed they received a copy of every post-mortem examination report and used these to evaluate implementation of the disease surveillance plan.

5.3.3 Disease surveillance and control of bovine, ovine, caprine, porcine animals and equidae

28. The CA confirmed that ABICs keeping domestic bovine, ovine, porcine and caprine animals were registered as a holding and allocated a holding number. Additionally, the requirements of Directive 64/432/EEC and Directive 91/68/EEC applied to these species when kept in an ABIC.

29. Commission Decision 2003/467/EC establishes Germany as being officially tuberculosis, brucellosis and enzootic- bovine leucosis free. The CA confirmed that surveillance of these diseases in ABICs, in domestic cattle, is based on pre-movement testing. The FVO audit team noted that pre-movement testing of domestic cattle originating in an ABIC was carried out consistently in ABICs visited for the three diseases. Certification was also provided for infectious bovine rhinotracheitis and bovine viral diarrhoea status.

30. Following an outbreak of M. bovis (subsp. Caprae) in two Länder (2013) all female domestic cattle in Germany aged over 24 months were tested for tuberculosis on a random sample basis using a simultaneous test and this included domestic cattle kept in ABICs.

5.3.4 Quarantine operations

31. All ABICs visited had quarantine facilities which were stand- alone buildings within curtilage of ABIC.

32. In two of ABICs visited, significant investment had been made in new quarantine facilities. In one, all intake and exhaust air was filtered using a high efficiency particulate arrestance (HEPA) filter and all waste water was treated at 121^{o}C. This same ABIC required all new animals to be quarantined for a minimum period of 30 days irrespective of origin. This included animals originating in another ABIC (no

legislative requirement for quarantine exists for animals moving between ABICs). The other two quarantines visited were, in general, structurally acceptable.

33. Records of observations made during any isolation or quarantine period varied between ABICs. In one ABIC, daily records were available for imported ungulates showing food consumption, animal health observations (none noted as animals were healthy during quarantine) and record of maintenance carried out during period of quarantine. In another, the ABIC had just started keeping a quarantine register so no records were available of observations made for any animal quarantined at this ABIC prior to the FVO audit, which is not in line with the requirements in point (1)(d)(vi) of Annex C to Directive 92/65/EEC. This had not been detected by the official veterinarian.

34. Two CAs (Berlin-Lichtenberg and MV) confirmed they did not have approved procedures for animals coming from non-approved sources as required by Annex C(1)(b) of Directive 92/65/EEC.

5.3.5 Official visits to ABICs

35. The CA issue all intra-union trade certificates from ABICs rather than allowing the approved veterinarians to complete them, thereby increasing the frequency of official veterinarian's presence in ABICs throughout the year. These visits alone do not fulfil the requirements of point 2(a) of Annex C to Directive 92/65/EEC as most of these visits are limited to certification duties.

36. Berlin CA confirmed that, in 2014, one ABIC received 246 inspections with 28 findings and a second ABIC received 82 inspections with no findings. Berlin CA confirmed the majority of these inspections were related to animal movements. CA(MV) visit ABIC at least once per year as required by point 2(a) of Annex C to Directive 92/65/EEC and reports on the official controls carried out were available.

5.3.6 Action in case of suspicion or confirmation of a notifiable disease

37. The CA affirmed there had been two confirmed cases of notifiable diseases listed in Annex A to Directive 92/65/EEC in German ABICs over the previous five years. During the same period there had been no notifications of suspicion of Annex A notifiable diseases.
38. The FVO audit team reviewed one of the confirmed cases, highly pathogenic avian influenza (HPAI) H5N8 (which occurred between January and February 2015) during a visit in Mecklenburg-Western Pomerania. The handling of the case included:
    - Restriction on movement of birds the same day CA was informed of unexpected deaths. All birds were housed or aviaries covered following an ABIC protocol developed in 2006 for dealing with avian influenza and in accordance with Article 13(2)(a) of Directive 2005/94/EC.

- Risk assessment to determine if the CA could derogate from killing all birds as permitted by Article 11(2) of Directive 2005/94/EC. The CA subsequently opted to use this derogation. There were no commercial poultry farms within 1 km radius of ABIC and no protection or surveillance zones were established as permitted by Article 16(2) of Directive 2005/94/EC.
- Cooperation with the Friedrich-Loeffler-Institute. Birds in ABIC were subdivided into eight distinct units each with dedicated staff. Each unit was then sampled and tested for HPAI in accordance with point 8.4 of Chapter IV of the Annex to Commission Decision 2006/437/EC i.e. 21 days following the date of the last positive finding of HPAI each unit was sampled (60 birds/unit or if less than 60 birds in unit, all birds were sampled) until there were two consecutive negative laboratory results taken at least 21 days apart.
- Removal of restrictions on 24 February 2015.
- Destruction of 57 rather than the total zoo population of 497 birds. The epidemiological investigation concluded infection occurred in birds which had access to open pasture accessed by wild birds.

39. The outbreak was discussed at Plant, Animal, Food and Feed (PAFF) committee on 13/14 January 2015. This included the use of derogations provided for by Directive 2005/94/EC and confirmation of prohibition of movements of birds from ABIC to other Member States and third countries.

40. The CA confirmed that the approval of the ABIC was not suspended or partially suspended during outbreak, which in not in line with requirements in point 6(b) to Annex C of Directive 92/65/EEC[3].

41. Once it was established that movement of birds no longer posed a significant risk of further spread of HPAI, no instruction was available for dealing with those movements- which is not in line with Article13(2)(c) to Directive 2005/94/EC[4].

[3] In their response to the draft report the competent authority noted that nevertheless, the zoo was placed under restriction until the avian influenza had disappeared and was under official supervision for the whole period of restriction. During that time, no animal was permitted to be removed from or introduced into the zoo.
[4] In their response to the draft report the competent authority noted that an instruction will be drafted.

Conclusions on disease surveillance and control measures

42. The lack of approval of ABIC veterinarians by the CA adds a degree of uncertainty to the ABICs actual animal health status.
43. Disease surveillance plans focus mainly on routine health issues rather than Annex A diseases and CAs do not always review and approve them. Notwithstanding, the post mortem examinations and extensive laboratory investigation carried out coupled with the controls on animal movements does give confidence that any suspicion of notifiable disease will be detected at an early stage.
44. The absence of approved procedures for animals coming from non-approved sources increases the risk of introducing diseases to ABICs. For Annex A notifiable diseases, the evidence observed indicates that they are dealt with professionally with the use of expert advice and that derogations are, with the exception of no instructions for movement of birds once they no longer pose a significant risk, correctly applied. The risk of spread of disease due to failure to suspend / partially suspend approval is mitigated by other actions taken quickly by the CA (e.g. ban on the movement of birds) and by the fact that it is officials who had the responsibility for issuing intra trade certificates.

5.4 MOVEMENT OF ANIMALS

Legal requirements

Commission Regulation (EC) No 1266/2007; Articles 5 and 13 and Chapter III of Directive 92/65/EEC; Annex C to Directive 92/65/EEC; Directive 96/93/EC; Article 4 (2) and 9 of Directive 90/425/EEC; Article 3a of Regulation (EC) No 206/2010; Commission Decision 97/794/EC; Regulation (EC) No 1760/2000; Regulation (EC) No 21/2004; Regulation (EC) No 504/2008; Article 8 of Directive 91/496/EEC; Article 4 of Commission Regulation (EC) No 282/2004.

Findings

5.4.1 Identification of animals and movement registers

45. All ABICs visited kept animal registers which recorded relevant information required by point(1)(d)(i)(ii) of Annex C to Directive 92/65/EEC e.g. individual identification (where practical), species, date of movement in / out. Most ABICs visited used a web based zoological information management system (ZIMS), which was accessible by other zoos, in parallel with their own in-house records. The in-house records included electronic databases and hand written stockbooks.
46. The FVO audit team verified, using pre-selected TRACES certificates, that ABICs visited kept up to date movement records as required by point1(d)(i)(ii) of Annex C to Directive 92/65/EEC.

5.4.2 Movements

For national movements

47. As indicated in paragraph 29, domestic cattle from ABICs are tested for tuberculosis, brucellosis and leucosis before movements and certification is provided for infectious bovine rhinotracheitis and bovine viral diarrhoea status. Test results were available for movements reviewed by FVO team (Berlin).

48. For the ABICs reviewed by the FVO audit team, HI-Tier database (national identification and information system for animals) was updated for in/out movements of domestic cattle and pigs.

For Intra-Union trade:

49. In Länder visited, all trade certification from ABICs was issued by District official veterinarians which, with the exception of trade certificates for apes, goes beyond the requirements of Article 13(1) to Directive 92/65/EEC. Certificates reviewed corresponded to the specimen in Annex E to Directive 92/65/EEC and attested to ABICs being approved in accordance with Annex C to the Directive.

50. For movements, official veterinarians met were generally not able to ensure that the holding of origin/ destination was an ABIC. E.g.:
    - They were not aware of the Commission website listing ABICs in other Member States[5] and they (Berlin and MV) were using TRACES- whose data may be unreliable - for this purpose.
    - One OV (Hessen) confirmed they did not check if the establishments they had certified apes to were ABICs to ensure the requirements of Article 5 to Directive 92/65/EEC were met.
    - Several intra trade certificates, reviewed by FVO team, for one ABIC (Hessen) referred to approval number DE00000476. This number did not relate to approval number granted in accordance with Annex C to Directive 92/65/EEC nor did it relate to the holding registration number of the ABIC. No explanation could be provided by CA as to the origin of this number.
    - In another ABIC, incoming intra trade certificates listed the post code as the ABIC approval number and this had not been detected by CA or AV.

51. One CA (MV) issued intra-trade certificates for species other than those the establishment was approved for. These certificates were based on Part 3 to Annex E of Directive 92/65/EEC.

52. Checks by CA- following movement of animals between Member States - are not compulsory at the point of destination, but approved veterinarian is responsible for the

[5] http://ec.europa.eu/food/animal/approved_establishments/establishments_vet_field_en.htm

day to day compliance with animal health requirements (Point (1)(g)(v) of Annex C to Directive 92/65/EEC).

53. FVO audit team reviewed documentation for the movement of a ruminant from an ABIC in Madrid, Spain to an ABIC in Germany (Hessen). Information made available to Member States by Spain indicates the autonomous community of Madrid to be a restricted zone for bluetongue serotypes 1 & 4[6]. The veterinary certificate from consigning ABIC veterinarian attested the animal as free from infectious disease and fit for transport. A certificate from CA in Madrid certified a negative PCR test for bluetongue on 23 February 2015. All certificates dated 25 March 2015. The Intra trade certificate attested animal was exempt from blue tongue exit ban but did not include conditions for exemption from the exit ban, provided for in Directive 2000/75/EC, and listed in Article 8 to Regulation (EC) No 1266/2007.

5.4.3 Imports of harmonized species

54. At the time of audit, Germany was the only Member State which had imported a consignment of ungulates from a third country ABIC into the EU as permitted by Article 3a of Regulation (EU) No 206/2010. In 2014, Germany informed the PAFF committee about their intention to import ungulates from Russia in line with final paragraph of Article 3a of Regulation (EU) No 206/2010.

55. Prior to establishing a list of ABICs from which the introduction of ungulates into its territory may be authorised, CA assessed compliance with the conditions laid down in Article 3c(2) of Regulation (EU) No 206/2010. This was done by means of written confirmation from Russian authorities dated 27 January 2014.

56. CA issued an authorisation to import ungulates from Russia on 9th April 2014 and ungulates were despatched from Russia on 10th June 2014.

57. The animals were imported through a BIP in Hessen and moved directly to an ABIC in a different Länd (Berlin, Mitte) for 30 days prior to being transported to final destination ABIC in same Länd (Berlin, Lichtenberg).This ensured compliance with Article3a(1)(e) of Regulation (EU) No 206/2010.

58. CA stated:

- The Supreme Land Authority had sole responsibility for completing the authorisation procedure and making the authorisation decision, and in this respect was also responsible for the animal health risk assessments. However, the Supreme Land Authority consulted the BMEL and reached agreement with it on

6 http://rasve.magrama.es/Recursos/Ficheros/Historico/09_Informe%20situaci%C3%B3n%20lengua%20azul%202014-2015%20%20%2819.01.2015%29.pdf

the decisions involved in the authorisation procedure. The BIP was responsible for all decisions relating to imports, in other words the crossing of the border and further transportation to the destination.

- Supreme Land Authority verified country of origin was listed in Part I of Annex I or Part I of Annex II to Regulation (EU) No 206/2010 as required by Article 3a(1)(b) of Regulation (EU) No 206/2010.

- Animal health risks that consignment presented to the Union were assessed by reviewing O.I.E. disease situation in exporting country at the time of import.

59. The process established and used for introducing ungulates from a third country ABIC to an ABIC in Germany is generally in compliance with the requirements of Regulation (EU) 206/2010. FVO team reviewed the documentation available, which included:
    - Import authorisation issued by Hessen Ministry for Environment, Energy, Agriculture and Consumer Protection which listed the conditions for import.
    - Veterinary export certificate from Russia issued by the Federal Service for Veterinary and Phytosanitary Surveillance (Rosselkhoznadzor) which corresponded to Model RUM-A certificate, Annex VI Part 2 to Regulation (EU) No 206/2010. This included, inter alia, that the requirements and conditions of Annex VI Part 3 and 4 of Implementing Regulation (EU) No 780/2013 were met.
    - Additional certificate issued by official state veterinarian confirming, inter alia, animals were quarantined for a minimum of 30 days prior to shipment and were transported to airport of departure in vector protected crates as required by Article 3a(1)(d) of Regulation (EU) No 206/2010.
    - Certificate, dated 27 January 2014, confirming requirements of Annex VI Part 3 and 4 of Implementing Regulation (EU) N0 780/2013 were met.

60. Germany has established, in accordance with Article 3c(1) to Regulation (EU) No 206/2010, a list of ABICs from which ungulates may be imported into its territory and this list is publically available via the internet at:

    http://tsis.fli.bund.de/GlobalTemp/201506171553032898.pdf

61. The list does not include the approval number for the ABICs in third countries.

Conclusions on movements of animals

62. Movement records kept by ABICs are generally well kept and reliable which allows competent authorities to trace animals through all stages of their life.
63. The system of checks at destination did not prevent risk animals (e.g. from a bluetongue restricted area) from moving into an ABIC, which could lead to introducing diseases in German ABICs. The fact that the movement occurred during a seasonally vector-free period in Spain limited the risk of introduction of bluetongue from the specific consignment reviewed.
64. The compliance of the system established and used for introducing ungulates from a third country ABIC is a good basis to prevent animal diseases entering Germany by means of these imports.

6 OVERALL CONCLUSIONS

Germany has a system to control animal health in ABICs. There is a variation in the quality and consistency of these official controls in different Länder, mainly due to the absence of documented procedures and limited supervision.

The CAs have limited capacity to demonstrate that they carry out systematic and adequate checks on ABICS, as in many cases there do not have written procedures and officials do not issue reports for the controls done. There is limited assurance that approved ABICs fully meet legal requirements.

Despite weaknesses in the disease surveillance plans, extensive post mortem investigations together with official controls on animal movements give confidence that suspicion of notifiable diseases will be detected quickly. The ability to trace animals and the professional approach to outbreaks of notifiable animal disease give assurance of the CA capacity to contain the diseases listed in Annex A of Directive 92/65/EEC.

The system in place to import ungulates from ABICs in third countries is robust and a good basis to prevent the entrance of animal diseases through imported animals.

7 CLOSING MEETING

A closing meeting was held on 28th April 2015 with the central competent authority. At this meeting the FVO audit team presented the findings and preliminary conclusions of the audit.

The CA did not express any disagreement with the preliminary conclusions at the closing meeting

8 RECOMMENDATIONS

No.	Recommendation
1.	The CA should ensure that there are documented procedures in place, as required by Article 8(1) and 9 (1) of Regulation (EC) No 882/2004, to ensure the effective delivery of official controls and that reports are issued after them. In particular, to ensure that; • official approval of ABICs is granted in a uniform and correct manner as required by Article 13(2) of Directive 92/65/EEC, • frequencies of controls meet the requirements in Annex C(2)(a)(i) of Directive 92/65/EEC Based on findings 6, 8, 12, 13, 14 and conclusions 9 and 16.
2.	CA should establish approved procedures for animals coming from non-approved sources as required by Annex C(1)(b) of Directive 92/65/EEC. Based on finding 34 and conclusion 44.
3.	The CA should verify that veterinarians employed by ABICs possess the knowledge and skills necessary for this particular field of animal health as required by Point1(g)(i) of Annex C to Directive 92/65/EEC Based on findings 17, 19, 33, 50 and 53 and conclusion 42 and 63.
4.	CA to ensure that all diseases listed in Annex A are subject to compulsory notification as required by Article 4 of Directive 92/65/EEC. Based on finding 2 and conclusion 10.
5.	To ensure instructions for dealing with the movement of birds (once it has established they no longer pose a significant risk of further spread of HPAI) are developed as required by Article13(2)(c) of Directive 2005/94/EC. Based on finding 41 and conclusion 44.

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=2015-7565

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
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. 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
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. 91/68/EEC	OJ L 46, 19.2.1991, p. 19-36	Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals
Dir. 91/496/EEC	OJ L 268, 24.9.1991, p. 56-68	Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC
Dir. 92/35/EEC	OJ L 157, 10.6.1992, p. 19-27	Council Directive 92/35/EEC of 29 April 1992 laying down control rules and measures to combat African horse sickness
Dir. 92/65/EEC	OJ L 268, 14.9.1992, p. 54-72	Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC

Dir. 92/66/EEC	OJ L 260, 5.9.1992, p. 1-20	Council Directive 92/66/EEC of 14 July 1992 introducing Community measures for the control of Newcastle disease
Dir. 2004/68/EC	OJ L 139, 30.4.2004, p. 321-360. Corrected and re-published in OJ L 226, 25.6.2004, p. 128.	Council Directive 2004/68/EC of 26 April 2004 laying down animal health rules for the importation into and transit through the Community of certain live ungulate animals, amending Directives 90/426/EEC and 92/65/EEC and repealing Directive 72/462/EEC
Dir. 2005/94/EC	OJ L 10, 14.1.2006, p. 16-65	Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC
Dir. 2009/156/EC	OJ L 192, 23.7.2010, p. 1-24	Council Directive 2009/156/EC of 30 November 2009 on animal health conditions governing the movement and importation from third countries of equidae
Reg. 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
Reg. 282/2004	OJ L 49, 19.2.2004, p. 11-24	Commission Regulation (EC) No 282/2004 of 18 February 2004 introducing a document for the declaration of, and veterinary checks on, animals from third countries entering the Community
Reg. 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
Reg. 504/2008	OJ L 149, 7.6.2008, p. 3-32	Commission Regulation (EC) No 504/2008 of 6 June 2008 implementing Council Directives 90/426/EEC and 90/427/EEC as regards methods for the identification of equidae

Reg. 206/2010	OJ L 73, 20.3.2010, p. 1–121	Commission Regulation (EU) No 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements
Reg. 1069/2009	OJ L 300, 14.11.2009, p. 1-33	Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)
Dec. 97/794/EC	OJ L 323, 26.11.1997, p. 31-36	97/794/EC: Commission Decision of 12 November 1997 laying down certain detailed rules for the application of Council Directive 91/496/EEC as regards veterinary checks on live animals to be imported from third countries
Dec. 2007/598/EC	OJ L 230, 1.9.2007, p. 20-26	2007/598/EC: Commission Decision of 28 August 2007 concerning measures to prevent the spread of highly pathogenic avian influenza to other captive birds kept in zoos and approved bodies, institutes or centres in the Member States
Dec. 2003/459/EC	OJ L 154, 21.6.2003, p. 112-113	2003/459/EC: Commission Decision of 20 June 2003 on certain protection measures with regard to monkey pox virus