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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

HUNGARY

FROM 24 NOVEMBER 2014 TO 28 NOVEMBER 2014

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

Executive Summary

The report describes the outcome of an audit carried out by the Food and Veterinary Office in Hungary from 24 to 28 November 2014.

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. Overall, the report concludes that:

Roles and responsibilities for the delivery of official controls in ABICs have been established at central, county and district levels. Certain shortcomings in the transposition of specific measures related to ABICs in Directive 92/65/EEC coupled with the absence of central guidance has led to an inconsistent application of this legislation across counties. Official controls cannot give assurance that listed ABICs are compliant with the requirements expected in EU legislation.

The weaknesses and inconsistent approach observed regarding animal health surveillance in ABICs, raises a concern that diseases might not be quickly diagnose.

Directive 92/65/EEC allows animals to be exchanged between European ABICs in a relatively unrestricted manner (e.g. no quarantine requirements). There is a degree of uncertainty in the actual health status in some Hungarian zoos with an associated threat to the animal health status of other animal populations when animals are moved.

National and intra-Union movements are controlled. The certificates used for intra-Union movements includes attestation that ABICs is approved in accordance with Annex C to Directive 92/65/EEC and is a difficult statement to make until full transposition of the Directive and official controls are carried out at the correct frequency.

Weaknesses detected in the import conditions of primates where the Hungarian requirements are less stringent than those required under European legislation result in reduced health guarantees when these animals are released from quarantine.

No immediate animal health risk has been identified.

The report makes recommendations to the Hungarian 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
NFCSO	National Food Chain Safety Office
TB	Tuberculosis
TRACES	TRAde Control Expert System, a trans-European network for veterinary health notification and certification.

1 INTRODUCTION

This audit took place in Hungary from 24 to 28 November 2014, as part of the planned audit programme of the Food and Veterinary Office (FVO). The audit team comprised two FVO auditors. At the opening meeting on 24 November the FVO audit team confirmed the objectives and scope of the audit as well as the itinerary.

The FVO audit team was accompanied by a representative from the central competent authority, the Ministry of Agriculture, throughout the audit.

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 (ABICs) 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	3	Opening, clarification and closing meetings
Regional and local Competent Authorities	3	Gyor (County and District offices) and Szeged (County office)
Approved bodies, institutes or centres	3	3 zoos

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 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 (hereafter "the Directive") 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 the Directive 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 National Food Chain Safety Office (NFCSO) indicated that Hungarian legislation transposes the Directive through a combination of 11 Ministerial Acts and Decrees. The FVO audit team review the legislation provided and found the following:
    - Decree No 3/2001 (II.23) of the Ministries of Environment Protection, of Agriculture and Rural Development, of National Cultural Heritage and of Home Affairs which is the national legislation containing rules on establishing,

operating and maintaining zoos. This legislation does not transpose requirements of Annex C to the Directive governing approval of ABICs. Instead, it addresses the implementation of Council Directive 1999/22/EC relating to keeping of wild animals in zoos. Decree No 3/2001 requires the licensing authority to check the operation of a zoo once every 5 years, which is not in line with point 2(a)(i) of Annex C to Directive 92/65/EEC requiring at least one official veterinarian visit per year.

- Decree No 113/2008 (VIII. 30) of the Ministry of Agriculture and Rural Development on the rules of notification of animal diseases. This legislation actually transposes Directive 82/894/EEC on the notification of animal diseases within the Union and it does not contain some of the diseases listed in Annex A to the Directive, namely: Brucella ovis, ebola, monkey pox and psitacosis. This Decree does not include any specific reference to the obligations ABICs must fulfil.
- Of the three Ministerial Acts and Decrees which include a reference indicating their link to the Directive, two did not relate to ABICs (i.e. one related to trade in bees and the other to movement of pet animals for trade purposes).

2. The Hungarian legal framework does not include the conditions governing approval of ABICs. There is no requirement for CA to carry out official controls, at least once a year, to fulfil requirements of Annex C to the Directive.
3. During the audit, officials had difficulty pointing out where certain requirements of Directive 92/65/EEC were in national legislation and began to draft a document to cross reference Directive requirements to national legislation. The FVO audit team did not see a final version of this document.
4. The CA confirmed that when part of an ABIC was also a registered holding then the requirements of Directive 64/432/EEC and Directive 91/68/EEC applied to domestic bovine, swine ovine and caprine when kept there. This makes it possible for an ABIC with a registered holding number to get an official tuberculosis (TB) status – otherwise, requirements of the Directive applied.

5.1.2 Competent authorities

5. The full structure and organisation of the CA, as well as the control system for animal health is described in the Country Profile for Hungary at :

   http://ec.europa.eu/food/fvo/controlsystems_en.cfm?co_id=HU

6. The Ministry of Agriculture has policy lead in this area and the National Food Chain Safety Office (NFCSO) - who report directly to the Ministry of Agriculture - is responsible for managing the operational tasks at central level, risk assessment and co-ordinating the control activities at county and district level. NFCSO has a system management and supervision directorate which has responsibility for internal audit and drafts an annual audit plan.

7. In Hungary, the Environmental and Nature Conservation Inspectorate is responsible for issuing approval to ABICs.

8. Article 8(1) of Regulation (EC) 882/2004 requires CAs to carry out official controls in accordance with documented procedures. No documented procedures on how to approve ABICs and verify their compliance with the Directive requirements have been issued at central or county level.

Conclusions on legislation and competent authorities

9. Roles and responsibilities for the delivery of official controls in ABICs have been established at central, county and district levels. The incomplete transposition of the requirements in the Directive and the lack of documented procedures to provide information and instruction to staff performing official controls in this area of work make it impossible for the CA to ensure uniform controls and consistent level of compliance for approved ABICs.

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

Findings

10. The approval for zoos issued by the Environmental and Nature Conservation Inspectorate is done in collaboration with NFSCO Directorate for Food Chain Safety and Animal Health, Policy Administration Services of Public Health (of the county Government offices) and the notary of the District. NFCSO acts as a technical authority and their endorsement of the ABIC is required before Environmental and Nature Conservation Inspectorate can issue the approval. Joint visits are performed for initial approval and once every 5 years for maintenance of approval in accordance with Decree No 3/2001 (II.23). However, the competent authority does not visit ABICs at least once a year for the maintenance of the approval (see also paragraphs 30 and 31) which is not in line with Annex C, 2 (a)(i) of the Directive.

11. Similarly, for suspension or withdrawal of ABIC's approval, approval related documentation must be issued by the Environmental and Nature Conservation Inspectorate following recommendation from NFCSO.
12. The FVO audit team reviewed approval documentation for one ABIC. There was no standard for approval or reference to the Directive included in the recommendation from NFCSO to the Environmental and Nature Conservation Inspectorate and no reference to the Directive in the approval document issued to the ABIC.
13. Consequently, the FVO audit team noted there is no common standard for approval of ABICs to meet the requirements of Annex C of the Directive or to maintain this approval once issued.

5.2.2 Listing of approved bodies, institutes and centres

14. A list of ABICs is publicly available on the NFCSO website as required by Article 13, 2(d) of the Directive.

15. The Chief Veterinary Officer wrote to county Directorates for Food Chain Safety and Animal Health in September 2014 requesting them to review and update ABIC list.

16. The list, updated on 10 October 2014, has a heading which clearly indicates that it refers to ABICs as defined in Article 2(1)(C) of the Directive but it also includes establishments not covered by this definition such as equine artificial insemination centres and apiaries.

17. The updated ABIC list included establishments with no approval number, two establishments with the same approval number and some establishments which appear to have more than one approval number listed.

18. One quarantine facility, for the importation of birds other than poultry, which was integral to an ABIC, was listed on the NFCSO website on a separate quarantine facilities list with a different approval number from that of the main ABIC. Notwithstanding, quarantine facilities are a pre-requisite for approval of ABICs.

Conclusions on approval of bodies, institutes and centres

19. The system does not ensure that ABICs meet the requirements of the Directive, as there is no common standard to grant initial approval and to maintain it.

20. The inaccuracy of the publicly available list complicates the ability of the CAs to plan and perform the necessary checks effectively and could misguide other Member States about the health status of the animals coming from Hungarian ABICs.

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

21. All ABICs visited had appointed at least one veterinarian to provide services from full time contracts through to providing 1-2 hours veterinary cover a day. These

veterinarians are not approved by and under the control of the CA, which is not in line point 1(g) of Annex C to the Directive.

22. No procedure existed to confirm that the veterinarians hired by ABICs possessed the necessary skills for this particular field of animal health which is not in line with point 1(g)(i) of Annex C to the Directive.

5.3.2 Disease surveillance and prevention

23. The official checks do not ensure that plans provide appropriate surveillance and control measures as required by Annex C, point 1 (g) to the Directive. Annex C, point 1(g)(ii) requires ABICs to have an annual disease surveillance plan which should be approved by the competent authority. The FVO audit team visited three ABICs and noted:

- One ABIC had a disease surveillance and control plan which was dynamic and reflected disease risks in the country e.g. the ABIC had a preventive vaccination plan for avian influenza approved by the EU and vaccinated against avian influenza during a period of increased risk following outbreaks in 2006 and currently plans to incorporate bluetongue testing from 2015 (in addition to 2 samples taken in 2014). This ABIC had extensive records showing histology, bacteriology and virology from post mortem examinations performed in accordance with point 1(g)(ii) of Annex C to the Directive.
- In other ABIC records of 32 post mortem examinations were reviewed by the FVO team - only two of these had a definitive diagnosis. In no cases had samples been submitted for histo-pathology or laboratory testing (i.e. serology) to determine if a transmissible disease was involved or for surveillance purposes. This had not been detected by OV.
- The disease surveillance plan in one ABIC consisted of a rule book on animal health which gave an overarching view of animal health requirements and was supplemented by more detailed animal health requirements by species group e.g. requiring annual tuberculosis (TB) testing for mixed deer herd and outlining requirements for TB and bluetongue testing of pigs- although pigs are not susceptible to this disease. The surveillance plan was not followed: no results were available for TB testing of deer and representatives of ABIC confirmed that pigs were not tested for TB or bluetongue. These deficiencies had not been detected by the official veterinarian during a re-approval visit in June 2014, when he should have carried out an audit on the implementation of the annual disease surveillance plan as required by point 2(a)(ii) of Annex C to the Directive.
- In another ABIC, the surveillance plan required annual TB surveillance of elephants and rhinos – no test results were available for rhinos and the test kit used for elephants was more than four years past its expiry date. This was not detected by official controls.

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

24. The CA confirmed that national legislation does not require TB testing of cattle in ABICs- and that they were currently re-drafting their national TB legislation to include requirements for cattle kept in ABICs. They indicated that, at the time of the audit, cattle could move from ABICs to holdings only when the ABIC is registered as a holding and has an official TB status. The audit team observed that this rule was not applied consistently across counties: one county CA stated it was not possible for a zoo to get an official TB status and consequently it did not allow movement of bovines out of a zoo.

25. For pigs, the same principle is applied and movement from an ABIC to a holding can only take place if the ABIC is declared free from Aujeszky's disease, porcine reproductive and respiratory syndrome, Brucella suis and leptospirosis. The same CA mentioned in the paragraph above did not allow movement of pigs out of zoos.

26. The CA stated that movements of sheep and goats from ABICs to a production holding were not allowed.

27. One County CA required an ABIC to carry out tests on domestic cattle, pigs and horses (as they do with small holdings in Hungary) which served to enhance its surveillance activities. These tests included sampling cattle for brucellosis and TB and pigs for brucellosis.

5.3.4 Quarantine operations

28. All ABICs visited had quarantine facilities which were stand-alone buildings within curtilage of ABICs. Attending staff were either dedicated to quarantine facility or had access to appropriate personal protective equipment. The FVO audit team observed:

- Structural and operational standards varied between ABICs visited e.g. individual animal identification (when practical) was not used consistently to identify animals in quarantine log book or on animal treatment records. Structurally, presence of wooden skirting boards and some wooden pens observed in most of the quarantine facilities made effective cleansing and disinfection difficult. In addition, records of cleansing and disinfection were not always kept.
- In one ABIC, the room which had recently been used as bird quarantine for psittacines, free flying within room, was accessed by a single door opening directly into a common corridor linking other rooms which may allow contact with other animals.
- Few observations on the animals, as required by point 1(d)(vi) of Annex C to the Directive were recorded during quarantine period in the ABICs visited.
- One ABIC began using a visitor registration book for the first time on 10 November 2014.

- Quarantine facilities are frequently used for housing animals seized by police or presented by members of the public and not intended to enter ABICs. In two ABICs visited, animals were added to the quarantine facilities when other animals were already present.
- These conditions were considered acceptable by CA who, in most cases, had records available to show their regular attendance in quarantine.

29. Consequently, the standard of quarantine facilities in ABICs is not always adequate, which is not in line with Annex C, point1(b) of the Directive.

5.3.5 Official visits to ABICs

30. For zoos, official controls are performed on a risk basis. The CA uses an assessment algorithm for the risk based planning of official controls and distributes the plan of holdings to be controlled – including audits of ABICs – to County directorates on an annual basis. County Directorates then have discretion to carry out additional controls as they deem necessary. This has resulted in some ABICs receiving less than one official visit per year which is not in accordance with point 2(a)(i) of Annex C to the Directive.

31. The FVO audit team noted a range of approaches: from two official visits per annum to controls not being carried out annually. No reports of official controls being carried out were available for one ABIC which is not in line with Article 9 of Regulation (EC) No 882/2004.

32. CA indicated that NFCSO official veterinarians use a centrally issued checklist (code 48 / dated 2009.12.31) to determine compliance with the Directive requirements during approval visits. Findings are recorded as compliant, non-compliant or not applicable - text is only entered if a non- compliance is recorded. The checklist does not cover the detailed requirements of Annex C to the Directive and does not have any guidance for completion.

33. An example of good practice was observed in one of the counties visited. The County CA recognised the need for a more detailed checklist to be used in ABICs to cover the approval requirements of Annex C to the Directive and had drafted their own checklist for zoos. This had been used during annual approval visits.

34. For research establishments, Decree 40/2013 on animal experiments requires these visits to be risk based. Annual visits are no required. The CA intends to inspect such establishments at least every 3 years unless they keep primates in which case annual visits are still compulsory. This reduced inspection frequency does not meet the requirements of point (2)(a)(i) of Annex C to the Directive.

35. In one county with a large number of research establishments, a centrally available checklist (code 49 / dated 2009.12.31) had been used annually up to 2013 for approval purposes. The FVO audit team saw evidence of good practice where this checklist had been used and supported by extensive narrative to highlight problems e.g. lack of

quarantine / improper cleaning and disinfection with timelines for corrective action and follow up visits to ensure compliance.

36. The CA has chosen to issue all intra-union trade certificates from ABICs rather than allowing the ABIC veterinarians to complete them thereby increasing the frequency of official veterinarian's presence in ABICs throughout the year. This does not however fulfil requirements of point 2(a) of Annex C to the Directive as most of these visits are limited to certification duties.

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

37. The CA stated that there had been 11 confirmed cases of Annex A notifiable diseases in Hungarian ABICs between 2009 - 2013. Seven of these cases were followed up by the FVO audit team in ABICs visited. These diseases included TB, psittacosis and rabies. Of these seven cases, one had been double counted. In a visit to an ABIC, the audit team observed that a case of rabies in 2011 had not been recorded on the centrally produced table of occurrences of notifiable diseases.

38. All the notified cases had been suspected or confirmed in animals that were in the ABICs quarantine facilities. In all cases reviewed by the FVO audit team, the animals involved had been seized by police or brought to the quarantine facility by members of the public and had been kept, under official control, in the quarantine area of zoos. No suspension / withdrawal of approval was deemed necessary as no animals outwith the quarantine areas had been involved. This is not in line with the requirements of point 6(b) and (c) of Annex C to the Directive.

39. There were no other recorded suspicions of notifiable disease in ABIC's animals over the period 2009 - 2013.

Conclusions on disease surveillance and control measures

40. The absence of mandatory official controls in some ABICs together with the lack of approval and control of ABIC veterinarians by the CA adds a degree of uncertainty in the ABICs actual animal health status. The inconsistent approach to animal health surveillance in ABICs prevents the CA ensuring and demonstrating that approved ABICs have the high animal health status that is expected of them.

41. The absence of records for cleansing and disinfection of quarantine facilities and the few observations on quarantine animals kept by ABICs make it difficult for officials to verify compliance and assess the health status of quarantined animals.

42. The absence of suspicions of notifiable disease reported which turned out to be negative together with the absence of definitive diagnosis and samples in many post-mortem examinations indicates a weak surveillance which may prevent early diagnosis of diseases. The existence of inadequate quarantine facilities, the practice of accepting seized animals into them – especially when they have other animals present- increases the risk of introduction and spread of diseases to ABICs.

43. The fact that the CA does not suspend ABIC approval on suspicion of an Annex A notifiable disease implies that these ABICs are kept on the list and able to trade, which increases the risk of spreading diseases.

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

44. All ABICs visited used the web based zoological information management system (ZIMS) to keep records of the number, identity, age, sex, species of animal on site and the movement of animals in / out of the premises.

45. Four fallow deer which moved from an ABIC to a game park in October 2014 were not individually identified. Consequently, there was no reference to individual identification in the ABIC's movement register or on the health certificate issued by the ABIC

veterinarian which undermines their traceability and is not in accordance with point 1,(d)(ii) of Annex C to the Directive.

46. FVO audit team verified, using examples of pre-selected TRACES certificates, that ABICs visited kept up to date movement records as required by point 1(d)(ii) of Annex C to the Directive.

5.4.2 Movements

47. For national movements, non-domestic animals moved from an ABIC must be accompanied by a health certificate signed by the ABIC veterinarian.

For Intra-Union trade:

48. Legislative requirements in Hungary require official certification for the trade of animals from zoos. These movements are controlled and recorded in TRACES. A health certificate must be signed and stamped by an official veterinarian. This certification includes certifying that the ABIC is approved in accordance with Annex C to the Directive when using a certificate corresponding to Annex E to the same Directive.

49. One official veterinarian met used TRACES, instead of the official list of approved ABICs, to obtain ABIC's details in other member states for certification purposes and he was not aware that such data may be unreliable. Some official veterinarians were aware of the Commission website listing ABICs in other member states.

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

5.4.3 Imports

50. Import permits are required for live animals whose import conditions are not harmonised at EU level. These permits are issued by the NFCSO at the request of the importer. Any import permits issued by NFCSO have the relevant model of the national import health certificate attached.

51. The FVO audit team selected three common veterinary entry documents from TRACES and reviewed the associated documentation. Import permits and completed animal health certificates were available and appropriate for each of the three imports.

52. National legislation (Decree 41/1997) requires imported animals to be quarantined and when species are not specifically listed in legislation, this quarantine period must be at least 30 days.

53. The Hungarian import permit for primates requires a single tuberculosis test with negative result during the 30 days prior to shipment and that the animals were either

born in place of origin or have been kept there for at least one year. This is not in compliance with point 3 of Annex C to the Directive which require OIE International Health Code (Chapter 6.11) to be respected (this code requires primates from premises under veterinary supervision to be subjected to a tuberculosis test on two occasions with negative results, at an interval of at least two weeks between each test during the 30 days prior to shipment and a further tuberculosis test during the quarantine period).

54. In the case reviewed by the FVO audit team, the imported primates met these national requirements and were kept in quarantine for 30 days.

5.4.4 Harmonized species

55. Hungary has not established a list of bodies, institutes or centres in third countries from which ungulates may be introduced. There have been no imports of ungulates into ABICs in Hungary following the entry into force of Regulation (EU) No 780/2013.

Conclusions on movements of animals

56. There are arrangements in place for the national movement of animals from ABICs. The official certification carried out for intra-union trade of animals from ABICs ensures that movements are controlled and recorded in TRACES.

57. The incomplete transposition of Directive 92/65/EEC together with the incomplete implementation of official controls and the weaknesses observed during the audit indicates that officials signing the certificates are not doing so in full compliance with the requirements of the Directive.

58. The Hungarian import requirements for primates are less stringent than those required under European legislation. This results in reduced health guarantees when these animals are released from quarantine.

6 OVERALL CONCLUSIONS

59. Roles and responsibilities for the delivery of official controls in ABICs have been established at central, county and district levels. The non-transposition of specific measures related to ABICs in Directive 92/65/EEC coupled with the absence of central guidance has led to an inconsistent application of this legislation across counties. Official controls cannot give assurance that listed ABICs are compliant with the requirements expected in EU legislation.

60. The weaknesses and inconsistent approach observed regarding animal health surveillance in ABICs, raises a concern that diseases might not be quickly diagnosed.

61. As Directive 92/65/EEC allows animals to be exchanged between European ABICs in a relatively unrestricted manner (e.g. no quarantine requirements) and there is a degree of uncertainty in the actual health status in some Hungarian zoos there is an associated

threat to the animal health status of other animal populations when animals are moved.

62. National and intra-Union movements are controlled. The certificates used for intra-Union movements includes attestation that the ABIC is approved in accordance with Annex C to the Directive and is a difficult statement to make until full transposition of the directive and official controls are carried out at the correct frequency.

63. Weaknesses detected in the import conditions of primates where the Hungarian requirements are less stringent than those required under European legislation result in reduced health guarantees when these animals are released from quarantine.

64. No immediate animal health risk has been identified.

7 CLOSING MEETING

A closing meeting was held on 28th November 2014 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 the obligations laid down in Directive 92/65/EEC are complied with. In particular, ensuring that national provisions include the conditions governing approval of bodies, institutes or centres, adequate level of official inspection and that all diseases listed in Annex A are subject to compulsory notification. *Annex C to Directive 92/65/EEC* Based on findings 1, 2 and conclusion 9
2.	The CA should have documented procedures in place 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 and the required standards of disease surveillance and control measures are approved and met. *Article 8(1) and 9 (1) of Regulation (EC) No 882/2004.* Based on findings 8, 30 and 31 and conclusions 9 and 40
3.	CA should ensure that the published list of ABICs is reliable, unambiguous and is kept updated. *Article 13(d) to Directive 92/65/EEC.* Based on findings 14, 15 and 16 and conclusion 20
4.	The CA should verify that veterinarians employed by ABICs possess the knowledge and skills necessary for this particular field of animal health. *Point 1(g)(i) of Annex C to Directive 92/65/EEC.* Based on findings 21 and 22 and conclusion 40
5.	The CA should ensure that the ABIC's approval is suspended when there is suspicion of an Annex A notifiable disease and where the notifiable disease is confirmed, that the approval is re-instated only after eradication of the disease and source of infection in the premises. *Point 6(b) and (c) of Annex C to Directive 92/65/EEC.* Based on finding 38 and conclusion 43
6.	CA should ensure that Hungarian import and quarantine requirements for non-human primates are in line with EU requirements. *Point 3 of Annex C to Directive 92/65/EEC.* Based on findings 50 and 51 and conclusion 55

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
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. 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. 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. 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. 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. 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
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. 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. 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
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
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
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. 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. 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
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
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