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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

THE NETHERLANDS

FROM 09 NOVEMBER 2015 TO 13 NOVEMBER 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

Executive Summary

The report describes the outcome of an audit carried out by DG Health and Food Safety in the Netherlands from 09 to 13 November 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 official controls of approved bodies, institutes and centres (zoo and laboratory animals) in the Netherlands benefit from a developed framework, mainly based on well-developed procedures, good traceability of animals in place, professionally dealt suspicions and occurrences of notifiable diseases and control measures applied.

The quality of CA' annual audits to verify ABIC compliance with the requirements is not subjected to effective supervision and varies, in one instance resulting in the maintenance of ABIC approval without meeting the essential requirements of Directive 92/65/EEC. The CA undertook to implement immediate measures to correct cumulated significant deficiencies that went unnoticed by official controls.

In addition, the full effectiveness of the system is weakened by systemic deficiencies noted, in particular regarding

- *Inadequate standard of disease surveillance plans in ABICs and their official controls, not focussing on regulated diseases and resulting in some uncertainty in relation to the health status of the ABICs.*
- *Movement of non-human primates from ABIC to non-ABIC establishment which is contradictory to current EU requirements.*

The current system for the import control of live animals not subject to harmonised conditions (e.g. non-human primates) does not ensure that the national conditions required by certain Member States are effectively controlled if the animals are introduced through another Member State. In the case of import of primates reviewed by the DG Health and Food Safety team, they pose significant risk for the introduction of diseases which could also affect people.

The report makes recommendations to the Dutch authority 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
BIP	Border Inspection Post
BTSF	Better Training for Safer Food
CA	Competent Authority
EU	European Union
OIE	World Organisation for Animal Health
TRACES	TRAde Control Expert System, a trans-European network for veterinary health notification and certification.

1 INTRODUCTION

This audit took place in Netherlands from 09 to 13 November 2015, as part of the DG Health and Food Safety planned audit programme. The audit team comprised two auditors from DG Health and Food Safety. At the opening meeting on 9 November the DG Health and Food Safety audit team confirmed the objectives and scope of the audit as well as the itinerary.

The DG Health and Food Safety audit team was accompanied by representatives from the Competent Authority (CA).

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**
Competent Authority	3	Opening and closing meetings
Approved bodies, institutes or centres	4	
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 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. Council Directive 92/65/EC was transposed into Dutch legislation by “Regeling handel levende dieren en levende producten” (Regulation for the trade of live animals and live animal products), in particular by Chapter 8 of this regulation. Article 8.6 of this regulation directly refers to Annex C of Council Directive 92/65/EC. This article stipulates that ABICs are required to meet the requirements of point 1 and 2 of Annex C to the Council Directive. However, no reference has been made to points 3 and 4 of the Annex C leading to some legal uncertainty on the enforceable requirements.

2. As regards of list of notifiable diseases the CA confirm that it is through this Regulation that animal keepers must notify the CA of suspicion of Annex A to Directive 92/65/EEC diseases.

3. The CA stated that the Netherlands has no national programmes for diseases listed at Annex B to Directive 92/65/EEC.

4. The CA confirmed that the requirements of Directive 64/432/EEC and Directive 91/68/EEC applied to bovine, ovine, porcine and caprine animals when kept in an ABIC. ABICs keeping domestic species were registered as a holding in central database for animal identification and registration of animals and allocated with a holding registration number.

5.1.2 Resources – documentation of controls

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 Netherlands at:
   http://ec.europa.eu/food/fvo/country_profiles/details.cfm?co_id=NL

6. The Ministry of Economic Affair, Department of Legal Affairs in close cooperation with the Department for Food, Animal Health and Welfare and Consumer Policy is responsible for drafting animal health legislation and for transposing relevant EU legislation into national legislation. It is also responsible for policy and strategy in relation to the control of animal diseases.

7. Netherlands Food and Consumer Products Safety Authority is responsible for the implementation of this policy in the scope of this audit and acts as the CA. The CA has a centralised structure but there are a number of support offices set up to provide office space and equipment for official staff when carrying out tasks in the local areas.

8. The audit team noted that a pool of trained official veterinarians has been set up as the contact points in the regions to deal with approval and maintenance of approval of ABICs. The staff involved (seven official veterinarians) either directly participated in Better Training for Safer Food (BTSF training) on health and disease prevention for Zoo animals or they were trained by BTSF participants in subsequent cascade trainings.

9. Documented procedures (instructions / guidance), required by Article (8)(1) of Regulation (EC) 882/2004, and related to official controls in ABICs were in place. They included inter alia:
   - The project protocol for ABICs, with procedures for approving, evaluation, suspending and withdrawing of ABIC approval.
   - Audit check list, for approval and maintenance of approval.

- Instruction for intra EU trade.
- The rules, procedures, instructions and guidelines for import of animals that can be consulted in online database 'Import Veterinair Online'[1].
- The procedures and instructions on live animals checks at the Border inspection posts (BIPs) that are accredited and available on the CA website[2].
- The rules on pre-export isolation and quarantine of animals, in which the general principles for quarantine in ABICs are laid down.
- The project protocol - Inspection of live animals and live products at the destination, which governs the frequency on official controls carried out at the place of destination, including ABICs.

Conclusions on legislation and competent authorities

10. Official controls of ABICs (zoo and laboratory animals) in the Netherlands benefit from a developed and well-defined framework. This framework is based on streamlined CA organisation and numerous documented procedures, well fit for purpose.

5.2 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

5.2.1 Approved veterinarian

11. All ABICs visited by the DG Health and Food Safety team had at least one veterinarian contracted by the ABIC to provide services as required by Directive 92/65/EEC.

12. The CA does not formally approve ABIC veterinarians. To be recognised by the CA as an approved veterinarian he/she has to meet certain conditions set out by the CA, e.g. registration in the Dutch register of veterinarians, contract with the ABIC, responsibility for the surveillance plan in ABIC and documentation of veterinarian responsibilities and his/her communication with the ABIC.

[1] http://wisdom.vwa.nl/ivo/RaadpleegSysteem.do
[2] https://www.nvwa.nl/onderwerpen/eten-drinken-roken/dossier/import-vanuit-derde-landen/import-van-dieren-en-producten-van-dierlijke-oorsprong

13. The CA does not specifically assess if the approved veterinarian possess the skills necessary for this particular field of animal health despite the fact that the compliance with this condition is required by point (1)(g)(i) of Annex C to Directive 92/65/EEC. However the audit team noted that the activities and skills of the approved veterinarians met during the audit were largely in line with the requirements of point (1)(g) of Annex C to Directive 92/65/EEC with the exception of one ABIC (for more see point 63).

5.2.2 Disease surveillance and prevention

14. All ABICs visited had disease surveillance plans in place, but some of them were limited in scope and not fully adapted to current threats in relation to the disease situation in Netherlands. This is not in line with point (1)(g) (ii) of Annex C to Directive 92/65/EEC:
    - Two out of four ABICs visited had their surveillance plans limited in scope. The plans were not designed to provide an evidence of absence of diseases from Annex A to Directive 92/65/EEC.
    - The plans gave only limited information relating to what surveillance and control requirements for Annex A diseases were necessary. These focussed on routine health issues e.g. vaccination plans and faecal examination for parasitology. Other actions taken as part of surveillance were not formalised and included in the surveillance plans, e.g. abortions investigations, surveillance for Avian Influenza (AI), making them difficult to audit and demonstrate absence from notifiable diseases.
    - The plans had not been adapted to the current health threats, in particular AI although the most recent outbreaks of Highly Pathogenic AI were recorded in the country during November/December 2014. This weakness in plans was partly compensated by the country nationwide monitoring programme for AI run by the CA.
    - In one ABIC visited the plan had been elaborated for all species incoming to premises based on advice given by the external specialists. This plan very well identified potential health risks and appropriately addressed them, and was fit for purpose – to demonstrate absence of notifiable diseases.

15. The disease surveillance plans in place were not always approved by the CA although this approval is required under point (1)(g) (ii) of Annex C to Directive 92/65/EEC:
    - There are no specific instructions in place as regards approval of annual surveillance plan in Netherlands.
    - The CA informed the audit team that they require that the surveillance plan has to include vaccination programme, anthelmintic treatments, laboratory testing in the case of disease suspicion, blood sampling in case of pre-export or for other reasons, e.g. immobilised animals, post mortem examinations, and procedures for newly arrived animals into ABIC. In addition, daily

observations by qualified ABIC staff, feedback observations to the approved veterinarian and reporting of notifiable diseases to the CA are to be in place.

- In the majority of ABICs visited the plans were not annually revised and approved by the CA. Two out of three official veterinarians met during the audit, who were responsible for annual audits in three ABICs visited, stated that during the annual audit they check if the plan is available and implemented but without an assessment/approval of this plan.

16. In all ABICs visited but one, animals which died in the establishment were subjected to post mortem examination as required by Annex C(1)(d)(v) to Directive 92/65/EEC. In ABICs visited, these post mortem examinations were undertaken at offsite independent laboratories.

17. The CA accessed the results of ABIC's post mortem examinations and any laboratory tests carried out to evaluate implementation of disease surveillance plan during the on-site visit. But in some ABICs visited their filing (record keeping) system in place made it difficult to audit these results in order to verify that these results confirmed no occurrence of the diseases referred to Annex A.

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

18. Commission Decision 2003/467/EC establishes the Netherlands as being officially tuberculosis, brucellosis and enzootic- bovine leucosis free.

19. The CA confirmed that in the national monitoring programme for brucellosis (*Brucella mellitensis*) ABICs are included.

5.2.4 Quarantine operations

20. As regards quarantine the CA requires the ABICs to meet certain conditions laid down in CA instructions, e.g. separated building, access via double door system, hygiene barrier, quarantine protocol (all in-all out, restricted admission, daily inspections, cleaning and disinfection, waste disposal, post mortem procedures etc). Additional requirements are in place for non-human primates (OIE terrestrial health code) and for birds (facilities must comply with Regulation (EC) 139/2013).

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

22. The infrastructure and related documentation was reviewed at the ABICs and found in most cases to be largely in compliance with the requirements:

- In one ABIC visited new high standard facilities for non-human primates were in place.
- Only minor deficiencies were generally noted, e.g. some small parts made of wood and some spots on walls with painting flakes, making it more difficult to clean and disinfect the premises at the end of quarantine period.

23. The ABICs visited implemented their procedures for animals coming from non-approved sources. These procedures to some extent varied between the ABICs visited, particularly as regards the tests to be carried out during quarantine of incoming animals. In some instances the procedures were too generic making it difficult to assess if the quarantine protocol was fully fit for purpose:
    - In one ABIC visited the most recent version of the quarantine procedures did not refer to any diseases from Annex A to Directive 92/65/EEC. Instead it provided a general framework under which the approved veterinarian could decide to test animals in the quarantine, mainly based on species concerned and place of origin of animals.
    - In another ABIC visited non-human primates' diseases, e.g. Ebola, Marburg and monkey pox, were considered in the veterinary procedures for the animals arriving into ABIC. But the final decision on the actions/tests to be taken to prevent introduction of those diseases was left at the discretion of the approved veterinarian without more formalised/documented specific rules in place (e.g. the criteria of risk analyses to be carried out in this context).

24. The records were kept for movements of personnel in/out of quarantine. It was possible to verify that personnel access to quarantine facilities was restricted to essential staff.

25. Records of observations and activities made during any isolation or quarantine period varied to some extent between ABICs visited, in some instances they were incomplete:
    - In one ABIC visited no records were kept as regards a cleaning and disinfection of premises after the end of quarantine and before the arrival of new animals. Therefore, it was not possible to verify ABIC compliance with internal quarantine rule to keep premises empty for seven days after the final disinfection.
    - In other ABIC only limited records on quarantine operations were available, not adequately documenting and demonstrating all in-all out system in place.

5.2.5 Official visits to ABICs

26. All ABICs had received an annual visit by the CA to maintain approval.

27. The CA issues 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.

28. Furthermore, CA' staff performs additional visits in ABICs on an ad-hoc basis with different objective (e.g. checks of quarantine, checks at the destination).

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

29. The CA stated that in 2014 there had been five suspected / confirmed cases of notifiable diseases listed in Annex A to Directive 92/65/EEC in Dutch ABICs (Psittacosis and tuberculosis).

30. Procedures for suspicion of Annex A diseases in ABIC include different steps, e.g. notification, anamnesis, census of animals, forward and backward tracing of animals, identification of contact animals, identification of people in contact with suspected animals, testing of contact animals and testing of human contacts by Public Health Authority, and measures, e.g. movement restrictions, cleansing and disinfection of stables, materials, products and other supplies, and isolation of suspected animals.

31. After positive test result and confirmation of suspicion, a culling of positive animals or treatment, if possible, is carried out. The procedures include communication and informing other zoos, CA of trading country, public health authority, and public.

32. The DG Health and Food Safety audit team reviewed four cases, two tuberculosis in elephants and two cases of psittacosis, and noted that the CA largely followed their instructions. Although the handling of the cases included a restriction on movement of certain categories of susceptible animals from and to restricted part of ABIC, when the suspicion was raised, contrary to the requirements of Point 6 of Annex C to Directive 92/65/EEC, the CA did not suspend ABIC approval.

Conclusions on disease surveillance and control measures

33. In order to guarantee high health status of the animals, ABICs visited had disease surveillance plans in place. In some instances, they were not sufficiently designed/or formalised to provide clear evidence of absence of notifiable diseases. Concentrating on routine health issues (e.g. vaccination plans and faecal examination for parasitology) rather than notifiable diseases created some uncertainty in relation to the health status of the ABICs (particularly for asymptomatic carriers).

34. Suspicions and occurrences of notifiable diseases are dealt with professionally and the control measures are generally correctly applied. Authorities correctly restricted movement of susceptible animals where they had suspicions of outbreaks of notifiable diseases in ABIC, but they did not officially suspend their approval as required under EU legislation. Therefore, the Commission and other Member States were not officially informed of these events, preventing them to act upon the situation and consider the potential risk involved.

35. The standard of quarantine facilities and their operation in ABICs visited largely complied with the well-designed national requirements bringing guarantees that the health status of ABICs will not be compromised when introducing new animals from non-ABIC establishment.

36. The lack of approval and of comprehensive verification of ABIC veterinarian skills by the CA adds a degree of uncertainty to the ABICs actual animal health status.

5.3 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

5.3.1 Identification of animals and movement registers

37. 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. ABICs used a web based zoological information management system (ZIMS), which was accessible by other

zoos. In one ABIC visited the medical records were still kept in their own in-house system. The representatives of the ABIC informed the audit team that they are in a transitional period with data being transferred from the old system to ZIMS.

38. The DG Health and Food Safety audit team verified, using pre-selected TRACES certificates, that ABICs visited kept up to date movement records as required by point 1 (d)(ii) of Annex C to Directive 92/65/EEC.

39. Animals of domestic species kept in the ABICs visited were identified in accordance with the rules for domestic species availing of derogation for bovines, sheep and goats. The animals were identified with electronic transponders (microchips). No eartags were applied to each ear. However ABICs were in possession of the ear-tags, and apply them to the animals before they leave the premises in accordance with legislation (Regulation (EC) 644/2005 for bovine animals and Point 8, Section A of the Annex of Regulation (EC) 21/2004 for sheep and goats).

5.3.2 Movements

For national movements

40. The audit noted that the national central database for identification and registration of animals was updated for in/out movements of domestic species (bovines, sheep and goats).

For Intra-Union trade:

41. All trade certificates from ABICs were signed by official veterinarians which, with the exception of trade certificates for non-human primates, 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.

42. The official veterinarians met were aware of the Commission website listing ABICs in other Member States[3]. They use information on this website to verify if the holding of destination of non-human primates was an ABIC, in accordance with the CA instruction for intra EU trade.

43. If the list of ABICs in Member State of destination was not available or the place of destination was not on the list, the official veterinarians certifying movement of non-human primates followed the CA instruction. According to it, in exceptional cases (approved by Chief Veterinary Officer) the movement was allowed as long as the CA at destination authorised this movement. However, this practise is not in line with Art.

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

5 of Directive 92/65/EC. This article stipulates that trade in non-human primates is restricted solely to animals consigned to ABIC (with no option for derogation). In addition, in one instance reviewed by the audit team, non-human primates were moved to non-ABIC establishment without a prior consent of the CA at the destination.

44. Some intra trade certificates to Netherlands, reviewed by the DG Health and Food Safety team, referred to approval number of ABICs which did not relate to approval number granted in accordance with Annex C to Directive 92/65/EEC. This miscorrelation had been detected and addressed by the CA.

45. As regards of the official checks carried out to verify if the place of origin was ABIC, the CA informed the audit team that they rely on a certification carried out in Member State of the origin of animals. Therefore they do not carry out any additional checks to verify if the information available on the certificates was giving a true status of place of origin.

46. Following movement of the animals between Member States the checks at the point of destination (ABIC) are carried out according to CA instructions (The project protocol on Inspection of live animals and live products at the destination). In case of increased animal health risk identified, the national system in place communicates to the regions the need of increase checks at the destination.

5.3.3 Imports of harmonized species

47. Neither import nor transit of ungulates from approved bodies, institutes or centres were allowed since the publication of Regulation (EU) No 780/2013. Netherlands have not established yet a list of bodies, institutes or centres in third countries from which ungulates may be introduced.

48. Since 2013 a total of 26 consignments of ungulates were imported to Netherlands, mostly Lamas from Chile (not destined to ABICs), certified according to EU legislation.

49. The audit team reviewed the documents related to one consignment of eleven giraffes in transit from South Africa to China, certified according to the model certificate as set in Part 3 of Annex E to Directive 92/65/EEG (health certificate for trade in animals, semen, ova and embryos from ABIC). Those giraffes were allowed for transit in contravention with EU requirements – South Africa is not listed for export or transit of ungulates to the EU. The CA indicated that the particular transit was allowed due to individual and not systematic error. The audit team verified that the current national system for import (IVO) indeed correctly does not allow such import/transit of giraffes from South Africa.

50. No agreement has been put in place in order to avail of the possible postponement of checks to ABICs when animals are imported through another Member State (possibility foreseen by Article 8(A)(1)(b)(ii)) of Directive 91/496/EC), nor is there any derogation for checks at BIPs for any category of animals going to ABICs.

Conclusions on movements of animals

51. The animal identification and movement records kept by ABICs are generally reliable which allows the CA to trace animals through all stages of their life.

52. All intra-Union trade movements from ABIC are certified by official veterinarians which, goes beyond the requirements of Directive 92/65/EEC for all animals but non-human primates. For this latter category, the CA allows movements to places not approved as ABIC (contrary to Article 5 of Directive 82/65/EEC), in most cases with authorisation of the CA at destination.

5.4 APPROVAL OF BODIES, INSTITUTES AND CENTRES

Legal requirements

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

Findings

5.4.1 Listing of approved bodies, institutes and centres

53. All approved bodies, institutes and centres are registered and issued with an approval number by the CA in line with Article 13(2)(d) of Directive 92/65/EEC.

54. The CA has drawn up and keeps up to date a list of ABICs and their approval numbers and has made it available to the other Member States and to the public. This is done through a EC website[4].

55. The audit team noted that the list has been recently updated when one of the ABIC, previously approved and not operational anymore, was delisted.

56. All ABICs visited were approved and approval documents were made available to the DG Health and Food Safety team confirming approval status.

5.4.2 Procedures and conditions for approval

57. The system for assessing the conditions for approvals is based on developed procedures:

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

- According to CA instruction in order to be approved, bodies, institutes or centres shall submit an application to the CA. Applications may only be submitted electronically via an application available at CA webpage[5].
- The application is then forwarded to the regional team responsible for area where the applicant body, institute or centre is located.
- The CA regional team carries out an on-site visit at applicant premises to assess compliance with the legal requirements.
- During the inspection a comprehensive checklist designed specifically for ABIC approval/maintenance of approval is used which covers the requirements of Annex C to Directive 92/65/EEC.
- The result of ABIC assessment is sent to the CA central level where, if all conditions are met, approval document is issued and approval number is allocated to ABIC.

58. In line with the existing CA procedures bodies, institutes or centres may be approved without available quarantine facilities despite that it is the requirement laid down in point 1 (b) of Annex C to Directive 92/65/EEC. In that instance the CA requires that the animals arriving to the concerned ABIC must come exclusively from other ABIC establishment.

59. The audit team noted that the information on missing quarantine facility in ABIC is not included in the approval document. At the time of the DG Health and Food Safety audit three out of 19 ABICs in Netherlands were operational without having adequate quarantine facilities. This information is included in the CA internal instruction for intra-EU trade. But the publicly available list of ABICs does not contain any remark on movement restriction to ABIC. The audit team noted the case when the animals were sent from non-ABIC establishment in another Member State to the Dutch ABIC approved without quarantine facility and the animals directly entered to ABIC without being quarantined. This is not in line with EU requirements (point 3 of Annex C to Directive 92/65/EEC). The case was not identified by the CA.

60. The national rule requires a keeping of site plan of premises referring to a time of approval (as part of approval document). This national rule, which goes beyond EU requirement, was not applied in the ABIC visited. In premises visited by the DG Health and Food Safety team no "approval" site plan of premises was available therefore it was not able to reconstitute which parts of the premises were approved. When a new quarantine facility was built on the site its adequacy and fitness for purpose was assessed during the routine annual audit when it had been already in use and no separate/amended approval was issued.

61. Maintenance of approval is based on annual audits carried out by the CA. Their objective is to ensure that the provisions of Directive 92/65/EEC are met. They are

[5] http://www.vwa.nl/onderwerpen/werkwijze-dier/dossier/erkenningen-vergunningen-registraties/erkenningen

documented and they cover requirements under point (2) of Annex C to Directive 92/65/EEC:

- In 2012-2014 all listed ABICs were annually audited.
- Completed checklists to verify compliance with the provisions of Directive 92/65/EEC were seen for 2012, 2013 and 2014. In instances where deficiencies were noted the corrective actions were taken to address them.

62. Only limited technical supervision covering official controls at ABICs are currently in place, mainly based on desk exercise without visiting ABIC facilities and assessing of performance of the official veterinarians on-site (as it was case in the past).

63. In one ABIC visited several significant deficiencies were noted by the DG Health and Food Safety team. This ABIC was major importer of non-human primates from a third country. The primates were subsequently traded to various Member States. The deficiencies noted by the DG Health and Food Safety team were not detected during the recent official controls, undermining the credibility of the ABIC approval status:
    - The activities of the approved veterinarians were limited and did not ensure a compliance with requirements of (1)(g) of Annex C to Directive 92/65/EEC:
        - The approved veterinarian was present in the ABIC 3-4 times per year.
        - The role of the approved veterinarian was limited to a consultancy.
        - The day to day compliance with the animal health requirements, animal welfare requirements and disposal of animal waste was not under the effective responsibility of the approved veterinarians (e.g. isolation and quarantine of incoming animals, and post mortem examination of dead animals).
    - The audit team reviewed the documents related to two consignments of primates from third country (China) and noted:
        - No official health certificates accompanied the consignment.
        - The exporter health attestations significantly differ from model of veterinary certificate set out by the CA, which includes OIE standards. As a consequence the attestations reviewed did not include the vast majority of the veterinary requirements required by the CA (e.g. requirement for pre-export quarantine, tests required to guarantee health status of the animals).
        - The exporter attested animal country residency for first consignment only seven days, and ten days for second consignment, instead of six months required by the CA.
        - Some laboratory tests on exported animals from China were attached, including tests for viruses but not Ebola, specifically required by the CA.
        - The consignments were cleared at BIP of other Member State. The CA informed the audit team that due to no communication on this matter the BIP was not aware of Dutch import conditions for non-human primates.
        - The most recent check at the place of destination was performed by the CA in September 2015, therefore after arrival of both consignments. The CA non-veterinarian staff had not detected any non-compliance with import conditions.

- The quarantine procedures were not fully in line with OIE requirements for quarantine of primates (e.g. no laboratory test for bacteriological pathogens carried out although required by the OIE standards). Tests for viruses covered the most relevant diseases but Ebola. Ebola was compulsory tested but only on customer demands. The tests for tuberculosis were carried out by a non-veterinarian ABIC staff (para veterinarian) without supervision of the approved veterinarian. In addition the animals were quarantined and released from the quarantined without a supervision of the approved veterinarian.
- The quarantine facilities did not comply with several requirements of Article 5.9.3. of the OIE code to provide adequate confinement and biosecurity (although the standard is required by point 3 of Annex C to Directive 92/65/EEC), e.g. no direction of the airflow in the quarantine facility inward from the outside of the quarantine facility (to quarantine access areas, and to animal holding rooms), no filtering of air exhausted and common access area for several units (each unit run as separate quarantine) where clothes, footwear and protective articles were changed. In addition, no adequate isolation facility was available for sick animals.
- Only limited documentation on quarantine operations was available.
- The approved veterinarian authorised the ABIC procedure, which does not foresee post mortem examination of dead animals but only freezing carcasses for certain time period before their destruction. No dead animal was subjected to post mortem examination in 2015. That concerned also an animal which died with clinical signs of infection and was under antibiotic treatment. This animal was not isolated from the rest of his group before he died. No consideration was given as regards potential movement restrictions to other animals of the same group from this ABIC. In addition the filing system in place did not provide sufficient information for an animal traceability, e.g. a list of animals which formed this particular group at that given time. This ABIC had no arrangement with competent laboratory to perform post mortem examination or premises where these post mortem examinations may be performed by the competent person under authority of the approved veterinarian. This practise is in contravention with EU legal requirements ((1)(e) of Annex C to Directive 92/65/EEC) and represented a risk of undetected health threat by the fact that this ABIC is very active in intra EU trade of imported animals.

Conclusions on approval of bodies, institutes and centres

64. ABICs are in general under effective and well organised official controls, performed according to developed procedures which include approval, auditing and maintenance of ABIC approval. However some deficiencies noted by the DG Health and Food Safety team (e.g. no quarantine of incoming animals to one ABIC, incomplete approval documentation) but not detected by the official controls slightly undermine the overall system performance and in some instances may jeopardise ABIC health status.

65. The quality of CA' annual audits to verify ABIC compliance with the requirements is not subjected to effective supervision and varies, in one instance resulting in the maintenance of ABIC (importing non-human primates) approval without meeting the essential requirements of Directive 92/65/EEC, therefore increases the risk of non-detecting/containment in timely manner of health risks posed by these imports and subsequent trade.

66. The system for the control of the health requirements for imports of live animals not subject to harmonised conditions currently does not ensure that the conditions required by Netherlands will be effectively controlled if the animals are introduced through a BIP in another Member State.

6 OVERALL CONCLUSIONS

Official controls of approved bodies, institutes and centres (zoo and laboratory animals) in the Netherlands benefit from a developed framework, mainly based on well-developed procedures, good traceability of animals in place, professionally dealt suspicions and occurrences of notifiable diseases and control measures applied.

The quality of CA' annual audits to verify ABIC compliance with the requirements is not subjected to effective supervision and varies, in one instance resulting in the maintenance of ABIC approval without meeting the essential requirements of Directive 92/65/EEC. The CA undertook to implement immediate measures to correct cumulated significant deficiencies that went unnoticed by official controls.

In addition, the full effectiveness of the system is weakened by systemic deficiencies noted, in particular regarding

- Inadequate standard of disease surveillance plans in ABICs and their official controls, not focussing on regulated diseases and resulting in some uncertainty in relation to the health status of the ABICs.
- Movement of non-human primates from ABIC to non-ABIC establishment which is contradictory to current EU requirements.

The current system for the import control of live animals not subject to harmonised

conditions (e.g. non-human primates) does not ensure that the national conditions required by certain Member States are effectively controlled if the animals are introduced through another Member State. In the case of import of primates reviewed by the DG Health and Food Safety team, they pose significant risk for the introduction of diseases which could also affect people.

7 CLOSING MEETING

A closing meeting was held on 13th November 2015 with the CA. At this meeting the DG Health and Food Safety 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. The CA undertook to implement immediate measures to address deficiencies noted during the audit, including measures to correct cumulated significant deficiencies in one ABIC visited that went unnoticed by official controls.

8 RECOMMENDATIONS

No.	Recommendations
1.	To ensure that an establishment maintains its approval only if the operator has demonstrated that it complies with the relevant provisions of Directive 92/65/EEC, particularly in accordance with point 2 of Annex C of this Directive. *Based on conclusions (64) and (65), and associated findings (17), (59), (60), (62) and (63).*
2.	To verify that veterinarians employed by ABICs possess the knowledge and skills necessary for this particular field of animal health as required by Point 1 (g)(i) of Annex C to Directive 92/65/EEC. *Based on conclusions (36) and (65), and associated findings (13) and (62).*
3.	To ensure that in case of suspicion of a disease listed in Annex A or B to Directive 92/65/EEC, the approval of the ABIC is suspended, and that the Commission is informed of suspension, withdrawal or restoration of approvals. Point 6 of Annex C to Directive 92/65/EEC. *Based on conclusion (34), and associated finding (32).*
4.	To ensure that trade in non-human primates is restricted solely to animals consigned to ABIC. Article 5 of Directive 91/496/EEC. *Based on conclusion (52), and associated finding (43).*
5.	To ensure approval of appropriate annual disease surveillance plans (demonstrating absence of the diseases referred to in Annexes A and B in relation to the disease situation of the country) applied in ABICs. Point 1 (g)(ii) of Annex C to Directive 92/65/EEC. *Based on conclusion (33), and associated findings (14) and (15).*
6.	To ensure adequate checks on animals of non-harmonised species subject to national animal health conditions, imported from third countries through border inspection posts in another Member State. Article 4 of Directive 91/496/EEC. *Based on conclusion (66), and associated finding (63).*

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=2015-7564

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. 92/65/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

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
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