European Commission

DG Health and Food Safety

OVERVIEW REPORT

Animal Health Controls in Zoos and Laboratories

Health and Food Safety

Europe Direct is a service to help you find answers to your questions about the European Union.

Freephone number (*):

00 800 6 7 8 9 10 11

(*) The information given is free, as are most calls (though some operators, phone boxes or hotels may charge you).

Online information about the European Union is available at: http://europa.eu/index_en.htm
Further information on the Health and Food Safety Directorate-General is available on the internet at: http://ec.europa.eu/dgs/health_food-safety/index_en.htm

Luxembourg: Publications Office of the European Union, 2017

Electronic version
ISSN 2315-2168
ISBN 978-92-79-43510-2
doi:10.2772/56814
Catalogue number: ND-BC-14-005-EN-N

Paper version:
ISBN 978-92-79-53350-1
doi:10.2772/33947
Catalogue number: ND-BC-14-005-EN-C

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health and food audits and analysis

DG(SANTE) 2016-8997 - MR

OVERVIEW REPORT ON ANIMAL HEALTH CONTROLS IN ZOOS AND LABORATORIES

Executive Summary

The objective of this report is to provide an overview of the effectiveness of official controls to ensure compliance of bodies, institutes or centres approved under Directive 92/65/EEC with applicable requirements. The report also aims at presenting the standards of animal health surveillance and control measures applied in these establishments to prevent the entrance and spread of infectious diseases.

This overview report concludes that the existing systems generally ensure the traceability of the animals kept in establishments approved in accordance with Directive.

The official approval of an establishment does not necessarily guarantee compliance with the requirements of Union legislation and is not always an indication of high animal health status. This is mainly due to general deficiencies in the approval and control of these bodies, institutes or centres. Absence of guidance for officials and the wrong scope and insufficient frequency of official visits are the main causes of the problem.

The annual disease surveillance plans that these establishments must have in order to demonstrate their high animal health status are not fulfilling their role. This happens because they do not generally focus on the diseases of concern for livestock and humans. They are based on more basic health management requirements and are not adapted to evolving disease risks.

Most Member States do not assess skills and knowledge of private veterinarians overseeing activities in these approved establishments. These veterinarians are clinically proficient but not always aware of their full obligations under the Directive and they don't play the role expected in it.

Currently, the import and trade of primates represents a vulnerable point for the Union health status. The incorrect controls and inconsistencies observed represent an increased risk for the introduction and spread of animal and human diseases in the Union.

Animals from approved establishments can and do move to farms and the existing standards to move livestock are not always applied.

It is difficult to find updated lists of approved establishments in the European Union - this is a factor that impedes verification and compliance with trade rules between such establishments.

Currently there is no guarantee that animals imported from non-EU countries comply with health standards set by the Member State of destination, particularly when they enter in the Union through another Member State. The current system also does not ensure that the conditions for import of these species are at least as strict as the conditions established for trade in the Union.

To protect the Union from exotic diseases, the current system to import ungulates relies now on assessment, approval and listing of establishments in non-EU countries by Member States and ultimately, on the assurance given by a non-EU country. The important weaknesses and misunderstanding of requirements detected in this area in Member States question their ability to verify that non-EU countries apply all the necessary requirements.

Table of Contents

ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
ABIC	Approved body, institute or centre
Approved establishments	Establishments which are approved under Council Directive 92/65/EEC and 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.
EU	European Union
Primate	Non-human primate (any mammal that includes lemurs, monkeys and apes).
The Directive	Council Directive 92/65/EEC
TRACES	Trade Control and Expert System
Zoonoses	Any disease or infection which is naturally transmissible from animals to humans.

1 INTRODUCTION

Zoos, animal parks and institutes which keep animals play an important part in education, recreation, research and conservation. Every year, thousands of people go to zoological and wildlife parks, pet zoos, and educational farms to see animals they would never otherwise see.

Such animals can carry diseases which may have serious consequences for livestock farming or people (zoonoses). For example, zebras imported from Namibia in 1987 were responsible for an outbreak of African horse sickness in Spain and Portugal. In the USA, the introduction of Reston Ebola virus in 1990 was through primates imported from the Philippines and the introduction of monkey-pox virus in 2003 was through African rodents. There are numerous references in literature to the incidence of tuberculosis in animals kept in zoological parks involving a range of species and many published reports documenting elephant to human transmission of tuberculosis.

Nevertheless, movements of such animals are necessary, if only to optimise genetic diversity and to complete animal collections (i.e. acquire species not yet owned). The introduction of new animals into the collection increases the opportunity for introduction of diseases and their transmission to other animals or people e.g. animal handlers and members of the public.

Establishments keeping or breeding animals for scientific research also need to exchange animals. The same potential for introducing and transmitting diseases to livestock or people exists, particularly when such animals are of domestic species or primates.

2 OBJECTIVE

The objective of this report is to provide an overview of the effectiveness of official controls to ensure compliance of bodies, institutes or centres approved under Council Directive 92/65/EEC (hereinafter "the Directive") with applicable requirements. The report also aims to present the standards of animal health surveillance and control measures applied in these establishments in order to prevent the entrance and spread of infectious diseases.

3 METHODOLOGY

The information included in this report has been obtained from the five audits that DG Health and Food Safety performed in Member States between 2014 and 2015. A list of countries audited is provided in Annex 2 and details of the individual reports can be found at:

http://ec.europa.eu/food/audits-analysis/audit_reports/index.cfm

DG Health and Food Safety sent questionnaires on this topic to the 23 Member States that were not audited and got replies from 20 of them which provided further information for inclusion in this report.

Other sources of information used are quoted as footnotes throughout the report.

Unless otherwise stated, the information provided reflects the situation at the time of the audits and of the questionnaire responses.

4 BACKGROUND

European law covering transmissible animal diseases, intra-union trade and import of animals from non-EU countries is complex and comprises many different legal acts. The Directive sets out the animal health conditions governing trade in and imports into the European Union (EU) of various species of animals not covered by other specific EU legislation. It covers for example most non-domestic species of mammals and birds.

This Directive provides a basis for bodies, institutes and centres - such as zoos or laboratories keeping or breeding animals for research - to become approved and use less stringent import and trading procedures. The law is set so bodies, institutes and centres that are approved under it apply a set of defined conditions related to biosecurity and animal health surveillance and are assumed to have a good animal health status.

It is important to note that all zoos or laboratories with animals are not required to be approved under the Directive as an approved body, institute or centre (ABIC). Such approval gives establishments the exclusive right to receive primates from other Member States, and equally send them to ABICs in other Member States, accompanied by a health certificate issued by an official veterinarian. For other species, movements between ABICs located in different Member States can be accompanied by a health certificate issued by the veterinarian of the sending establishment, while a health certificate issued by an official veterinarian is necessary if these animals move to or from an establishment which is not an ABIC.

In 2013, EU legislation was amended to authorise the importation of ungulates from a wider range of countries and species than before. This should be done under the strict conditions that they would go to an approved establishment in the EU, originate from an establishment in the exporting non-EU country approved by the Member State of destination (in line with the similar standard laid down in Annex VI Part 3 of Commission Regulation (EU) 206/2010) and accompanied by the relevant certificate in Annex VI Part 2, in which all specific import conditions, including testing and isolation in a pre-export quarantine protected from vector insects, are provided. These mitigation measures were introduced in recognition that "individual animals may still carry infectious diseases that could spread into the Union and consequently constitute a danger to animal health in the Union"[1].

The recently adopted Animal Health Law[2] states that the approach for species representing no significant health risk for humans or other animals would remain the same (no detailed health rules, unless the risk evolves). For other species the approach established in the Directive, including the conditions for trade, may be reviewed.

---

1 Recital 10 of Commission Implementing Regulation (EU) No 780/2013

2 Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')

In 2013, on the basis of these evolutions, the Commission decided to audit and evaluate the official controls in this sector with the objective to verify compliance with the Directive and the applicability and suitability of the rules to real scenarios, with the aim to identify possible gaps or areas for improvement in the legal framework aimed at protecting the animal health status of the Union.

5 Overview of Main Findings and Conclusions

5.1 Legal framework and competent authorities

The Directive sets out the requirements that all Member States must achieve in this area of animal health. Each Member State must bring into force the laws, regulations and administrative provisions necessary to comply with this Directive.

Several of the audited Member States had not included all of the Directive requirements into national laws. Lists of notifiable diseases were incomplete and the requirements governing approval of bodies, institutes or centres were, in some cases, not fully incorporated into national laws e.g. to ensure approval of ABICs is granted in a uniform and correct manner and that approval is carried out at the correct frequency.

Member States have designated competent authorities to perform official controls and the standard of delivery of official controls varies within and between Member States. Controls are frequently delivered by local veterinary staff with few approved establishments to supervise. Consequently, it is difficult for them to build expertise in this area and this is further compounded, in many cases, by a lack of documented procedures and guidance.

5.2 Approval

Each Member State is required to maintain a list of approved establishments and make it available to other Member States and the public, via the internet, in conformity with a set model[3]. The Commission provides a link to these lists at its webpage[4]. In September 2016, there was no information available via the Commission link about such lists in 10 Member States as they had provided no link, their link was not working or was not providing relevant information.

Competent authorities in some Member States have a misunderstanding of the type of establishment which can be granted approval under the Directive. This resulted in establishments being approved and listed notwithstanding, they did not fall within the definition in the Directive and included e.g. equine artificial insemination centres and apiaries. This misunderstanding was further emphasised when two out of five Member States audited significantly reduced the number of approved establishments on their list immediately before the audit (one from 380 to 69 and another from 150 to 42). The replies to

[3] Commission Decision 2009/712/EC implementing Council Directive 2008/73/EC as regards Internet-based information pages containing lists of establishments and laboratories approved by Member States in accordance with Community veterinary and zootechnical legislation.

[4] http://ec.europa.eu/food/animals/live_animals/approved-establishments/index_en.htm

the questionnaire indicate that the majority of EU countries do not have procedures to update the list regularly and claim to modify it on an ad-hoc basis.

Competent authorities allocate approval numbers to the establishments at approval, as required by the Directive, and in the main this is correctly done. Irregularities detected during the audits, while not generalised, are a result of the absence or poor application of procedures in this area and included establishments with no approval number and two establishments with the same approval number.

This inaccuracy of publicly available lists complicates the ability of competent authorities to plan and perform their necessary checks effectively e.g. verifying the approval status of establishments when apes are moved between Member State as these movements can only take place between ABICs. In addition, the wrong listing could misguide other Member States about the health status of the establishments and result in animal health certificates being issued by an approved rather than an official veterinarian (see 5.5 Intra-union movements).

There is a high variability among Member States in the completeness of approval procedures. This ranges from detailed instructions, standards and checklists to absence of common standards within a country or total absence of documentation. Information provided in questionnaires confirmed that around a quarter of respondents had no guidance available for approval of these establishments with several indicating they had no documented approval process. Most countries responding to the questionnaire indicated that they perform on-the-spot visits before granting initial approval and inspect the establishments at least annually to maintain approval. Commission audits found establishments being officially approved with no on-site inspection (which is not required by the Directive, although can be considered good practice) and maintenance of approval without official visits (which is required by the Directive at least once per year).

The official procedures in place give limited assurance that the establishments granted initial approval and extension/renewal of the approval consistently met the requirements set in the Directive. In many cases the competent authorities have poorly documented procedures for the delivery of official controls in this area and incomplete records of these activities contrary to Regulation (EC) No 882/20045. This hinders the ability of competent authorities to review their official controls and improve their own interventions in this area.

5.3 SUSPENSION / WITHDRAWAL OF APPROVAL

Authorities should withdraw the approval of an establishment when it no longer meets the requirements of the Directive and they should suspend it when there is suspicion or confirmation of one of the notifiable diseases listed in Annex A to the Directive.

All countries audited had suspicions or outbreaks of diseases listed in the Directive in the five years before the audit. These included diseases such as tuberculosis, psittacosis, rabies and

[5] Articles 8 and 9 of Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Newcastle disease affecting a wide variety of species (elephant, gorilla, antelope, camels, birds,…). In contrast, the majority of Member States responding to the questionnaire indicated they did not have suspicions or outbreaks of notifiable diseases in the preceding five years.

The suspicions and occurrences of notifiable diseases analysed by DG Health and Food Safety were generally dealt with effectively by competent authorities who restricted the movements of susceptible animals to prevent the spread of the disease and carried out appropriate epidemiological investigations. Exceptions to this include occurrences of bluetongue (presence of virus in asymptomatic ungulates and diseased animals) which were not reported as outbreaks to the Commission by the competent authority and no or incomplete epidemiological investigation was performed after confirmation of a disease. This further highlights the risk of introducing and transmitting diseases to livestock from approved establishments.

The audits uncovered a tendency to keep the approval of the establishment active when diseases were suspected or confirmed. Thus, in numerous cases, the authorities did not suspend the approval of the establishment on notification of suspicion, but only once the disease had been confirmed. In some cases, the approval was not even suspended when the disease was confirmed. Consequently, the Commission and other Member States were, in many cases, not officially informed of these events. This prevents Member States from planning their checks at destination taking into account the potential risk. However, this risk was mitigated by the fact that trade only took place with official veterinary certification which was suspended for the susceptible species.

5.4 MOVEMENTS OF ANIMALS

Records kept in approved establishments include all relevant information required by the Directive e.g. details of individual identification (where practical), species and date of movements in / out. Many of the zoological establishments visited during audits were members of the European Association of Zoos and Aquaria[6], and as such used a web-based zoological information management system as a stand-alone animal register, or in tandem with their own in-house records. This management system has the added advantage that the animal's lifetime history, including medical records, can be accessed by other zoos. These records demonstrated that animal identification and movement records are generally well kept and reliable, permitting competent authorities to trace animals through all stages of their life.

Approved establishments may receive animals from non-approved ones in which case they should have procedures approved by competent authority to introduce these animals. During the audits, these procedures were frequently not in place and their absence had not been detected during official controls. Consequently, this is a factor that may create a higher risk of introducing diseases to the existing animal population.

[6] http://www.eaza.net/

Many zoos or laboratories include livestock (e.g. cattle, sheep and goats, pigs, equidae) within their animal collections. These animals are generally identified according to the specific EU rules for such species and are recorded in relevant national databases. Movements of these animals within one country are generally accompanied by a health certificate or attestation and updated in the national livestock movement databases. In general, Member States allow movement of these domestic species from approved establishments to other holdings (farms) within their territory. This highlights the contact between zoo populations and farm animals, the potential risks for spread of disease and how this may affect the official status on holdings for diseases such as brucellosis or tuberculosis.

5.5 INTRA-UNION MOVEMENTS

Health certification for trade of animals susceptible to Annex A and B diseases (of the Directive) between approved establishments is consistently based on the correct certificate model corresponding to the specimen at Part 3 of Annex E to the Directive.

Animals can be traded between approved establishments accompanied by this intra trade certificate which can be issued by the approved veterinarian in charge of the establishment (with the exception of primates, where the certificate must be signed by an official veterinarian). In practice, Member States do not use this possibility and almost all trade of animals from approved establishments is certified by official veterinarians which results in a stricter control of movements from ABICs than required by EU legislation.

There is a significant lack of knowledge among certifying officers on how to verify the approval status of establishments located in other Member States[7]. Many certifying officers do not know where to locate the lists or use the lists available in the Trade Control and Expert System (TRACES) which are neither official nor reliable. The TRACES lists do contain data which has neither been validated e.g. it is entered directly by business operators, nor updated.

Some competent authorities carry out checks at arrival when animals are traded, and in most cases, they are useful to confirm the number and species of the animals traded. However, these checks are not effective at detecting whether all other requirements have been complied with e.g. whether the animals originate from an approved establishment and if animal health requirements are complied with.

Member States competent authorities do not always implement correctly the specific pieces of legislation together in a single sector. For example, during an audit, a ruminant from an approved establishment situated in a bluetongue-restricted area moved to an approved establishment situated in a non-restricted area with improper certification. The deficiency in certification was not detected at the approved establishment of destination or by the official veterinarian who performed the check at destination.

For trade of primates, both establishments - the one sending them and the one receiving them - need to be approved. The authorities may derogate from this and allow an approved

[7] http://ec.europa.eu/food/animals/live_animals/approved-establishments_en

establishment to acquire a primate belonging to an individual, but there is no derogation for the establishment of destination. The audits identified that trade of primates to non-approved establishment occurred, and these irregularities were not detected and/or sanctioned even when the competent authorities performed checks at destination.

5.6 IMPORTATION OF ANIMALS

There have been very few importations of ungulates to approved establishments within the Union since Commission Implementing Regulation (EU) No 780/2013 came into force. The review of one case indicated the system in place complied with Union law. The Member State that imported the animal listed the establishment sending the animal (in a non-EU country) on the basis of an official letter from the authorities of that country certifying that it complied with all the required conditions. To date, there have not been visits from the Commission or authorities in Member States audited to non-EU countries to check compliance with animal health requirements in establishments that may send ungulates to Europe, and no information on such visits carried out by authorities from other Member States has been made available. The correct application of the import requirements for ungulates into the EU (aiming at preventing entry of diseases) relies in great part on the correct interpretation and control, by the non-EU country, of the structural and operational requirements for approved establishments (including vector-protected facilities for pre-export quarantine).

There are no common health rules for the import into the EU of certain animals (non-harmonised species) - these include primates and reptiles. For primates, their importation can only take place to an ABIC. For non-harmonised species, each Member State establishes its own animal health conditions provided they are not less stringent than those for intra Union trade. In cases where animals enter the EU through another country which is not the final destination, Member State arrangements do not guarantee that the border inspection post is aware or informed of the national requirements established by the final destination country. Consequently, the final destination country cannot confirm that checks at entry are performed against its national requirements. Animals have been cleared at border inspection posts where staff did not know the import conditions of the final destination Member State, e.g. consignments of primates were imported without health certification although this was required. There are examples where authorities were proactive and contacted the entry points in other countries to make them aware of their national provisions, or published their conditions on the internet (in their national language), but generally they did not solve the problems indicated above.

None of the Member States audited used the exemption to defer physical checks from the border inspection post of entry to the Member State of final destination[8] where handling facilities for exotic species are more likely to be present.

[8] as permitted by Article 8(A)(1)(b)(ii) of Directive 91/496/EEC

5.7 VETERINARIANS AND DISEASE SURVEILLANCE PLANS

Approved establishments must contract the services of a veterinarian possessing particular knowledge, approved by the competent authority, who shall ensure appropriate disease surveillance and control measures are approved by the authorities and applied. The diseases relevant for such surveillance and control (and the concerned species) are listed in Annex A to the Directive. Member States have not presented to the Commission (for its approval) programmes for most of the other diseases that are listed on Annex B of the Directive and potentially relevant for ABICS (with the exception of varroasis). In practice, only the diseases in Annex A to the Directive have to be considered.

Many Member States approve the veterinarian responsible for the establishment, but the extent to which they verify his/her expertise is generally unclear. The majority of countries audited did not have a framework to approve veterinarians or to confirm they possessed the necessary knowledge. In contrast, the majority of questionnaire responses indicated that authorities formally approve these veterinarians and had in place guidance, instructions and/or specific requirements for approving veterinarians for these duties.

In many of the approved establishments visited, the approved veterinarians had an extensive clinical knowledge of the animals under their care but were less knowledgeable of the legal framework in this area. This was evidenced by e.g. lack of laboratory diagnosis in cases of suspect transmissible diseases and lack of adaptation of the annual disease surveillance plan to emerging disease threats or to diseases listed in Annex A to the Directive.

Disease surveillance and control measures in approved establishments should be appropriate and adapted to the disease situation. These measures must be approved by the competent authorities and include at least an annual disease surveillance plan, clinical, laboratory and post-mortem testing of animals suspected to be affected by transmissible diseases, and vaccination of susceptible animals.

Many of the disease surveillance plans drafted and implemented in approved establishments are not designed to provide evidence of absence of the notifiable diseases in the Directive. Instead, they focus on routine health issues such as vaccination plans and faecal examination for parasitology. Shortcomings uncovered during audits included infrequent revision of the plans, surveillance requirements in the plan not being actioned and plans not being updated when the disease situation of the Member State changed (e.g. avian influenza, bluetongue).

For the approved establishments visited by DG Health and Food Safety, official endorsement of the disease surveillance plans by competent authorities highlight that their controls are not always effective in detecting weaknesses and that there is a lack of understanding of the purpose of the plans not only from the veterinarians of the establishments, but also from the competent authorities. Approximately half the respondents to the questionnaire indicated they do not formally approve the plans and three quarters of respondents indicated they had no guidelines for approval of plans.

Most approved establishments carry out post-mortem examinations either in-house or in external laboratories. This passive surveillance provides useful information on the establishments' animal health status. The extent of follow-up laboratory analyses varied greatly between the establishments, being at times infrequent or absent for viral diseases in the scope of the Directive despite inconclusive or suggestive clinical or post-mortem findings. In such cases, official controls do not always detect these shortcomings.

One approved establishment involved in research developed its disease surveillance plan on the basis of guidelines of the Federation of European Laboratory Animal Science Association[9]. This provides a good basis for a disease surveillance plan though not all relevant diseases in Annex A to the Directive were included.

The inclusion of livestock kept in approved establishments into national disease control programmes such as tuberculosis, brucellosis and enzootic bovine leucosis is inconsistent. Some countries or regions include approved establishments in their national testing schemes and test domestic bovine or ovine/caprine species present, whilst other countries exclude them. Around two thirds of Member States which replied to the questionnaire give approved establishments an official classification for bovine tuberculosis, brucellosis and enzootic bovine leucosis. The proportion of Member States allocating official status for brucellosis in small ruminants is lower (around half). Some Member States also give approved establishments an official status for Aujeszky's disease.

A Member State was giving an officially tuberculosis-free status to the approved establishments in order to permit movements to other holdings. At the same time, the Member State excluded testing domestic cattle of the approved establishment using a derogation foreseen in the legislation for animals taking part in cultural events.

Livestock kept in approved establishment are at particular risk of exposure of tuberculosis or brucellosis, as they are kept with non-domestic species, for which methods of investigations of these diseases are not validated, and usually not subject to active surveillance. Four of the five Member States audited experienced cases of tuberculosis in approved establishments. They all took measures, including epidemiological investigations, testing and culling of certain categories of animals, but in many cases the re-instatement of the officially-free tuberculosis status of the holding was not documented, or not in line with the minimum requirements of the EU legislation[10].

The examples of insufficient measures for surveillance and control measures for tuberculosis show that the attribution of officially free status of these establishments allowing bovine animals to move out without testing is questionable.

Disease surveillance plans usually have important shortcomings and the plans are not systematically reviewed and assessed by competent authorities. However, useful surveillance

[9] http://www.felasa.eu/

[10] Directive 64/432/EEC

data is obtained when post mortem examinations and extensive laboratory investigations are carried out.

5.8 QUARANTINE

Quarantine refers to a period of isolation when animals are observed for signs of infectious disease and possible testing prior to their introduction to a new population. It is a way of preventing the introduction of diseases into an existing animal population.

To be approved, establishments must have available adequate quarantine facilities for the introduction of animals from non-approved sources. A common finding during audit was the absence of approved procedures or instructions from the competent authorities for the introduction of such animals.

Specific and stringent structural and operational standards are required for quarantine of primates (in line with chapter 5.9 of the World Animal Health Organisation)[11].

Some approved establishments visited during audits had no quarantine facilities. The competent authorities of a Member State visited did not require quarantine facilities to approve an ABIC, in which case they would expect the ABIC to source animals only from other approved establishments. . However, neither the approval nor the public list of approved establishments indicated such restrictions. Consequently, animals coming from non-approved establishments were traded and introduced directly to these approved establishments, creating a health risk that was not identified by the approved or official veterinarian of the approved establishment of destination.

The structural standard of the quarantine facilities visited was variable and ranged from new, state of the art establishments to the modification of pre-existing buildings. In some cases the biosecurity of the quarantine was compromised as the materials used for construction did not allow proper cleaning and disinfection. Many approved establishments receiving primates from non-approved sources had adequate quarantine structures, while in some cases quarantine of such animals were performed in structures falling short of the required standards.

Operational standards of quarantine operations varied between approved establishments. The quality of record keeping ranged from daily logs registering all presence and activities in the quarantine by means of individual animal records to no records being maintained of animals present in the quarantine (hindering the control of their effective isolation in quarantine). Clinical controls during quarantine presented in some cases shortcomings or bad practice, such as the absence of link of medical treatments to individual animals, or the absence of investigation of the cause of death of imported primates falling sick during quarantine and not reacting to antibiotic treatments. There was not always complete separation between different groups of quarantined animals which increased the possibility of exposure to infectious

[11] http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_quarant_non_huma_primates.htm

agents between the groups. In case of disease outbreak, the absence of adequate records would make the tracing of contact animals very difficult.

In some cases, quarantine facilities were used also to keep animals seized by customs, police or handed in by members of the public. Additionally, some approved establishments use their quarantine facilities to isolate sick animals from their main collection. As an all in / all out system was not generally in use, these practices increased the risk of exposure to infection for all animals present in the quarantine facility.

Approximately half the respondents to the questionnaire indicated they had developed guidance relating to both the structural and operational requirements of a quarantine facility.

6 OVERALL CONCLUSIONS

Existing systems generally ensure the traceability of the animals kept in establishments approved in accordance with the Directive.

The official approval of an establishment does not necessarily guarantee that the expected high health status is met. This is mainly due to general deficiencies in the approval and control of these bodies, institutes or centres. The wrong scope and insufficient frequency of official visits and the absence of guidance for officials are the main causes of the problem.

The annual disease surveillance plans that these establishments must have in order to demonstrate their high animal health status are not fulfilling their role assigned by the legislation. This happens because they do not generally focus on the diseases of concern for livestock and humans. They are based on more basic health management requirements and are not adapted to evolving disease risks.

Most Member States do not assess knowledge of private veterinarians overseeing activities in these establishments nor formally approve them. These veterinarians are clinically proficient but not always aware of their full obligations under the Directive and they don't play the role expected in it.

Currently, the import and trade of primates represents a vulnerable point for the Union health status. The incorrect controls and inconsistencies observed represent an increased risk for the introduction and spread of animal and human diseases in the Union.

Animals from approved establishments can and do move to farms and the existing standards to move livestock are not always applied.

It is difficult to find updated lists of approved establishments in the EU - this is a factor that impedes verification and compliance with trade rules between such establishments.

Currently there is not always certainty on the compliance with national guarantees when animals imported from non-EU countries comply with health standards set by the country of destination and when they are introduced through another Member State. The current system also does not ensure that the conditions for import of these species are at least as strict as the conditions established for trade in the Union.

To protect the Union from exotic diseases, the current system to import ungulates relies now on assessment, approval and listing of establishments in non-EU countries by Member States and ultimately, on the assurance given by a non-EU country. The important weaknesses and misunderstanding of requirements detected in this area in Member States questions their ability to verify that non-EU countries apply all the necessary requirements.

7 MATTERS FOR CONSIDERATION BY MEMBER STATES

The following matters, for consideration by Member States, are based on the conclusions from this series of audits and analysis of questionnaire responses.

1) Official controls should follow documented procedures[12] and be targeted so that they bring about improvements in compliance with the most common and significant problems e.g.: to ensure that official approval and maintenance of approval of approved establishments is granted in a uniform and correct manner.
2) Disease surveillance plans should be approved by the competent authority, adapted to changing animal health risks and include appropriate surveillance for notifiable diseases listed in Annex A to the Directive.
3) For the import of non-harmonised animals via a Border Inspection Post in another Member State, strengthen the communication between Member States to ensure they comply with the health conditions defined by the Member State of destination.

8 ACTION TAKEN OR PLANNED BY THE COMMISSION SERVICES

1) The Commission services organised a workshop for Member States to present the findings and conclusions of this overview report to help them improve their official control activities in this work area.

   The workshop allowed Member States to gain an understanding of good practices elsewhere in the EU and how these might be adopted to their own situation. In addition, weaknesses and recurring problems in the functioning of the existing ABIC system were discussed.

   There was an agreement between Member States that, in general, this is not a high priority work area. Problem areas identified by participants during the workshop were common to the issues found during audit e.g. difficulties establishing systems to approve veterinarians to work in ABICs, difficulties building up expertise to approve and audit surveillance plans and with the importation of exotic species from non-EU countries.

   To improve official controls in this area, Member States considered that further training should be provided by the Commission (e.g. "Better Training for Safer Food" course on zoo animals) along with updating guidance on implementation of the Directive (Transmissible disease handbook). A need for a networking group on ABICs was also

[12] Article 8 of Regulation (EC) No 882/2004

identified by Member States as a way to improve the delivery of official controls in this area.

The Commission undertook to consider these issues.

2) The Commission, in co-operation with Member States, should improve the accuracy of the publicly available lists of approved establishments.

3) The risk mitigation measures for the import of ungulates, both at the place of departure and at arrival, should be re-assessed by the Commission.

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
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. 64/432/EEC	OJ 121, 29.7.1964, p. 1977-2012	Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine
Dir. 90/425/EEC	OJ L 224, 18.8.1990, p. 29-41	Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra- Community trade in certain live animals and products with a view to the completion of the internal market
Dir. 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. 2008/73/EC	OJ L 219, 14.8.2008, p. 40-54	Council Directive 2008/73/EC of 15 July 2008 simplifying procedures of listing and publishing information in the veterinary and zootechnical fields and amending Directives 64/432/EEC, 77/504/EEC, 88/407/EEC, 88/661/EEC, 89/361/EEC, 89/556/EEC, 90/426/EEC, 90/427/EEC, 90/428/EEC, 90/429/EEC, 90/539/EEC, 91/68/EEC, 91/496/EEC, 92/35/EEC, 92/65/EEC, 92/66/EEC, 92/119/EEC, 94/28/EC, 2000/75/EC, Decision 2000/258/EC and Directives 2001/89/EC, 2002/60/EC and 2005/94/EC

Dec. 2009/712/EC	OJ L 247, 19.9.2009, p. 13-25	2009/712/EC: Commission Decision of 18 September 2009 implementing Council Directive 2008/73/EC as regards Internet-based information pages containing lists of establishments and laboratories approved by Member States in accordance with Community veterinary and zootechnical legislation
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. 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. 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

ANNEX 2 – DETAILS OF INDIVIDUAL DG HEALTH AND FOOD SAFETY AUDITS CONSIDERED FOR THIS OVERVIEW REPORT

Country	Date of Audit	SANTE ref. no.
Spain	18 to 25 March 2014	2014-7050
Poland	22 to 26 September 2014	2014-7049
Hungary	24 to 28 November 2014	2014-7048
Germany	20 to 28 April 2015	2015-7565
Netherlands	9 to 13 November 2015	2015-7564

HOW TO OBTAIN EU PUBLICATIONS

Free publications:

- one copy:
  via EU Bookshop (http://bookshop.europa.eu);
- more than one copy or posters/maps:
  from the European Union's representations (http://ec.europa.eu/represent_en.htm);
  from the delegations in non-EU countries (http://eeas.europa.eu/delegations/index_en.htm);
  by contacting the Europe Direct service (http://europa.eu/europedirect/index_en.htm) or calling 00 800 6 7 8 9 10 11 (freephone number from anywhere in the EU) (*).

  (*) The information given is free, as are most calls (though some operators, phone boxes or hotels may charge you).

Priced publications:

- via EU Bookshop (http://bookshop.europa.eu).

ND-BC-14-005-EN-N

ISBN 978-92-79-43510-2
doi:10.2772/56814