Appendix XII

SUPPORTING DOCUMENT FOR THE OIE INTERNATIONAL ANIMAL HEALTH CODE CHAPTER 3.9.1. ZOONOSES TRANSMISSIBLE FROM NON-HUMAN PRIMATES

(Ad hoc Group Report, Paris, 19-22 November 1996)

Introduction

At the 63rd meeting of the International Committee, May 1995, the Chairman of the Code Commission, Dr W.H.G. Rees, presented a first draft of a chapter on zoonoses transmissible from non-human primates, inviting Member States to submit comments no later than by August 1995. As only a few responses were received, the Code Commission felt unable to formulate final recommendations. Consequently, the Commission asked Dr P. Dollinger of the Swiss Federal Veterinary Office to review and revise the draft in consultation with experts from different countries. Dr Dollinger suggested that this task should be given to the European Association of Zoo and Wildlife Veterinarians (EAZWV) which was to be constituted in May 1996. This was accepted by the Office International des Epizooties (OIE). Subsequently, an EAZWV Working Group was formed, comprising experts from various countries. The group liaised with experts from Brazil, Israel and the United States who had commented on the original draft, with the Chairman of the Veterinary Specialist Group of the International Union for Conservation of Nature and Natural Ressources (IUCN), Washington DC (USA), the European Association of Zoos and Aquaria (EAZA), and the Working Group on Primate Health Control established by the Federation of European Laboratory Animal Science Association (FELASA).

On 19-22 November 1996, the OIE convened a meeting of an Ad hoc Group on Zoonoses Transmissible from Non-Human Primates. The meeting was chaired by Dr Dollinger, Switzerland. It was attended by three members of the EAZWV Working Group, an expert appointed by the US Department of Agriculture (USDA), a member of the State Veterinary Service of Israel and a representative of the World Health Organization (WHO).

The Ad hoc Group defined its overall objective as the promotion of public health and safety by providing guidance to all parties, national Veterinary Services administrations, importers and exporters, in the safe international transfer of non-human primates. It was also hoped that the guidance provided would help facilitate the processes of international shipment in order to promote the maximisation of animal health and well-being.

The following is a clarification of the some the terms used in the draft chapter and explanation of the reasoning behind some of the Group's recommendations.

Definition of terms used

Common English names are used when identifying groups of primates in order to facilitate the ease in reading and understanding the text. "Prosimians" include the following taxonomic families: Lemuridae, Cheirogaleidae, Daubentoniidae, Lorisidae, Galagidae and Tarsiidae. For the purposes of the present Chapter, "marmosets and tamarins" include the Callithrichidae (marmosets and tamarins proper) and the Callimiconidae (Goeldi's monkey). "New World monkeys" and "Old World monkeys" mean Cebidae and Cercopithecidae, respectively, and "apes" includes the Hylobatidae (gibbons) and the Pongidae (great apes).

The group felt that the term regular veterinary supervision could be misconstrued to mean veterinary supervision on a regular basis but at such infrequent intervals to basically prevent any veterinary input into the care and observation of the animals. The term permanent veterinary supervision was chosen instead to imply the need for both frequent and participative involvement in the health monitoring programme by qualified veterinary personnel.

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Life history: the history of the occurrences of events in an animal's life; i.e. birth, reproductive history, social groupings and interactions, trauma, illness, tests, vaccination or other medical treatment etc.

Wild caught: originating from an uncontrolled wild state with no previous health history available; introduced from its natural environment.

Premises: discrete area under the supervision and control of a veterinary medical and husbandry programme. Premises may vary depending on the purpose of the animal colony, but should include a readily identifiable demarcation between what is within and what is without the premises. Premises must have the ability to contain animals and limit their contact with the outside.

Quarantine facility: premises with a distinct and fully limiting barrier between the inside and the outside for the purpose of holding animals in isolation from other animals and non-essential personnel. It can be a separate and isolated compound comprising grounds and buildings, a separate closed off building in association with other buildings or grounds, or a separate closed off area or room in a building where there is no traffic or contact between it and other areas of the building. It must provide for the complete isolation of the animals being contained. It comprises both a physical structure, and an established and implemented programme for maintaining animals in isolation. The programme includes: established criteria for animal admission, procedures for the isolation or elimination of diseased animals, a description of the animal disease monitoring programme, procedures for the health screening and surveillance of humans entering the facility, facility cleaning arrangements, the disposal of used feed, water, supplies and animal wastes, measures to exclude pests, and dead animals disposition. Entry and exit of animals, animal care staff and other humans must be controlled to minimise environmental exposures to animals and inadvertent exposure to transmissible infectious agents.

Basic Chapter Format

Unlike other chapters of the OIE *Code* dealing with zoonotic disease transmission, the recommendations of this chapter have been developed in recognition of the particular and unique nature of the subject animals, non-human primates. Chapter recommendations, therefore, do not give primary emphasis to the steps necessary for the control of any specific zoonotic agent, but rather stress the need to address the zoonotic disease potential of the entire group of animals. To that need, the recommendations focus on defining the health and infectious disease status of non-human primates and on the practice of protective measures against the transmission of infectious diseases. Prudence dictates the assumption that a non-human primate harbours a transmissible disease dangerous to humans until specifically and unequivocally proven otherwise. For purposes of public health, this assumption must transcend the specific activities of the transportation process and be applied to all activities where close contact occurs between humans and non-human primates. The recommendations of this chapter are based on this principle.

In drafting the Chapter, it was recognised that the two basic elements needed in the international transportation of non-human primates system for assuring public health and humane animal care were a process of health certification before international transportation, and a process of quarantining after international transportation. Both fall under the jurisdiction of national veterinary service administrations as these government agencies are routinely charged with handling national animal health and zoonotic disease issues. Delegating the responsibility of these activities to importers, exporters or other interested parties is not considered appropriate. This Chapter should serve as guidance to national veterinary services administrations for developing and implementing their non-human primate international transportation policies and regulations.

By working through the health certification and quarantine processes, national veterinary officials and other persons working with non-human primates should gain an understanding about non-human primate zoonotic diseases and on the protection of personnel at risk from exposure to such diseases. They should also gain experience in the safe and efficient international transportation of these animals.

The Chapter should not be interpreted as relieving the individual or group wishing to transport non-human primates internationally from the ultimate responsibility for the health and well being of the animals. Rather, that individual or group is fully responsible for working with national Veterinary Services administrations and providing them with all required background material and documentation for assuring adequate animal care and usage, and public health protection.

Based on the unique zoonotic disease implications of non-human primates, and the need to assume that non-human primates harbour zoonotic diseases unless specifically proven otherwise, the outline of the recommendations follow a division centred on the level of certainty realistically obtainable about an animal's zoonotic disease status in the health certification process. The main discriminator is the existence and level of certainty obtainable about the animal's current and previous history of disease exposure and status. A distinction is made between wild-caught animals for which no previous disease history was available, and animals captive born and reared in captivity, i.e. in a controlled environment, for which there has been a permanent veterinary and animal care presence and for which very accurate and full disease histories are available.

It must be understood that the above distinction between animals, based on their available past health history, does not imply that there is no risk for zoonotic disease transmission from non-human primates under some circumstances. On the contrary, it must be stressed that some amount of risk for zoonotic disease transmission should always be recognised. All risk can not be eliminated. It can only be minimised by following proper techniques and procedures. For this reason, an Article was attached to the end of the Chapter recommending "universal" precautions to be followed by persons working with non-human primates. A preliminary draft appendix is also included on the design and functioning of a proper quarantine facility.

Introduction and General Recommendations (Articles 3.9.1.1. and 3.9.1.2.)

The Chapter addresses non-human primates in general, and not only the principal species used in biomedical research, which [are] include (according to the FELASA Working Group on Primate Health Control), but are not limited to: cynomolgus monkeys (*Macaca fascicularis*), rhesus monkeys (*Macaca mulatta*), vervet monkeys (*Cercopithecus aethiops*), baboons (*Papio* spp.), squirrel monkeys (*Saimiri sciureus*), and marmosets (generally *Callithrix jacchus*).

The tree shrews (Tupaiidae) are not included since they are not currently considered to be non-human primates. All other species of non-human primates, from prosimians to great apes are included. The amount of knowledge currently available about the zoonotic disease potential of any particular species was not a determining factor for inclusion or exclusion. However, different species of non-human primates may require specific recommended practices to accommodate particular species needs and characteristics, and this is reflected in the articles of the Chapter. Certainly, it is not intended that the recommendations be restrictive or inflexible when dealing with these different species requirements. It is hoped that as further understanding about these animals becomes available, the presented framework will allow for scientifically sound flexibility in the health assessment process, and still provide a system for maximising public health and safety.

The Group felt that it was essential to develop guidelines that would support and complement existing international agreements on animal transportation and usage, in particular the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) which subjects all international movements of non-human primates to the issuance of permits or certificates and which is, in a number of countries, implemented by the Veterinary Service administrations.

The linking of the requirement for CITES documentation with the health certification process is a practical method of assuring adherence to CITES provisions, and helps assist those veterinary services administrations that are responsible for implementing CITES. It would also educate non-human primate exporters and importers on the necessity to have proper CITES documentation available on their animals before the international transportation process, and to help avert any seizures or confiscations of improperly documented animals. Such seizures or confiscations could present zoonotic-disease transmission problems for confiscating agents.

It is emphasised that this proposed Chapter should place no restrictions on a nation's domestic use of non-human primates. Any such restriction is outside the authority of the Office International des Epizooties. It is hoped however, that the recommended design and implementation of the chapter would encourage national evaluations of public health and animal welfare issues, and would foster the development of mechanisms to address those issues as they interface with the subject of this chapter.

It is not realistic to aim at excluding from international transportation all animals harbouring infectious agents. Such an exclusion is not considered a practical solution to the problem of the potential for disease transmission. Rather, zoonotically infected animals can and are being transported currently with minimum risk as long as safety precautions are practised.

Health Certification

In analogy to the *International Animal Health Code*'s recommendations on domestic livestock, the responsibility for health certification for non-human primates is placed with the Veterinary Services of the exporting country. While the individual exporter should be responsible for the description of the health status of the animals, it may not be realistic to require the exporter to make an extensive verification of that health status by diagnostic testing and other veterinary medical examinations. The individual exporter may simply not have the resources to perform these tasks without increasing the infectious disease risk to the animals. Also, it may not be sound to expect the exporter to treat all detected diseases to resolution before export. Latent infections can be difficult to detect, may not be diagnosed before or even after the time of transportation. The health certification process should be viewed as producing the best attainable assessment of the animal's health before exportation, but it should never be equated to a guarantee of a disease-free health status.

As part of the documentation needed for health certification, a description of the veterinary and animal health monitoring programme implemented at the site from which the animal is coming is needed. This information will serve to help both the Veterinary Services administrations and the persons receiving the animals make appropriate decisions on the quarantine procedures required for the animals.

A link between the health certification process and the individual identification of animals is essential to the success of zoonotic disease control measures. Different methods of identification should be considered acceptable so long as the end result is the permanent unmistakable identification of an individual animal. The necessity of matching specific health certificates and its accompanying documentation with a specific animal cannot be emphasised enough. The animal's unique identifier (tattoo or other physical marker, microchip etc.) is the linking device needed between previous clinical and life histories, diagnostic testing, health certification, and quarantine programme testing and observation.

Quarantine

A quarantine procedure at the time of animal receipt into a country is an essential element, if not the critical element for predictable and controlled animal health assessments. Even though, the exact design and maintenance of quarantine facilities is a national issue, the proper functioning of a quarantine is also a vital part of the international transportation process. During the quarantine, activities are directed at protecting personnel and other animals against communicable agents. Its basic components include isolation of imported animals, veterinary health observations, necropsies of dead animals, diagnostic testing, and personnel health protection.

The practicality of the quarantine programme must reflect the zoonotic potential of non-human primates in general, and depend on the information available on individual animals undergoing the quarantine procedures.

The life history of the animal concerned, and the presented documentation on the animal's zoonotic disease potential, should influence the length and extensiveness of the quarantine process. The less information available on an animal, the more lengthy and stringent the quarantine procedures required. This approach should serve to alert exporters of non-human primates to the preferred (from a public health standpoint) sources of non-human primates, and encourage the development of those sources.

Establishments, where the animals are born and raised in controlled environments, and where regular and defined husbandry care and veterinary medical attention is available, are such sources.

Captive but free ranging animals, i.e. animals from environments not closely controllable, such as open enclosures, islands etc. could also represent another such a source. Since these animals have a higher likelihood of harbouring adventitious infectious agents than animals originating from a closely monitored environment, the desirability of this source is dependent on the level to which such colonies represent a closed population, and on the extent that a medical history of the colony is developed.

It should be noted that, nowadays, most non-human primates imported by zoological gardens are born and raised in controlled environments, in the case of non-human primates destined for biomedical research, only three species are bred in larger quantities in captivity or under semi-captive conditions: cynomolgus monkeys (Philippines, other South East Asian countries, Mauritius), rhesus monkeys (People's Republic of China, USA and to a lesser extent in Europe), and marmosets (USA, Europe).

By properly considering the zoonotic disease risks, identifying the general processes needed, and defining the end results required, Veterinary Services administrations should be able to design a quarantine programme to meet their needs and resources.

Who should provide quarantine services should be decided by the national Veterinary Services administrations. Zoos or other private but nationally recognised establishments should not be eliminated from consideration as long as they can meet the standards set by the national Veterinary Services administrations, and the Veterinary Services administrations have a mechanism for assuring the proper functioning of these quarantine facilities. In choosing quarantine facilities, Veterinary Services administrations should consider the adequacy of the physical plant to securely isolate animals, and the adherence to recommended operating procedures.

The periods of time chosen for quarantine represent those which are sufficient for animals incubating diseases, before or during international transportation, to become clinically ill during quarantine and to resolve their infections before release from quarantine. For some latent infections harboured for the life of the animals, such as herpes B virus, no amount of time in quarantine will make the animal non-infectious. For these diseases, it must be assumed that target animals are universally infected and infective, and that public health protection should not be placed on eliminating infectious animals, but by protecting persons coming in contact with these animals by the practice of personnel protection methods.

Zoonotic Disease Agents Addressed

The table of zoonotic disease agents is limited to those agents of particular concern for the quarantine period. The list is not all inclusive for all non-human primate zoonotic diseases, but rather is limited to those agents which should be actively addressed by all quarantine programmes. The agents listed are those for which reliable testing is readily available, and effective interventions can and should occur to correct the disease condition before the end of the quarantine period.

There are many other significant zoonotic diseases not listed in the table and their absence should not be interpreted as meaning they have no significance to public health. On the contrary, because of the difficulties in accurately defining the presence of these agents in non-human primates, these agents should be assumed present in relevant species, and animals should be handled accordingly at all times. The need to address these agents may depend on the ultimate use of the animals and on the importer's willingness to accept potentially infected animals.

A good example is herpes B virus in macaques. Many experts consider it impossible to certify these animals free of virus even after negative diagnostic testing. Although the probability of attracting a herpes B virus infection is extremely small, the possible fatal implications for humans coming into contact with latently infected and intermittently infective animals, requires that the disease potential is not ignored. Mandatory testing for B virus in quarantined animals, however, is not an effective means of identifying problem animals. A better approach is to consider all macaques infected and handle all macaques accordingly.

To supplement the table given, a second listing of agents possessing zoonotic potential was added to alert persons to the existence of these agents. It is not considered practical to mandatorily test for and exclude these agents during the quarantine process, however. These agents include hepatitis A virus, hepatitis B virus, herpes B virus, filoviruses, poxviruses, retroviruses, and rabies, etc.

It is also considered unnecessary to mandate testing for agents which, if present, would become clinically apparent during the quarantine period; for example: Monkeypox.

Discussion on specific agents

1. Tuberculosis

Since it takes a minimum of three weeks for a healthy but infected animal to develop delayed hypersensitivity to tuberculosis testing, a series of testings is recommended during the quarantine period to increase the likelihood of detecting positive animals. Careful interpretation of test results is essential. False negative tests can result from improper testing techniques, very recent infection (no sensitivity developed yet), anergy, masking by concomitant viral infections such as measles, immunosuppression, other severe illnesses, immunisations, and species specific conditions (orangutans are notorious for false negatives).

So far, there is no universally accepted method for tuberculosis testing of non-human primates. A recommended method of testing is the intradermal injection of 0.1 ml of tuberculin at the edge of the upper eye lid. Eye lid swelling and erythema at 24, 48 or 72 hours is considered a positive test result. A negative response indicates the animal has not been exposed to tuberculosis, has not had time to mount an immune response, or is incapable of mounting an immune response due to immunosuppression. The eyelid is the preferred site for testing, because it is easily observed without actually restraining the animal. Subsequent tests are generally alternated between eyelids. Alternatively, an intradermal test may be done on a marked, non-haired area of abdominal skin. This site is recommended for small species such as marmosets, tamarins, bushbabies or mouse lemurs. It allows for physical palpation and/or measurement for induration, and it is often used for retesting an animal with a questionable eyelid test or as part of the baseline testing in quarantine. In the United States of America, mammalian tuberculin, which is less purified but has more tuberculin units (TU) than Purified Protein Derivative (PPD) is used on non-human primates because PPD may not elicit a strong enough response to facilitate the identification of infected animals. Tuberculin, Mammalian, Human Isolates, Intradermic - a heat inactivated, concentrated filtrate of *Mycobacterium tuberculosis* - is the product currently recommended in the US. The minimum dosage is 0.1 ml of undiluted USDA veterinary tuberculin (which is equivalent to 15,000 TU based on trichloroacetic acid (TCA) precipitated protein content).

Practices are different in Europe, where, according to a 1996 EAZWV survey carried out in Belgium, Denmark, France, Germany, Italy, the Netherlands, and Switzerland, most zoos use bovine and avian PPD for routine tuberculosis testing. The results of this survey are compiled in table 1 (see end of the document).

Serologic tests for tuberculosis may become available in the near future which may allow for alterations in the testing programme without compromising the ability to detect diseased animals.

For New World monkeys, Old World monkeys and apes, it is recommended that a series of a minimum of three tests at three to four week intervals during the quarantine period be conducted. These species should not be desensitised by this schedule if correctly performed. For marmosets and tamarins, fewer tests are thought necessary because of the lower probability of infection in these species. Prosimians should be tested as other Old World species.

The performance of pre-export tuberculosis testing on animals coming from controlled and well documented environments is desirable since this testing can be done aseptically, in a controlled manner under veterinary supervision. This testing is proposed to help shorten the testing requirements during the post-importation quarantine. It should help strengthen the health status documentation available for the health certification process as well.

2. Bacterial Agents

Enteric bacteria pose the highest risk potential to public health during the quarantine period. Since these agents can cause chronic infections with intermittent shedding from apparently healthy animals, testing during the first five days of quarantine is suggested to take advantage of the heightened probability of detecting positive animals during this period of probable stress.

The detection of these agents should not necessarily lead to positive animals not being allowed out of quarantine, but should lead to decisions on the future introduction of these animals into environments known to be free of these agents or into situations where animals will come into close contact with humans not practising personnel protection methods. The prophylactic treatment of non-human primates with antibiotics should be discouraged as it will handicap the diagnosis of infected animals and will probably facilitate the development of antibiotic resistant strains of bacterial pathogens.

3. Parasitic agents

Parasitic agents are included in the list because of their zoonotic potential and because of the ease and effectiveness of treatments during the quarantine period. It is not appropriate to specifically detail treatments for these agents in this chapter, however, because treatment should be tailored to the specific parasite detected, and the species of animals concerned.

Personnel health protection measures

Given the nature and implications of zoonotic diseases in non-human primates, an Article was added at the end of the Chapter to describe recommended personnel protection methods to be used for persons coming into contact with primates during the quarantine period. This departure from previous OIE positions to not to address personnel health issues is necessary given the reality that personnel in quarantine facilities are at direct risk for zoonotic diseases. Occupational safety considerations are integral to the development and implementation of quarantine programmes.

Generally, occupational safety procedures include immunisations of personnel against high risk diseases; provisions for tuberculosis and enteric parasite monitoring; protocols for treating bites, scratches and other injuries; and observance of good personnel hygiene practices. Quarantine programmes may wish to also incorporate measures aimed at protecting workers from agents endemic in the country of origin of the quarantined animals, i.e. yellow fever, or to consider making provisions for any future epidemiologic investigations by establishing documentation and detection systems for disease occurrence and spread, i.e.. the establishment of serum banks on personnel and/or animals, or the establishment of systems for notifying medical authorities of the potential for zoonotic diseases in patients with histories of non-human primate exposure.

The quarantine programme should have an educational component included to provide staff with the training necessary to safely work with non-human primates and their tissues and body fluids with respect to zoonoses containment and personnel safety.

The safe handling and disposal of animal tissues, fluids and wastes should also be addressed.

Specific Quarantine Requirements

To serve as an example only, the contents of this Appendix was essentially patterned after the quarantine requirements of one country. It was envisaged that more input from other OIE Member Countries would be received, and that this appendix may undergo considerable revision.

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Table 1

Survey on Tuberculosis Testing in European Zoos, December 1996

Zoo	PPD			Kochs Old Tuberculin			Location			Additional tests
	bovine	human	avian	bovine	human	avian	palpeb.	Abdom.	Other	
Anvers (BE)	0.1 ml = 2000 TU	-	0.1 ml = 2000 TU	-	-	-	yes	no	no	Serology, X-ray (new arrivals)
Zurich (CH)	0.1 ml 1000 TU	0.1 ml 10 IU	-	-	-	-	yes	no	no	simultaneously
Frankfurt (DE)	0.1 ml = 5000 TU	-	0.1 ml = 2500 TU	-	-	-	yes	no	no	
Rostock (DE)	0.1 ml = 5000 TU	-	-	-	-	-	yes	no	no	
München (DE)	0.05-1.0 ml = 2500-5000 TU	-	-	-	-	-	yes	no	no	serology and X-ray are not carried out on a routinely basis
Zoo Berlin (DE)	0.1 ml	-	-	-	-	-	yes	no	no	ELISA (in Lelystad (NL)
TP Berlin (DE)	0.1 ml = 5000 TU	-	0.1 ml = 2500 TU	-	-	-	yes	no	no	X-rays regularly, CFT, ELISA (Lelystad (NL) if necessary
Hamburg (DE)	0.1 ml = 5000 IU	-	-	-	-	-	yes	no	no	
Karlsruhe (DE)	0.1 ml = 5000 IU	-	0.1 ml = 5000 IU	-	-	-	yes	no	no	Serology at Lelystad (NL) or Braunschweig (DE)
Leipzig (DE)	-	0.1 ml	-	-	-	-	yes	no	no	
Osnabrück (DE)	-	-	-	-	0.04-0.06 ml = 125 TU	0.04-0.06 ml = 125 TU	yes	no	no	
København (DK)	-	0.1 ml = 1 TU	-	0.1 ml = 1.0 mg= 25000 iu	-	-	yes	no	no	
Mulhouse (FR)	0.1 ml = 2000 TU	-	0.1 ml = 2500 TU	-	-	-	yes	yes*	no	*marmosets and tamarins
Paris Mén. (FR)	-	0.1 ml = 10 IU	-	-	-	-	yes	no	yes*	*orang utan
Peaugres (FR)	-	0.1 ml = 10 IU	-	-	-	-	yes	no	no	
La Palmyre (FR)	-	0.1 ml = 10 IU	-	-	-	-	yes*	-	-	*apes
Port St.-Père (FR)	0.1 ml = 2000 IU	-	-	-	-	-	yes	no	no	
Pistoia (IT)	-	-	-	-	-	-	no	no	no	in case of suspicion: X-ray
Castelnuovo (IT)	-	-	-	-	-	-	no	no	no	in case of suspicion: X-ray plus bact. culture of the sputum
Amsterdam (NL)	0.1 ml = 5000 TU	-	0.1 ml = 2000 TU	-	-	-	yes	no	no	ELISA, if pos. Repeated X-rays
Beekse B. (NL)	0.1 ml = 5000 TU	-	0.1 ml = 2000 TU	-	-	-	yes	no	no	ELISA, if pos. Repeated X-rays
Rhenen (NL)									chest	concerns orangs, X-ray, faeces
Rotterdam (NL)	0.1 ml = 5000 TU	-	0.1 ml = 2000 TU	-	-	-	yes	no	no	ELISA, if pos. Repeated X-rays

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