The Balai Directive of the European Union – a difficult piece of veterinary legislation

The original Balai Directive

On 13 July 1992, the Council of the European Communities adopted the „*Directive 92/65 laying down the 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*“ (EU 1992). This Directive is more concisely referred to as one of two „BALAI Directives“, the other one being Directive 92/118/EEC governing trade in certain products under animal and public health criteria. The term “Balai” is French, meaning broom. It is used in this context because, with a view of completing the European Union’s Internal Market, all veterinary issues that were not yet regulated were swept together and packed in the two Directives. As time was pressing, Directive 92/65 was prepared very hastily and without consulting with the zoo community. It was poorly drafted, in particular its English version, thus unclear and misleading, and impractical. And it seems that even the Veterinary services were taken by surprise when the EU Council signed the proposal as a Directive in July 1992 to come into effect on 1st January 1994.

There was probably no appreciation by either the authorities of the Member States, or the Commission itself, of the different animal species involved or of the type and number of movements of animals between zoos that occurred annually, and that the majority of these transactions were for conservation breeding purposes. In practical terms, the Directive proved to be rather an obstacle for the exchange of zoo animals than facilitating these movements. Consequently, zoos hesitated to seek approval under the directive, and national governments were rather lazy in implementing it.

The European Association of Zoos and Aquaria (EAZA) became very concerned about the new legislation and, as from 1992, it was the main topic of the meetings of the EAZA Veterinary Committee. All members of the Committee were asked to contact their Ministry authorities to seek clarification of a number of points and to offer assistance. In September 1993 four members of the British Veterinary Zoological Society met an official of the Animal Health (International Trade) Division of the British Ministry of Agriculture (MAFF) from which arose that the term „Apes“ would in fact included all non-human primates. Other points remained, however, still unclear, e.g. how zoos could obtain the status of official freedom from tuberculosis and brucellosis in order to remove the necessity for testing in the 30 days prior to movement. In 1994, Gerry Benbow (United Kingdom), the then Chair of the EAZA Veterinary Committee, wrote a letter to the competent General Directorate VI (later DG SANCO) of the European Commission outlining the problems and reminding the Commission of an article of the Directive, which says that transitional measures may be adopted for a period of three years to facilitate the transition to the new arrangements. Despite a reminder letter no reply was ever received.

By July 1995, there had still been no progress with the Directive, but some countries were resolving their problems. In order to facilitate movement of primates, the UK MAFF were advising that, as primates could only be moved from an individual or an approved zoo to an approved zoo, they would accept a derogation that a primate could be imported from a named individual at a zoo, say the Director or Curator, in order that *ex situ* breeding programmes for primates should be able to continue. This compromise situation was not regarded as wholly satisfactory, and it was suggested that zoos should seek Approved Status only for their primate sections. In view of all uncertainties and differing interpretations in Member States the application for whole Zoo Approved Status at that time seemed inappropriate. “Monkey approval” became thus common practice in a number of EU Member States, including Austria,

Germany and the UK. In some other countries the Directive was not applied to zoos at all.

Because of the continued unsatisfactory situation, the EAZA Veterinary Committee decided that another letter should be sent to the EU Commission, this time to the Agriculture Commissioner, Franz Fischler, with a copy to be sent to the veterinary authorities of all Member States. Mr Fischler kindly replied but his answer was not really helpful as some of the main problems were not addressed. One of the most problematic provisions was that a zoo would loose its approved status if accepting animals from non-approved sources within the European Community. Because the import of animals from non-approved sources outside the EU was possible under a permit, Zoos wishing to exchange some primates with zoo in another Member State were sometimes forced to export the animals to a Third Country, say Switzerland, from where they could be re-imported by the receiving zoo in the other Member State.

EAZWV's involvement in the revision of the Directive

On May 18, 1996, the European Association of Zoo and Wildlife Veterinarians (EAZWV) was founded by 194 veterinarians, veterinary students and interested biologists from some 20 different countries. The new organisation grew rapidly, and it was clear that it should become a driving force regarding the revision of the Balai Directive. To pave way for a more successful approach than tried before by EAZA alone, Peter Dollinger, the Honorary Secretary of EAZWV, and Gerry Benbow published a series of articles under the title "*The Balai Directive – a Never-ending Story*" in the EAZWV Newsletter (Dollinger1997/98), in which the contents of the current Directive were explained, the resulting problems were highlighted, and an account of EAZA's interventions was given. In January 1998, when the Association unified already 321 members in 34 countries, a joint letter signed by Alex Rübel, the new Chairman of the EAZA Veterinary Committee, and Peter Dollinger was sent to DG SANCO, outlining all the major problems,

urging the Commission to revise the Directive and offering assistance to that end. When still no substantial progress was made, a a dialogue by phone and email was taken up with Brussels, and on 23 May 2000 EAZWV – now backed by 448 members - and EAZA representatives met in Paris with one of the relevant officials of the EU Commission. At this meeting it was agreed that the Commission would accept a draft amendment to the Directive prepared by an EAZA/EAZWV working group with a view of forwarding that draft to the Permanent Veterinary Committee (Annex C of the Directive) and the EU Council (Core text) respectively. Already in June 2000 a first draft was submitted to the Commission, and in July the Commission organized a first meeting of experts in Brussels. In March 2001 work was completed and the final draft could have brought to the political level for decision. However, an outbreak of foot-and-mouth disease tied up all resources at DG SANCO for a while, and so the "*Commission Regulation (EC) No 1282/2002 amending Annexes to Council Directive 92/65/EEC.…*" was adopted on 15 July 2002 only (EU, 2002). To allow both Member States and zoos to get ready for implementation, the date of entry into force was determined to be the 1st of March 2003.

Under the legislative procedures prevailing now in the European Union it had been found difficult to amend the core body of the Directive. Instead, the Annexes A, containing the list of diseases relevant for the Directive, C, defining the conditions for approval, and E containing model certificates were amended. Because the amendment was done in the legal form of a regulation, the Annexes A, C and E became directly applicable in Member States, which should guarantee a relatively uniform implementation. EAZWV had a keen interest in a uniform implementation as this would ensure that the sanitary level of all approved zoos became as high and as uniform as possible to permit the circulation of animals between approved zoos with a minimum of health risks. This implied that zoo veterinarians were fully aware of the provisions of the revised BALAI Directive, that they would take their obligations under the Directive seriously, that they attempted to approach their duties in a uniform way, and that they covered also a number of diseases, which were not, or

not explicitly, addressed by the Directive. To this end, EAZWV:

- organised a BALAI Workshop at its 2002 EAZWV Conference in Heidelberg;
- presented the contents of the revised BALAI Directive to zoo veterinarians and zoo directors at. different meetings;
- established an infectious diseases working group, ably chaired by Jacques Kaandorp of Beekse Bergen Safari, with the mandate of developing a Transmissible Diseases Handbook (EAZWV, 20xx); and
- hired, on a part-time basis, a veterinarian to act as Secretary of the Infectious Diseases Working Group.

As it was noted that ANNEX C contained a few points leaving considerable room for interpretation, EAZWV conducted a survey in 35 selected zoos to assess the current levels of disease surveillance, and as a basis for elaborating guidance on how to implement the diseases surveillance plan which was a mandatory requirement for approved zoos. 26 zoo veterinarians representing zoos in 13 different countries responded to the questionnaire. It turned out that seven of these zoos in four different countries had been approved under the old directive, whereby the conditions for approval varied greatly. The general conclusions from the survey were the following (Ryser, 2003):

- Although only eleven zoos had a written protocol for disease surveillance, all zoos regularly checked the animals, at least by means of behavioural observation, mostly also vet rounds. All zoos regularly examined faeces samples (parasitology), many also took blood, and most zoos kept frozen samples for later studies.
- All zoos regularly treated the animals against parasites, and all but 2 had a vaccination programme. Further prophylactic treatments were uncommon but existed (e.g. vitamins,

treatments of newborn).

- Most zoos had so-called quarantine facilities, but in most cases without specific staff. The size of the cages varied a lot.
- Most zoos had a lab, mainly for necropsies and for parasitology, less commonly for blood analysis.
- Most zoos performed the necropsies at the zoo and sent only samples to a specialised institute. Only 1/26 zoo did not perform systematic necropsy of all dead animals.
- Most zoos regularly immobilized the animals – at least of certain taxa - for clinical examinations. However, several zoo vets said clearly that they thought that immobilizing animals for periodic checks resulted in too much stress for the animals (and also too much work for the zoo staff) and that they didn't want to start to work in the American way with compulsory yearly checks of all animals.
- All zoos kept the data records for an extended period of time, in most cases for more than 10 years, mostly in folders, partly as a computer database. Only a minority used MedArks. About half of the zoos summarized the data in an annual report, usually unpublished.

From the people who answered the question, several were satisfied with their disease surveillance, but many whished improvements. Points criticized related to inadequate quarantine facilities, non-existing computer databases, lack of personnel etc.

In addition, the Honorary Secretary of EAZWV, who had been an official of the Swiss Federal Veterinary Office until 2001, wrote to the Chief Veterinary Officers in all EU Member States noting that, while most of the requirements for approval were straightforward, others left room for different interpretations, and asking some specific questions to find out what the Veterinary Services considered to be

- "*adequate quarantine facilities for animals from non-approved sources*" (which could be a nearby fallow deer farm or a private parrot holder in the next town) in the terms of requirement 1.(b) of Annex C of the Directive;
- "*approved quarantine procedures*" in the terms of requirement 1. (b) of Annex C, in particular, whether "approved" was understood to be a general term, meaning good veterinary practice, or compliance with the relevant articles of the OIE Animal Health Code (OIE 2005), or whether it meant approval on a case by case or zoo by zoo base, in which case an additional question was, which authority would be responsible for the approvals;
- *"appropriate disease surveillance measures"*.

Rather few substantial answers were received, and from these it became clear that Veterinary Services had no uniform interpretation of the Directive, indeed, most of them had not even seriously dealt with the new piece of legislation.

The development of Recommendations for the Application of the BALAI Directive

The conclusion from the two surveys was that EAZWV should provide some guidance to both zoos and Veterinary Services throughout the European Union as well as in Andorra, the British Crown Dependencies (Channel Islands, Isle of Man), Liechtenstein, Monaco, Norway, San Marino and Switzerland, where the BALAI is applicable too, either under the Agreement on the European Ecomic Area (EEA) or under bilateral treaties.

.To this end, two meetings were held on 15/16 September 2003 and 5 February 2004 at Cologne Zoo with the participation of representatives of the European Commission (DG SANCO - Health and Consumer Protection), the British Department for Environment, Food & Rural Affairs (DEFRA), the Dutch Rijksdienst voor de Keuring van Vee en Vlees (RVV), the German

Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft (BMVEL), the EAZWV, in particular its Infectious Diseases Working Group (IDWG) and zoo veterinarians from France, Germany, Italy, The Netherlands and the United Kingdom representing also their respective professional organisations at the national level.

The Recommendations, which were finalized on February 20, 2004, were disseminated by EAZWV and EAZA to their respective constituencies and by the EU Commission to the Veterinary Services of the Members States, which implied that they received some kind of official status. They contain six chapters dealing with the term 'animals', the approved annual disease surveillance plan, the added animals procedure, the quarantine / isolation requirements, and the certificates:

A. The term 'animals'

'Animals' in the terms of Article 2 (b) of the Directive means 'specimens of animal species other than those referred to in Directives 64/432/EEC, 90/426/EEC, 90/539/EEC, 91/67/EEC, 91/68/EEC, 91/492/EEC and 91/493'. It is obvious that the average zoo veterinarian has no clue what this means, and even many official veterinarians may have problems in finding out what exactly is covered by the directive, and what is not. Therefore a list of the species covered by the various other Directives is given. The recommendations state, however, that it would not make any sense to exclude these species not addressed by the BALAI from the health surveillance plan.

B. The approved veterinarian

In order to be granted official approval under Article 13 of the Directive, a zoo must secure by contract or legal instrument the services of a veterinarian approved by and under the control of the competent authority. The role of the approved veterinarian is to ensure that the requirements of the present directive and other related legislation are complied with on a day to day basis.

Where this veterinarian is a member of a practice, other members of the same practice may be included provided that they are also approved by the competent authority and individually nominated in writing. Also in the case of the approved veterinarian, the BALAI refers to other EU legislation by requiring that approved veterinarians shall comply *mutatis mutandis* with the requirements referred to in Article 14(3)(B) of Directive 64/432/EEC. The recommendations explain what this exactly means. It was agreed with the EU Commission that in the case of the requirement of Directive 64/432/EEC that the approved veterinarian must have no financial interest or family links with the owner of or person responsible for the holding, a liberal interpretation would be acceptable as zoo animals have a conservation value rather than an economic value and because, for the purposes of the BALAI, the approved veterinarian is working under the supervision of the official veterinarian. It is thus up to the official veterinarian to assess whether there could be a conflict of interest, and whether the approved vet appointed by the zoo fulfils the requirements above, and in particular has appropriate specialist knowledge in relation to zoo animals.

C. The annual disease surveillance plan

The approved veterinarian has to draw up and implement an annual disease surveillance plan. This plan is subject to annual audits by an official veterinarian from the competent authority. The Recommendations explain that, for the purposes of approval under the BALAI, the surveillance plan must cover those diseases listed in Annex A (and B if relevant), and suggest that the plan may also include other general measures as may be required under *Council Directive 1999/22/EC of 29 March 1999 relating to the keeping of wild animals in zoos* (EU,1999), and specific measures for individual taxonomic groups as may be agreed by the relevant Taxonomic Advisory Group from the European Endangered Species Program (EEP) of the European Association of Zoos and Aquaria (EAZA). As a general rule such specific measures would be

elaborated by the EAZWV Infectious Diseases Working Group and subsequently be integrated into the Husbandry Guidelines for the taxon concerned.

As agreed with the representatives of the EU Commission and the national Veterinary services participating in the Cologne Meetings, the Annual Disease Surveillance Plan and the measures based thereon must include:

a. Immediate notification to the competent authority if there is any cause for suspicion that animals may be affected by any disease, including zoonoses, that is notifiable under Community legislation or national legislation.
b. Close observation of each animal at least once per day by suitably qualified staff, under the direction of the approved veterinarian (in the case of large group species, such as fish in an aquarium, the veterinarian may decide that observation of the group is sufficient).
c. Immediate notification of the approved veterinarian by zoo staff if any animals appear unwell or die. In the case of large group species, notification may be triggered by mortality above an agreed, expected level..
d. Laboratory examination to establish the infective agent in any live animals that appear to be affected by an infectious disease (in the case of large group species the veterinarian may decide that a representative sample is sufficient). In the case of suspicion of a disease that is listed on Annex A and B and/or is notifiable under national legislation, the official veterinarian must be informed immediately.
e. Procedures for newly arrived and diseased animals, taking into account the relevant risk factors.
f. Regular parasitological examination of faecal samples in particular with regard to zoonotic parasites. All relevant groups should be checked at least once a year; the frequency of examination should be related to the prevalence of parasites.

g. Opportunistic examination and taking of appropriate samples from immobilised or otherwise restrained animals, all serum samples should be retained and stored at -18^0 C or below.

h. Specific guidelines for the systematic testing of specific animal species may be developed and recommended by the Infectious Diseases Working Group of EAZWV.

i. Post mortem examination without unnecessary delay to check for significant pathology, and as far as possible to establish the cause of death in every animal that dies or foetus that is aborted unless there is clearly no suspicion of infectious disease.

j. The vaccination programme should be based on the availability of safe vaccines. It should take into account the species involved and the risk of diseases likely to occur in the zoo, and may cover zoonotic diseases other than those mentioned in Annex A or B, but these vaccinations must be in compliance with the applicable legislation.

k. Records must be kept in an easily accessible form, to be available as necessary for audit purposes, and retained for at least 10 years. The recommendations define in detail which information the records must contain.

D. The added animals procedure

The fact that no animals originating from non-approved sources (unless imported from Thir Countries) could be added to an approved collection was the main obstacle that prevented zoos from seeking approval under the original BALAI Directive. The introduction of an “added animals procedure” from was thus the main measure allowing to normalize the situation. Under the revised BALAI, animals from non-approved sources can be introduced to an approved collection provided that certain conditions are respected. The Recommendations look at the various situations and provide guidance as to how to handle them:

Animals coming *from another approved establishment in the same member state* fall

outside the scope of Directive 92/65, and hence under Community legislation there is no requirement for the animal to be accompanied by the model health certificate in Annex E. However, national rules governing certification may apply. For the same reason, there is no official requirement for post-arrival isolation, although the establishment may choose to carry out isolation and/or testing for its own private purposes. If the animals are coming from an *approved establishment in another Member State* they must be accompanied by the model health certificate in Annex E type 3. Depending of the health situation there may be additional requirements imposed by EU or national legislation.

Animals coming from a *non-approved establishment in the same member state* fall outside the scope of Directive 92/65, and hence under Community legislation there is no requirement for the animal to be accompanied by the model health certificate in Annex E. However, in accordance with Annex C of Directive 92/65, the animals must undergo post-arrival isolation in the isolation area, designated in the terms of approval, for at least 30 days or such longer period as may be required by the approved veterinarian and/or the competent authority to be satisfied that the health status of the animals is not inferior to the health status of the other animals in the collection. During isolation the animals may be required to undergo testing for any disease covered by Annex A of the BALAI Directive that the approved veterinarian and the competent authority consider appropriate.

Member states may, by way of derogation, allow the movement of animals *from non approved establishments in another member state*. Specific conditions under which transfer must take place may be laid down. The animals must undergo post-arrival isolation in the isolation area, designated in the terms of approval, for at least 30 days or such longer period as may be required by the approved veterinarian and/or the competent authority.

In the event of animals from *non-approved establishment to a non-approved establishment*

within the same Member State, national rules apply. Between establishments in different Member States, the Member State of destination can request specific requirements for introduction.

Animals being imported into the Community *from Third Countries* must fulfil the animal health conditions as laid down in Directive 92/65. However where harmonised rules for a particular species have not been laid down in the Directive, then national rules shall apply. The importing zoo must apply for a specific import licence, which will contain the conditions relevant to the species and place of origin.

E. Quarantine / Isolation requirements

'Isolation' and 'quarantine' are not precisely defined in European Union legislation, and one word is usually described by reference to the other. For the purposes of adding animals from non-approved sources within the European Union and other countries where the BALAI Directive applies, or listed Third Countries, to an approved establishment, the requirements are therefore specified in the Recommendations. The basic principle is that a risk analysis has to be made and the quarantine / isolation requirements must cope with the risk. Quarantine requirements for comparable livestock could provide some guidance. In this context it is noted that management procedures could be adjusted easily to each individual case, but that the availability of suitable facilities is a prerogative for approval and has to be seen without a specific case in mind but considering that there are three main risk groups:

- Primates: they can be imported from anywhere (there is no Third Countries List), they may be carriers of zoonoses. It is therefore recommended that the quarantine requirements laid down in the OIE Terrestrial Animal Health Code (Chapter 2.11 and Appendix 3.5.1) shall be respected (OIE 2005).
- Birds: the introduction from areas where OIE list A diseases exist can not be excluded (occurrence of diseases in wild, in particular miogratory birds), and the relevant diseases,

NCD, AI and Psittacosis are easily transmitted via the air or, in the case of West Nile Virus, by mosquitoes. Birds must therefore be isolated in buildings and the possibility of disease transmission by air or insects has to be taken into account. Windows should be kept closed, and it is strongly recommended that the isolation rooms should be ventilated, and the exhausted air should pass through a dust filter

- Mammals other than primates: Under EU legislation the introduction is allowed only only from areas free from highly contagious diseases. All diseases that are relevant in pravtice are not transmittable by air over a longer distance. In most cases direct contact is required. As a general rule, mammals other than primates should therefore be isolated indoors, but no special precautions have to be taken regarding the exhausted air to cope with the relevant diseases listed in Annex A of the Directive. If, for specific reasons, mammals have to be isolated outdoors, the ground should be solid and easy to disinfect. If this is not possible, the isolation enclosure should be relatively small to allow for other treatment of the soil, e.g. removal of top soiling. No zoo will be able to have specific isolation facilities for all mammalian taxa, which may include a diverse range of species, including e.g. big cats, dolphins, elephants, hippopotamuses. In such cases it should be possible to use the standard facility for isolation purposes.

The Recommendations make clear that, in order to be granted approval, zoos must have *available* adequate quarantine / isolation facilities, and that this wording does not imply that the facilities are on the ground or owned by the zoo concerned. This allows for the option of several zoos to jointly operating a facility, or having contracts among themselves. In this last case, the option should be specified in the annual plan.

The Recommendations also provide guidance regarding the structural requirements of isolation quarters: These must be physically separated from other animal accommodation by a

reasonable distance, taking into account the species concerned and the ability of the relevant viruses to spread on the air. This distance can be much reduced if the exhausted air is filtered. For animals originating from within the EU or from listed Third Countries the use of dust filters is sufficient, otherwise High Efficiency Particulate Extraction (HEPA) may be required. The limits of the isolation area must be clearly demarcated by walls or fences as appropriate. This does not preclude the possibility that specific areas or pens within the premises may be designated as isolation areas for a limited time and a particular purpose, provided that they meet the general requirements. There must be a double door system to prevent escape at the entry/exit with sufficient space between the doors to allow one to be closed before the other is opened. Entry/exit doors must be lockable and must display a notice stating: 'QUARANTINE: No Admission to Unauthorised Persons'. Facilities must be available at the entry/exit point for attendants to change overalls, to change and disinfect boots, to wash hands, and if appropriate to shower. Suitable facilities must be available to load or unload animals between transport crates and isolation pens without the risk of escape. Suitable crush or penning facilities should be available within reasonable access of the isolation area, so that animals may be safely restrained for clinical and diagnostic procedures such as blood sampling. The route from isolation to restraint must not put other animals at risk of infection from the introduced animals. The design of the pens or cages within the isolation area must be such that the animals may be visually inspected at any time, with adequate light and ease of access. The physical structure and all equipment must be made of such materials that they can be effectively cleansed and disinfected, or destroyed after use. The design must be suitable to minimise access by rodents, wild birds and insects, as appropriate for the species in question. Where drains are present, they must be fitted with rodent proof covers. The feed store must be suitably protected from vermin. Adequate storage facilities must be available to contain the litter and animal waste produced during the isolation period, and the

storage facility must be bird and vermin proof. There must be facilities to dispose of the waste either during or after the isolation period in a way which will ensure that there is no risk of the spread of disease. Refrigeration facilities or equivalent must be available within the isolation area, or in a suitably disease-protected location nearby, to hold carcases of animals that die until they can be subject to post mortem examination. Procedures for conveying carcases safely to the storage facility must be laid down in writing by the approved veterinarian.

General requirements are also laid down regarding the management procedures:

Every animal in isolation must be visually inspected at least once a day by suitably competent staff. Any signs of illness must be recorded and reported immediately to the responsible veterinarian, who should make a further examination of the affected animals without any unreasonable delay. The premises must have designated staff who are present on a sufficiently regular schedule to ensure surveillance of the animals on a daily basis, and more frequently if appropriate. Staff entering the isolation premises must always change into protective clothing and footwear. On leaving, the overalls and footwear must be removed and left within the isolation area, and the footwear must be disinfected. Hands must be washed, or otherwise disinfected, on entering and leaving. None of the moveable items used in the isolation unit should be taken outside the unit, or used with other stock outside the unit, for the entire duration of the isolation period. Litter and waste material must be collected regularly, stored in the containers provided, and disposed of either during or after the isolation period in such a way that disease agents will not be spread. Premises must have an effective programme, laid down in writing by the approved veterinarian, for cleansing and disinfection after each isolation session; approved disinfectants must be specified and used in the programme; and an appropriate resting period (usually 7 days) must be specified after each cleansing and disinfection operation. Crates or cages used for transport, if to be re-used, must be made of materials which allow effective cleaning and

disinfection, and this should be carried out within the isolation unit. If not re-used, the crates and cages must be destroyed in such a way that disease agents cannot be spread. An ‘all-in, all-out’ policy should be followed in the isolation unit. If it is necessary to add animals whilst others are already present in the unit, the isolation period of all of them must be extended until the latest completion date of any of the animals. If any animals become ill during isolation and the approved veterinarian considers that they need to be moved to a specialised hospital facility for diagnosis or treatment, he/she must ensure that this is done under his/her personal supervision in such a way as to ensure no possible risk of disease spread. In particular the approved veterinarian must personally supervise the arrangements for maintaining isolation throughout the movement, and for disinfecting any vehicles, rooms and equipment with which the animal has had contact. Any sign of any disease or death during isolation must be reported immediately to the approved veterinarian. All suspicions of any infectious disease on Annex A and any deaths in isolation must be reported immediately to the competent authority. Carcases of animals, which die during isolation and, if necessary those that are dead on arrival, must be submitted to a post mortem examination without unreasonable delay. The establishment must designate suitable staff to attend to the animals in isolation, taking appropriate precautions to ensure that there is no risk of transferring infection from the isolation unit to any other animals, and the arrangements must be agreed in writing by the approved veterinarian. Visitors must not be allowed to enter the isolation unit. If personnel apart from the designated attendants need to enter for essential maintenance etc., they must be required to wash thoroughly on entering and leaving, and wear protective clothing which shall be put on prior to entering and removed prior to leaving. There must be a visitors' book to record the dates, names and addresses of all visitors. The person in charge of the isolation unit must keep detailed records, which should be retained for at least ten years. Isolation should normally last for at least 30 days, unless a longer period is required to exclude specific

risks such as rabies.

In addition to these general requirements, some specific recommendations are made for the isolation of birds, primates and ungulates.

F. Certificates

The last chapter of the recommendations is a very short one, explaining for which zoo animals other certificates than those contained in annex E of the Balai Directive are required.

Consequences

Although the Transmissible Diseases Handbook (EAZWV, 20xx) containing the text of the revised Balai Directive, the Recommendations and other relevant information was sent to all zoos, all national and, in the case of Austria, Germany and Switzerland, also State Veterinary Authorities, not much changed for a while. Zoos were reluctant to be among the first to apply for approval, and within the Veterinary services information was often not transmitted to the official vets directly responsible for supervising a zoo. By the end of 2004, only the United Kingdom and several German Länder had approved a number of zoos, and there were two approved zoos in Switzerland and one in Austria. The EU Commission therefore urged Veterinary Services to go ahead with the approvals by making use of the recommendations provided by EAZWV.

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