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The Balai Directive - a Never-ending Story

by Peter Dollinger

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". This Directive is more concisely referred to as one of the „Balai Directives", the other one being Directive 92/118/EEC governing trade in certain products under animal and public health criteria. It is 15 pages long and is rather poorly drafted, in particular its English version.

The following is a summary of provisions of the Directive that are relevant for zoological gardens and similar institutions:

Article 2 - Definitions:

An „approved body, institute or centre" in the terms of the directive means any permanent, geographically limited establishment, approved in accordance with Article 13, where one or more animal species are kept or bred, whether or not for commercial ends, and exclusively for educational, conservation and / or scientific purposes. To facilitate reading, in this article the term „approved zoo" is used instead of „approved body, institute or centre".

Article 3 / 4 - Trade restrictions:

Animals may be traded (= moved to another approved zoo) only if they comply with the provisions of Articles 5 to 10, and if they come from approved zoos or, for some species, from registered dealers.

Approved zoos are obliged to notify outbreaks of the following diseases listed in ***Annex A*** to the competent authorities:

- New Castle Disease an avian influenza in any kind of bird
- Psittacosis in psittacines
- FMD, brucellosis (*Brucella* spp.), tuberculosis in ruminants
- FMD, Classical swine fever, African swine fever in pigs
- Rabies in all susceptible species

In cases where the Member State concerned has drawn up a control programme for a disease listed in ***Annex B***, also Annex B diseases have to be reported.

This concerns in particular viral enteritis and Aleutian disease of mink, tuberculosis of primates, felids and ruminants, and myxomatosis, VHD and tularaemia in lagomorphs.

Article 5 - Primates:

Trade in primates has to be restricted to animals consigned from and to approved zoos, except that the acquisition by an approved zoo of monkeys belonging to an individual may be authorised.

Article 6 - Ungulates:

Ungulates not covered by other Directives must be individually marked, must not be intended for slaughter under a disease eradication programme, must meet certain health standards, and must come from a holding, which is not the subject of animal health measures under various other directives, and have been kept therein permanently since birth or for the last 30 days before dispatch. **Ruminants** must be accompanied by an official veterinary certificate stating a.o. that they come from an officially tuberculosis-free and brucellosis-free herd, or from a holding where no cases of tuberculosis or brucellosis have been recorded in the 42 days preceding loading, and must have undergone, with negative results, specified tuberculosis and brucellosis tests in the 30 days prior to their dispatch. **Suidae** must come from areas free from African swine fever, and from holdings which are brucellosis-free and not subject to any restrictions as a result of classical swine fever.

Water buffaloes are to be treated like domestic cattle as far as health requirements are concerned.

Article 7 - Birds:

Birds must come from a holding not subject to NCD control measures and in which avian influenza has not been diagnosed in the 30 days preceding the dispatch.

Psittacine birds must, in addition, be individually marked and come from a holding in which no case of psittacosis has been diagnosed within the last two months preceding the dispatch. To **ratite birds**, the provisions of Council Directive 90/539/EEC (Poultry Directive) are applicable. Certificates are mandatory for psittacines and birds falling under the Poultry Directive. For other birds national legislation applies.

Article 9 - Lagomorphs:

Lagomorphs must not come or have been in contact with animals from a holding on which rabies (!) is present or suspected or having been present within the last month, and must come from a holding in which no animal shows clinical signs of myxomatosis. Whether or not a certificate is required, depends of the Member State of destination.

Article 10 - Carnivores:

Ferrets, minks and foxes must not come or have been in contact with animals from a holding on which rabies is present or suspected or having been present within the previous six months, inasmuch as no systematic vaccination programme is applied. There are detailed provisions regarding identification and rabies vaccination of cats and dogs. It seems, however, that they apply to domestic cats and dogs only.

Article 12 - Checks:

This article stipulates the application of the rules on checks contained in Directive 90/425/EEC also to animals covered by the present Directive.

Article 13 - Transport document and approval of zoos:

Animals of species susceptible to the diseases listed in Annex A or to diseases listed in Annex B, where the Member State of destination has drawn up a voluntary or compulsory control or monitoring programme, must be accompanied by a transport document which must be completed by the veterinarian responsible for the approved zoo.

To be approved, bodies, institutes or centres shall, as regards notifiable diseases, submit to the competent authority of the Member State all relevant supporting documents relating to the requirements contained in Annex C (which is a most remarkable document, reason why details are given below). The competent authority shall examine the documentation, and each Member state shall send the Commission a list of approved bodies, institutes and centres. The Commission shall forward this information to the other Member States.

Annex C - Conditions Governing Approval of Bodies, Institutes or Centres

1. In order to be granted official approval, a zoo must

(a) be clearly demarcated and ***separated from its surroundings***;

(b) be situated in a reasonable ***distance from farms*** whose health status might be jeopardised by the presence of the approved zoo;

(c) be under the ***control of a veterinarian*** (responsible for day-to-day compliance with the animal health requirements of this directive) who monitors the animals, which it must be possible to ***catch, confine and cage at any time***;

(d) have adequate ***quarantine facilities***;

(e) have one or more appropriate ***premises*** to to practise ***post-mortem*** examination;

(f) be ***free of the diseases*** listed in annex A and, as regards the diseases covered in the country concerned by a control or monitoring programme, the diseases listed in Annex B;

(g) keep up-to-date ***records*** indicating the number of animals of each species, with information as to their ages, the number of animals arriving in the zoo or leaving it, together with information on their transport and the animals' health, observations made during the quarantine period, the results of regular examinations of excreta, the results of blood tests or any other diagnostic procedures, cases of disease and, where appropriate, the treatment administered, the results of any animals that die in the establishment, including still-born animals;

(h) have facilities for appropriate ***disposal of the bodies*** of animals which die of a disease;

(i) be monitored by an official veterinarian who must carry out ***at least two health checks per year***. Health checks must include examination of the records which must be kept, one ***inspection of all the animals*** in the zoo, and ***representative samples*** taken from all the species referred to in Annexes A and B or detection of these diseases by other methods. The samples must be analysed by an approved laboratory to check whether they contain agents of the diseases for each species in Annex A. Samples may be taken throughout the year, the results of the laboratory tests must reveal no evidence of the pathogen in question.

2. Approval shall be retained where the following requirements are met:

(a) the animals brought into the zoo ***must come from another approved zoo***;

(b) domestic cattle, water buffaloes and pigs may leave the zoo only under official control;

(c) ***health checks*** must be carried out ***twice a year*** in accordance with 1 (h) (*sic!*) of this Annex;

(d) the results of the laboratory tests must reveal no trace of agents of the diseases referred to in Annexes A and B;

(e) any suspect deaths or presence of any symptoms suggesting that animals have contracted one or more of the diseases referred to in Annexes A and B must be ***notified*** without delay to the competent authority.

3. This section contains the criteria under which the approval may be suspended, restored or withdrawn when the presence of a notifiable disease is suspected or proven.

(To be continued in the next issue.)

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The Balai Directive - a Never-ending Story (2)

by Peter Dollinger

In Newsletter 1/97, we reviewed the Balai Directive up to **Article 13**. In this issue follows the rest.

Articles 14 and 15 describe the procedure, by which a Member State having drawn up a voluntary or compulsory control or monitoring programme for one of the diseases referred to in Annex B (i.e. viral enteritis and Aleutian disease of mink, European foulbrood, varroasis and acariasis of bees, tuberculosis of „apes and felids" and ruminants, and myxomatosis, VHD and tularaemia of lagomorphs), or considering itself free of one of these diseases, may obtain „additional guarantees". These guarantees will be defined in a Commission Decision, and could imply that an animal may be moved to a zoo in the country concerned only, if the establishment of origin meets certain health standards, and if the animal is accompanied by a specific veterinary certificate.

Chapter III - Provisions applicable to imports into the Community

Article 16 stipulates that import conditions must be at least equivalent to those reigning the intra-community trade.

For the purposes of uniform application of the import regimes, **Article 17** is more specific. It requires that animals (and ova, embryos and semen) may be imported into the Community only if they satisfy the following requirements:

(a) They must come from a third country on a list to be drawn up by the Commission. This list may include only countries from which imports are not prohibited as a result of the existence of one of the diseases referred to in Annex A of the Directive or of any other disease exotic to the Community.

(b) They must be accompanied by a health certificate corresponding to a specimen to be drawn up by the Commission, signed by the competent authority of the exporting country and certifying that the animals, semen, ova or embryos meet the additional conditions or offer guarantees equivalent to those applicable in intra-community trade. Experts from the Commission and the Member States shall carry out on-the-spot inspections to verify whether the guarantees given by the third country regarding the production and placing on the market can be considered equivalent to those applied in the Community.

Article 18 obliges Member States to ensure that the animals, semen, ova and embryos are imported only if they

- are accompanied by an official veterinary certificate meeting the requirements defined by the Commission;
- have satisfied the border veterinary checks;
- have undergone, prior to shipment to the Community, an official veterinary check to ensure that the animal welfare requirements for transport are met;
- have, in the case of primates, ungulates, birds, bees, lagomorphs, ferrets, mink and foxes, been quarantined before being placed on the market, in accordance with detailed rules to be established by the Commission.

Pending the establishment of specific rules for this article, the national import regulations shall continue to apply.

Article 19 contains the declaration of intent to lay down

- specific animal health requirements for imports into the Community, and
- the nature and content of accompanying documents

for animals intended for zoos, circuses, amusement parks or experimental laboratories according to the species.

Article 20 notes that the principles and rules laid down in Directive 90/675/EC, e.g. regarding inspections and safeguard measures, shall apply. Where no specific Community rules exist, national regulations shall continue to be applied.

For the benefit of all those who speak English as a foreign language, the first article of the **Common final provisions**, i.e. **Article 21,** shall be quoted literally:

„Any specimens of certificates applicable to trade and the animal health conditions to be met in order for it to be possible to trade in animals, semen, ova and embryos other than those covered by Article 5 to 11 shall, where the need arise, be determined under the procedure laid down in Article 26."

Did you get the point ?

It does not seem necessary to address, in the present context, the remaining articles of the Directive, as they relate primarily to procedural questions, relevant for the veterinary administrations and not for the zoos.

In 1996, the Balai Directive was amended twice. These amendments essentially refer to semen collection centres for horses, and adapt the Directive with regard to the accession of former EFTA countries to the Community. They are not relevant for zoos.

In the next issue we will review how EAZA responded to the perceived problems arising from the Balai Directive

(To be continued in the next issue.)

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The Balai Directive - a Never-ending Story (3)

by Gerry M. Benbow, Warminster, former Chairman of the EAZA Veterinary Committtee

In EAZWV Newsletters 1/97 and 2/97, Peter Dollinger has reviewed very comprehensively the Articles and conditions governing „Approved Status" for Zoos under the Balai Directive. This article will report on the concerns regarding implementation of the Directive expressed by EAZA, through its Veterinary Committee, and the attempts to obtain clarification and possible amendment of a number of conditions.

The Directive was put forward initially entitled „Animals and Products of Animal Origin" and was regarded as a catch-all Proposal covering all those animals not included in other specific legislation. The EAZA Veterinary Committee first discussed the Proposal in March 1992, but at that time we were told that there was little consensus of opinion between Member States, except that it had been decided that the requirements would be for movements of animals between Member States and not within the State as originally proposed ! Even U.K. MAFF were taken by surprise when the proposal was signed as a Directive in July 1992, to come into effect on 1st January 1994. I am quite sure that there was no appreciation by either the authorities of the member States, or the Commission itself, of the different species involved or of the number of movements of animals between Zoos that occurred annually and that the majority of these movements were for captive breeding purposes.

Points of concern at the Committee meetings in March and November 1992 and March 1993 concerned the detailed rules regarding the tuberculin and brucellosis testing. The importation of birds from third countries , the inspection under Article 17 of Third Countries to verify that conditions of production and placing on the market were equivalent to those in Member States, the conditions for Approved Status particularly the definitions of Quarantine, and the requirement to take representative samples from all species subject to the diseases in annexes a and B.

It was obvious that that many of the conditions of Approved Status were already complied with in major Zoos, particularly regarding record keeping, regular faecal examinations, laboratory tests and post mortem examinations. Prior to any knowledge of the Balai Directive and all its requirements the Veterinary Committee, following a suggestion by Professor Peer Zwart and Dr. Martin Frankenhuis, had started to prepare a Code of Practice of tests and examinations which it advised should be carried out on animals prior to inter-zoo movements and it was believed that it could improve the health status of animals in Zoos and in many cases prevent a sub-clinical condition following the stress of movement. The Committee felt that the Code, which has been accepted by EAZA, could be helpful in satisfying the requirements for record keeping.

All members of the Committee were asked to contact their Ministry authorities to seek clarification of the points raised and to offer assistance. In September 1993 four members of the British Veterinary Zoological Society met Mr. Robert Bell, head of Animal Health (International Trade) Division of MAFF and had a very full and frank discussion about the Directive. The first important point to arise from the meeting was that the term „Apes" would in fact include all non-human primates. We discussed 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. There is still no answer to that question. The danger to certain ungulates of anaesthesia for tuberculin testing and blood sampling was raised and accepted.

MAFF understood the concerns of Zoo veterinarians and undertook to communicate this to their colleagues on the Standing Veterinary Committee. From the U.K. point of view quarantine was defined as isolation and not

sharing the same air-space. It was accepted that this could be a difficult condition to fulfil, particularly for animals such as giraffe, elephants or rhinos !

A further meeting with Mr. Bell was held in May 1994 when problems encountered today were discussed. The advantages of all zoos having Approved Status were detailed. Once all detailed rules have been laid down and each Country has listed the Zoos which have been given Approved Status, movement of animals between those Zoos would entail a standard certificate signed by the zoo's own Veterinary Surgeon. The receiving Zoo could specify certain tests if it so wished. The problems of Approved Zoos being able to import or trade in animals from non-Approved Zoos without losing their Approved Status was discussed. One possible solution suggested was that there should be three categories of Zoo, under what would be called the „Added Animals Procedure":

- Approved
- Not Approved (because they have not sought Approval)
- Approved but with a non-Approved section on the premises.

In the last category, an animal from a non-Approved source would enter the non-Approved section, undergo regular monitoring and health checks and stay in this section for a period of time dependent on the species.

It became apparent at the Veterinary Committee meeting in June 1994 that meetings between members and their respective Authorities were indicating differing interpretations of conditions, e.g. in France quarantine had not been defined and there was uncertainty about what constituted representative samples. A letter from EAZA was sent to Bernard van Goethem of D.G. VI with copies to Authorities in Member States, outlining the problems and reminding the Commission of articles 23 and 28, particularly the latter, 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 received.

(To be continued in the next issue.)

1997/4

The Balai Directive - a Never-ending Story (4)

by Gerry M. Benbow, Warminster, former Chairman of the EAZA Veterinary Committee

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 captive breeding programmes for primates should be able to continue. This compromise situation was not regarded as wholly satisfactory by some members of EAZA when it was suggested that is would be used as an interim measure. The more satisfactory solution was for zoos to 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.

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. This letter highlighted the questions of

- representative samples being taken with potential risk to the animals concerned. It stressed that anaesthesia of any zoo animal is not taken lightly, but is carried out for necessary treatments and for pre-export testing when necessary, and that the EAZA Veterinary Committee did not consider the collection of samples as a twice yearly routine in some animals to be a justifiable risk.
- the importation of animals from third countries into the European Union which was proving difficult, therefore interfering with captive breeding programmes.

If a flexible approach to the granting of Approved Status could not be agreed in all countries, an amendment to Annex C 1(i) would be necessary and the following suggested:

(i) be monitored by an official veterinarian who must carry out at least two health checks per year. Health checks must include at least:

- one inspection of all animals in the establishment;
- in scientifically run zoological gardens, and parks that are recognised institutes or licensed under other national legislation such as the U. K. Zoo Licensing Act, the necessity for testing or the taking of representative samples twice a year is removed if

(a) all dead animals of the relevant species are examined in a recognised institute or laboratory for the presence of diseases listed for these species in Annexes A and B;

(b) records indicate that the diseases listed in annexes A and B were not diagnosed in the species in question by clinical, serological, microbiological or pathological examination in the last five years;

(c) animals of the species in question are anaesthetised for other reasons, tests appropriate to the species are carried out;

(d) the EAZA Code of Practice is implemented prior to movement of animals between zoos.

Mr Fischler replied that, in relation to the granting of official Approved Status for zoos, it appears that Annex C gives the necessary flexibility to the official veterinarian to ensure that the required health status is achieved. Indeed, as an alternative to the taking of samples, the official veterinarian can decide to use other methods for the detection of the diseases concerned, thus avoiding unnecessary stress for the animals.

He also said that Article 23 gives the necessary flexibility to the Commission to ensure that animals intended for zoos and in particular for those who take part in international breeding programmes will be introduced into the Community without jeopardising the animal health situation of the Community.

I have suggested to EAZA that, in order to help the official veterinarian in giving the necessary flexibility for the granting of officially Approved Status, member zoos should carry out

(a) opportunistic testing of animals subject to the diseases in Annexes A and B when these animals are anaesthetised for other reasons;

(b) post mortem examinations, which when appropriate, should include an examination for the presence or absence of these diseases.

There has been an indication that there could be a review of the Annexes in 1997, so hopefully all the problems can be solved within a not too distant future. Watch this space !

(To be continued in the next issue.)