

**GUIDANCE NOTES AND CHECKLIST FOR PREMISES WISHING TO APPLY FOR APPROVAL UNDER ARTICLE 13 AND ANNEX C OF THE BALAI DIRECTIVE 92/65/EEC, AS AMENDED BY COMMISSION REGULATION EC No. 1282/2002**

1. Premises that are approved under the above legislation should be able to send animals to/from UK approved premises to similarly approved premises in other EU Member States under special certification procedures, which should generally be simpler than those procedures for certification of animals from non-approved premises. The procedure described below is not necessary if a premises only wishes to move animals between institutions in the UK. If moving animals covered by the Balai Directive to Northern Ireland, zoos, institutions and bodies should check whether an import permit is required.
2. The requirements for obtaining approved status are set out in Annex C of the Balai Directive (as amended by Regulation EC No. 1282/2002.). The Checklist below lists each of the conditions in Annex C, together with some notes for guidance about how each condition should be interpreted and implemented.
3. The “Checklist for Initial approval inspection” will be used by the Veterinary Officer (VO) who will inspect the premises prior to approval. If the VO finds that all the conditions for approval can be met, the owner or owner's representative and the approved veterinarian will both be asked to sign the last page of the checklist. By their signatures they confirm that they have read the checklist and undertake to observe all the conditions, and it is a requirement for approval that they should both give this undertaking.
4. If the owner/manager of a premises wishes to have their premises approved, they must complete the application form EC 3164 and return it to the local DVM/RVL. On the application form they will be asked to nominate a veterinarian who will act as the 'approved veterinarian' for the premises. The DVM/RVL will arrange for a VO to make an inspection visit, using the Checklist as above. The DVM/RVL will also arrange to interview the approved veterinarian and train him/her in the requirements of approved status.
5. If approval is granted the DVM/RVL will inform the premises in writing, giving the premises its unique approval number. If for any reason it is not possible to grant approval, the applicant will be informed in writing, and will be invited to re-apply once the deficient points have been corrected.
6. Approved premises will be re-inspected once a year by a VO, but if the DVM/RVL considers it advisable because of the disease situation or any other reason, he/she may require additional inspection visits.
7. Data Protection Act: From 1<sup>st</sup> January 2010 it is a requirement that Member States make available Internet-based information pages containing lists of

establishments and laboratories approved in accordance with Community veterinary and zootechnical legislation, including the Balai Directive. This list will be put on the Animal Health public website. When a premises makes its initial application for approval, they will be asked to confirm that they would not have any objection to relevant details being published. For certain premises only the approval number and LVU will be included in the list.

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**CHECKLIST FOR INITIAL APPROVAL INSPECTION OR ANNUAL RE-INSPECTION BY VETERINARY OFFICER TO ENSURE THAT THE PREMISES CONFORMS WITH ANNEX C OF THE BALAI DIRECTIVE**

*(NOTE: The Declaration at the end of this checklist must be signed by both the Approved Veterinarian and the Management of the Establishment, to confirm the agreement of both parties to all the conditions herein.)*

<u>Conditions governing approval</u>	Tick for YES Cross for NO	<u>Details/Remarks</u>
<p><b>1. Does the establishment habitually keep or breed animals exclusively for one or more of the following purposes:</b></p> <ul style="list-style-type: none"> <li>- display of the animals and education of the public</li> <li>- conservation of the species</li> <li>- basic or applied scientific research ?</li> </ul> <p><i>Guidance: premises cannot obtain or retain approval unless they satisfy at least one of these purposes.</i></p>		
<p><b>2. Is the establishment clearly demarcated and separated from its surroundings?</b></p> <p><i>Guidance: There must be a solid wall or secure perimeter fence. One of the provisions of the Zoo Licensing Act 1981 is that the premises must have a secure perimeter fence which as far as practicable will ensure that the animals cannot escape. If a premises has been inspected and approved by the Local Authority under the Zoo Licensing Act, it can be assumed that the perimeter fence is sufficient to meet the requirements of the Balai Directive.</i></p> <p><i>Similar provisions about secure perimeters are required for a laboratory to be designated under the Animals (Scientific Procedures) Act 1986, and it can be assumed that if a laboratory is designated under this Act its perimeter will be sufficient to meet the requirements of the Balai Directive.</i></p>		
<p><b>3. Is the establishment located a reasonable distance from agricultural holdings, to which it might pose a</b></p>		

<p><b>health hazard?</b> <b>Are there any poultry units nearby?</b></p> <p><i>Guidance: There must be no direct contact with animals in contiguous fields. Double fencing with an adequate sanitary gap would normally be required. Regional Veterinary Leads may apply discretion about reasonable safeguards.(See Annexes 4a and 4b, “Biosecurity guidance”)</i></p>		
<p><b>3.1. Does the establishment have adequate means for catching, confining and isolating the animals? Give details.</b></p> <p><i>Guidance: There should be appropriate facilities for catching, confining, performing a physical examination and collecting diagnostic samples for each species in the premises. If this cannot be done by physical restraint or hand injection of anaesthetic, the premises should ensure access to suitable remote injection equipment (dart gun, blow pipe or jabstick). A veterinarian experienced in the use of this equipment and appropriate anaesthetic protocols should perform this activity.</i></p>		
<p><b>4. Does the establishment have adequate isolation facilities for animals to be added from non-approved premises? Give details.</b></p> <p><i>Guidance The isolation unit must be capable of being disinfected, or cleansed from disease which may include leaving outdoor enclosures fallow or removing and replacing the substrate, should disease be diagnosed. This will be dependent on the species and disease diagnosed. Also see “added animals procedure” – Annex 6.</i></p>		
<p><b>5. Is the establishment free from the diseases listed in Annex A of Directive 92/65/EEC ?</b></p> <p><i>Guidance: See Annex 5 Health Surveillance Programme Guidance.</i></p>		

**Although national programmes are not in place for these diseases, any cases should be reported to the DVM/RVL.**

Write  
N/A if  
Not  
applicable

**6. Is the establishment free from the following diseases in Annex B of Directive 92/65/EEC for which national programmes are in place.**

Species	Disease
Mink	Viral enteritis Aleutian disease
Bees	European foulbrood varroasis and acariasis
Apes and felids	Tuberculosis
Ruminants	Tuberculosis
Lagomorphs	Myxomatosis Viral haemorrhagic disease Tularaemia

*Guidance: See Annex 5 Health Surveillance Programme Guidance.*

**7. Does the establishment keep up-to-date records indicating:**

- the number of animals of each species present in the establishment, with information as to their age, sex and identification as appropriate;
- details of any animals arriving in the establishment or leaving it, including dates of arrival and departure, addresses of source and destination, the animals' health status,
- results of blood tests and other diagnostic procedures;
- cases of disease, and treatment if applicable;
- results of post mortem examinations, including records of still births;
- observations during any periods of precautionary isolation or quarantine.

*Guidance: Records must be kept in an easily accessible form, to be available as necessary for audit purposes, and retained for at least 10 years, to show at least the following information:*

- *Date of illness report;*
- *Date of assessment by*

<p><i>veterinarian;</i></p> <ul style="list-style-type: none"> <li>• <i>Diagnosis;</i></li> <li>• <i>Outline of a diagnostic protocol;</i></li> <li>• <i>Outline of therapeutic protocol;</i></li> <li>• <i>Biosecurity and isolation requirements;</i></li> <li>• <i>Preventative medicine requirements for the case;</i></li> <li>• <i>Link to specific post mortem examination report if animal dies.</i></li> </ul> <p>The Approved Veterinarian will be required to make records available to the Veterinary Officer for auditing purposes. The Veterinary Officer may look for the following information: Disease trends, zoonotic disease cases, imports/exports, diseases found during quarantine/isolation and details of significant post mortem examinations.</p>		
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**Paragraph 7: Identification\***

In order to become approved, the premises must be actively implementing a policy for individually identifying animals with the exception of invertebrates and colony species such as small fish. Provided that such a policy is being actively pursued, it can be accepted that certain individuals may not yet be identified. For example, it may be inappropriate to catch and identify young animals before a certain stage in their development. If catching and handling resident individuals involves some risk to the animals, possibly including the need for anaesthetic, it can be accepted that they may be caught for identification on an opportunistic basis. As a minimum requirement, all animals that are introduced or despatched from the approved collection should be uniquely identified when they are being handled for movement however exceptions can be made if the animal is not being anaesthetised during the translocation process.

The method of identification must be unique, permanent and readable. Microchips fit this requirement in most species, but other methods may be accepted if they meet the criteria. Some species may be identifiable successfully by photographs. Tattoos in any species are frequently disappointing as they become hard to read after a certain time, and better methods should be encouraged.

<p><b>8. Does the establishment have suitable facilities to carry out post-mortem examinations? Give details.</b></p>		
<p><i>Guidance: Post-mortem facilities may either be provided on the premises or arrangements made at suitable premises elsewhere, subject to satisfactory</i></p>		

<p>arrangements for the transfer of carcasses. If the approved veterinarian is not personally involved in examinations, they may be performed by a competent person under the direction of the approved veterinarian. Any suitable diagnostic facility may be used or non-human primates tissue samples or carcasses can be sent to:  Centre for Emergency Preparedness and Response (CEPR), Porton Down  Tel: 01980 612100  Fax: 01980 610848  <a href="mailto:Specialpathogens@hpa.org.uk">Specialpathogens@hpa.org.uk</a></p> <p>Senders should contact CEPR before dispatch to confirm that the laboratory will accept the specimen and to agree packaging and transport arrangements. Further guidance on transportation may be found in the ACDP guidance Management and control of viral haemorrhagic fevers: <a href="http://www.hpa.nhs.uk/infections/topics_az/AHF/ACDP_VHF_guidance.pdf">www.hpa.nhs.uk/infections/topics_az/AHF/ACDP_VHF_guidance.pdf</a>  (If rabies is indicated the local DVM/RVL must be notified. The DVM/RVL will take responsibility for further action.)</p> <p>Post mortem of all other animals can be submitted to the veterinary laboratories agency for examination.</p>		
<p><b>9. Are suitable facilities available for the storage and disposal of carcasses of animals which die, whether or not diseased? Give details.</b></p> <p><i>Guidance:</i> The storage of carcasses prior to disposal should be bio-secure and leak-proof. If disposal facilities are not available on-site, there should be suitable leak-proof means of transport to another facility which must have fully adequate disease control measures.</p>		
<p><b>10. Does the establishment retain the services of a veterinarian who is explicitly approved for the purpose by the DVM/RVL in writing?</b></p> <p><del><i>Guidance:</i> See specific guidance in Section A, paragraph 9.</del></p>		

**11. Does the Approved Veterinarian understand the requirements of Article 14(3)(B) of Directive 64/432/EEC?**

Guidance:

*This Directive lays down conditions for intra-Community trade in domestic bovines and swine. Article 14(3) (B) provides for Member States to set up surveillance system 'network', which would include the services of an 'approved' veterinarian. Article 14 (3) (B) says:*

*'The approved veterinarian shall be under the control of the competent authority and must comply with the following requirements:*

- meet the conditions for pursuing the veterinary profession.*
- have no financial interest or family links with the owner of or person responsible for the holding.*
- possess particular knowledge in the field of animal health as it applies to animals of the species concerned.*

*This means that they must:*

- regularly update their knowledge, especially as regards the relevant health regulations;*
- meet the requirements laid down by the competent authority to ensure the proper functioning of the network;*
- provide the owner of or person responsible for the holding with information and assistance in order that all steps are taken to ensure that the holding's status is maintained, particularly on the basis of preventative health programmes agreed with the competent authority (See Annex 5);*

*-Ensure compliance with the requirements concerning:*

- the identification and health certification of the animals of the herd, the animals introduced, and those exported];*
- compulsory reporting of infectious animal diseases and any other risk factor for animal health or welfare, and for human health;*

<ul style="list-style-type: none"> <li>• <i>establishing as far as possible the cause of death of animals and where they are to be consigned;</i></li> <li>• <i>the hygiene conditions of the herd and of the livestock production units.</i></li> </ul>		
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<p><b>12. Does the Approved Veterinarian ensure that appropriate disease surveillance and control measures are in place, including:</b></p> <ul style="list-style-type: none"> <li>- an annual programme of disease surveillance by testing and/or other methods?</li> <li>- an annual programme of control for zoonotic infections? see Annex 5a Zoonotic Disease Procedure.</li> <li>)</li> <li>- clinical, laboratory and post mortem testing of all animals suspected of being affected by infectious diseases?</li> <li>-an appropriate vaccination programme? see Annex 5 <i>Surveillance Programme Guidance.</i></li> </ul> <p><b>Give details (if necessary a schedule may be attached describing disease surveillance and control measures).</b></p> <p><i>Guidance: Written protocols should be drawn up for each of the above points.</i></p>		
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<p><b>13. Does the Approved Veterinarian understand the need to immediately report to the DVM/RVL any suspicion of the presence of any of the diseases in Annex A (or Annex B if applicable), in addition to reporting any diseases that are notifiable in Great Britain.</b></p> <p><i>Guidance: Notifiable disease regulations in Great Britain take precedence over any of the provisions in this or other regulations affecting zoos or laboratories.</i></p>		
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<p><b>14. Does the Approved Veterinarian understand the rules concerning isolation of added animals, both within the context of Directive 92/65/EEC, and in the context of national import quarantine regulations?</b></p> <p><i>Guidance: Rules for isolation of added animals are given in paragraph 3 of Annex C (see also sections 22 and 23 below). Animals imported from Third Countries will be subject to additional quarantine requirements under specific EU and/or national rules.</i></p>		
<p><b>15. Is the Approved Veterinarian familiar with and responsible for compliance with this Directive, as well as other relevant EU legislation on welfare of animals during transport, and disposal of animal waste?</b></p> <p><i>Guidance: Welfare of animals during transport is covered by Council Regulation (EC) No 1/2005. Amongst other things it lays down criteria for 'fitness to travel' and gives recommended space allowances. Animal waste is dealt with under Council Regulation 1774/2002, and is particularly relevant to the disposal of dead animals. Dead zoo animals are classed as Category 1 material, and must be disposed of by incineration or rendering.</i></p>		
<p><b>16. Does the establishment keep animals intended for laboratories carrying out experiments, and if so does it operate in conformity with article 5 of Directive 86/609/EEC?</b></p> <p><i>Guidance: Directive 86/609/EEC lays down rules for the protection of animals used in experimental and scientific procedures. It applies to all living, non-human vertebrates, but does not apply to foetal or embryonic forms. Article 5 reads:</i></p> <p><i>"Member States shall ensure that, as far as the general care and accommodation of animals is concerned:</i></p>		

- *all experimental animals shall be provided with housing, an environment, at least some freedom of movement, food, water and care which are appropriate to their health and well-being;*
- *any restriction on the extent to which an experimental animal can satisfy its physiological and ethological needs shall be limited to the absolute minimum;*
- *the environmental conditions in which experimental animals are bred, kept or used must be checked daily;*
- *the well-being and state of health of experimental animals shall be observed by a competent person to prevent pain or avoidable suffering, distress or lasting harm;*
- *arrangements are made to ensure that any defect or suffering is eliminated as quickly as possible.*

*For the implementation of the provisions of first two points, Member States shall pay regard to the guidelines set out in Annex II." Annex II presents comprehensive guidelines for the care of laboratory animals, including detailed recommendations of space allowances.*

**17.\* Was the establishment visited and inspected by a Veterinary Officer at least once within the past 12 months?**

**Is sufficient information available to audit the activity of the approved veterinarian, and to audit the implementation of the annual disease surveillance plan?**

**Are the provisions of Directive 92/65/EEC being met?**

*Guidance: In order for approval to be maintained a whole time veterinary officer must make a re-inspection visit at least once per year.*

**18.\* Since the last approval inspection visit has the establishment introduced**


<p><b>animals only from another approved body, institute or centre?</b></p> <p><i>Guidance: If any animals have been introduced from a non-approved source, see section 21 below. Animals introduced from a non-approved source must conform to the rules in Article 3 of Annex C of Directive 92/65/EEC.</i></p>		
<p><b>19.* Do the results of clinical, post-mortem and laboratory tests, carried out since the last approval inspection, confirm the absence of any of the diseases listed in Annex A of the Directive 92/65/EEC? (and Annex B if relevant)</b></p> <p><i>Guidance: Annex B diseases are relevant only if they are the subject of a national GB control or eradication programme, approved by the EU Commission.</i></p>		
<p><b>20.* Has the establishment made suitable arrangements to retain the records referred to in Annex C. 1. (d) [see section 7 above] for at least 10 years, or since approval?</b></p> <p><b>Give details.</b></p> <p><i>Guidance: If the establishment has not yet been approved for the past 10 years, it must have provided facilities of a suitable size to store and retrieve as necessary the volume of records that will be accumulated over 10 years.</i></p>		
<p><b>21.* Since the last approval inspection visit have any animals been introduced from a non-approved source, and if so did they follow the procedures laid down in paragraph 3 of Annex C?</b></p> <p><b>Give details</b></p> <p><i>Guidance: Added animals from a non-approved source must complete a period of isolation in accordance with Annex 6 “added animals procedure”, and with Annex 7 “isolation conditions for added animals entering approved premises”.</i></p>		

<p><b>22.* If species were introduced from non-approved sources outside Great Britain, did they complete the period of quarantine specified in any relevant import licences issued by Defra?</b></p> <p><b>Or, in the case of animals covered by the Rabies (Importation of Dogs, Cats and Other Mammals) Order 1974, did they complete quarantine under that Order?</b></p> <p><i>Guidance: Duration of isolation for different species will be specified on the import licence. Note that in certain cases general licences may apply. For non-rabies susceptible species, no import licence is required.</i></p>		
<p><b>23.* Since the last approval visit, have any animals been consigned to another establishment that was not approved?</b></p> <p><b>Give details</b></p> <p><i>Guidance: Animals may be consigned to a non-approved premises only with the authorisation of the DVM/RVL, and that authorisation may be given only on condition that there is no risk of the spread of disease. Testing/Isolation should be carried out when moving animals from non-approved premises to an approved premises.</i></p>		

\* Applies in principle to annual re-inspection visits, and may not be relevant to initial visits

**Declaration by the Owner/Manager/Owner's Representative\* of the Establishment:**

I declare that I have read this checklist together with the surveillance programme and added animals procedure and undertake to observe all the conditions therein

Signed .....

Name in block letters .....

Status or job title .....

Date.....

**Declaration by the Approved Veterinarian of the Establishment:**

I declare that I have read this checklist together with the surveillance programme and added animals procedure and undertake to observe all the conditions therein

Signed:.....

Name in block letters.....

Practice Address.....

.....

Date.....

**Signature of the inspecting Whole Time Veterinary Officer:**

I declare that I have inspected the Establishment and completed this checklist

On.....(date)

Signed:.....

Name in block letters .....

Divisional Office Address .....

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Date.....