

REGISTRATION AND APPROVAL PROCEDURES

BALAI REGISTRATION

Registration applies in effect only to trade species for which the Balai Directive lays down conditions in detail. These are:

- Non-domestic ungulates
 - artiodactyla : deer, llamas and alpacas, antelopes, wild pigs.
 - perissodactyla: tapirs and rhinos.
- Captive Birds and poultry for exhibition, shows and contest which are not covered by EU Directive 90/539/EEC
- Lagomorphs: Rabbits and hares (if commercially traded)
- Dogs and Cats (if commercially traded)
- Non domestic carnivora
- Certain other mammals listed in Schedule 1 of The Rabies (Importation of dogs, cats and other mammals) Order 1974 (as amended) which are subject to National Rabies Rules.

In theory, the Directive also applies to all other non-domestic species. For movements from non-approved premises of other non-domestic species (except non-human primates) there are no conditions laid down in the Directive, Consequently, trade conditions and certification requirements for such movements are subject to bilateral agreements between the trading States.

Application process

For Registration, application forms EC3163 must be completed and submitted to Central Operations Carlisle. No inspection is required though the applicant must agree to abide by certain conditions set out in the Directive. Registration is not time-limited (subject to continued compliance with the basic requirements for registration and that the applicant continues to function as a relevant trader).

Granting Registration

Central Operations Carlisle hold a record of registered establishments for GB and allocate a unique reference numbers to each premises. The number consists of the prefix RH followed by the AH office code number, followed by the last 2 digits of the first year of registration, followed by a national sequential three digit number starting at 001 (e.g. RH/33/10/001 for Chelmsford in 2010, RH/12/10/002 for Lincoln, etc.). As registration solely pertains to exports of animals and birds, there is no need for Carlisle to regularly provide each Animal Health office with a list of Registered Holdings in their region, but may supply this information if requested to.

Destination Premises

For trade between Approved premises, the Directive requires that BOTH the premises of origin and the premises of destination are approved (although certain derogations are permitted). However when trade takes place from a Registered premises, there is NO requirement for the premises of destination to be registered. This means that registration applies ONLY to the premises of origin.

APPROVAL OF BODIES, INSTITUTES AND CENTRES

INTRODUCTION

Approved bodies, institutes or centres are defined in the Directive as "permanent, geographically limited establishments where one or more species of animal are habitually kept or bred, whether or not for commercial ends, and exclusively for one or more of the following purposes:

- display of the animals and education of the public;
- conservation of the species;
- basic or applied scientific research or breeding of animals for the purposes of such research.

Approval will be withdrawn if the premises ceases to fulfil at least one of these purposes.

The Balai Directive lays down the basic condition that, for export trade in the relevant species, the exporting premises must be either Registered or Approved by the authorities in the exporting country.

The relevant species on approved premises are those present on the establishment that are affected by one or more of the diseases listed in Annex 1. The approval letter will state which taxonomic groups (classes, orders or families) of animals or birds are covered by the approval.

Mechanism for approval

1. Application

For Approval, an application EC3164 will need to be completed and submitted to the RVL/DVM, see below. In addition, an inspection visit by an Animal Health Veterinary Officer is required to ascertain whether the premises meets the requirements of Annex C of the Balai Directive. The zoo or research premises operator/manager and the nominated Approved Veterinarian will need to attend the inspection. During the inspection, the Veterinary Officer will go through a checklist. After the inspection, the VO will write a report to the RVL/DVM giving a recommendation. Approval is valid for one year, when a further inspection will be required. If a premises becomes approved, it is automatically considered to be registered. Under certain circumstances, such as failure to maintain compliance with the requirements of Annex C of the Directive, approval may be withheld, suspended or withdrawn.

i. If an establishment wishes to become approved, the operator/manager should complete the application form and review the checklist. On receipt of the completed application form, RVL/DVMs should arrange for an inspection visit to be made by a Veterinary Officer using the checklist.

ii. The approval of establishments for the purposes of trade under the Balai Directive does not remove the need for any other current local authority or licensing requirements such as those for the Dangerous Wild Animals Act 1976 (as amended). Those establishments which import and keep animals subject to the Rabies (Importation of Dogs, Cats and other Mammals) Order 1974 (as amended)(ROI) will need to be inspected and approved separately under that Order.

iii. From 1st January 2010, EU Decision 2009/712 requires Member States to make available Internet-based information pages containing lists of establishments and laboratories approved by Member States in accordance with Community veterinary and zootechnical legislation. The format for the information required is set out in Annex II Commission Decision 2009/712/EC. This list will be put on the Animal Health public website.

For certain approved establishments and laboratories only the approval number and LVU will be included in the list.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:247:0013:0025:EN:PDF>

The operator of the premises will be required on the application form to confirm that it is willing for the identity of the approved body to be recorded on a publicly available list on the Animal Health website.

2. Inspection

i. In order to be granted approval, bodies, institutes or centres must comply with the conditions laid down in Annex C of Directive 92/65/EEC (see Annex 2). The checklist at Annex 4 corresponds to all the requirements of Annex C of the Directive, amplified with guidance on interpretation and VOs must use the checklist when inspecting the premises.

ii. A detailed map must be provided by the establishment showing the whole premises. This is particularly important because the partial approval system currently in place (as of 2009) will be phased out within the next 3 years. This also means that existing or new establishments will be required to be totally approved to ensure containment in case of disease outbreak in the establishment.

iii. All the animal health records including clinical and laboratory reports for at least the past 3 years must be inspected.

iv. After completing the checklist, the VO must arrange for it to be signed by both the Approved Veterinarian and the owner, or owner's representative or manager. These signatures indicate that the Approved Veterinarian and the owner undertake to observe all the conditions of approval contained in the checklist. The VO should then submit the completed checklist to the RVL/DVM, together with a recommendation as to whether approval should be given.

3. Granting Approval

i. Approval must be granted for the **whole premises** delineated on the map. This is because the partial approval system currently in place will be phased out within the next 3 years (as of 2009). Therefore, existing or new establishments will be required to be totally approved to ensure containment in case of a disease outbreak in the establishment. There may, on limited occasions, be exceptions when this is not possible. Balai "islands" may be re-approved in the interim period but this will not be available from 2011. The current mechanism for approving discrete taxonomic groups will be phased out as well so that Balai approval will be for all relevant species within the premises.

ii. The RVL/DVM will create a unique reference number to be allocated to each approved establishment. The number consists of the prefix AB followed by the Animal Health office

code number, followed by the last 2 digits of the first year of registration, followed by a three digit number starting at 001 (e.g. AB/36/10/001). If an establishment is only approved for rabies quarantine and not as an approved body, the Rabies Operations Branch at Chelmsford only need to be informed.

iii. AHIT Chelmsford hold a record of approved establishments and maintain the list of approved establishments as per EU Decision 2009/712 up to date in the AH website.

iv. The RVL/DVM sends approval letter to the establishment.

4. Withholding Approval

Where approval is withheld the establishment should be informed in writing.

5. Annual Re-Inspection

RVL/DVMs must arrange for each approved premises on the local register to be inspected once a year by a Whole Time Veterinary Officer (WTVO). At this inspection, the WTVO must verify that all the items on the checklist (Annex 4) are being observed.

6. Suspension of Approval

i. When a sample is taken from an animal suspected of having a disease listed in [Annex A of the Directive](#) the Approved Veterinarian must immediately inform the RVL/DVM. The RVL/DVM must suspend temporarily the approval of the establishment for the species susceptible to the suspected disease until the results of the test are known.

ii. When an animal is suspected of having a disease that is notifiable in Great Britain, regardless of whether or not the disease is also listed on Annex A of the Directive, the Approved Veterinarian must immediately inform the RVL/DVM. The RVL/DVM will apply the appropriate measures under GB national legislation, which will take precedence over any requirements of the Directive 92/65/EEC (as amended). At the same time, the RVL/DVM must suspend temporarily the approval of the establishment for the species susceptible to the suspected disease and inform the establishment in writing.

iii. If the RVL/DVM becomes aware that any of the conditions of Annex C of Directive 92/65/EEC or any other relevant conditions of the Directive are not being observed, he/she must suspend approval in writing. At the same time, the Approved Veterinarian will be warned in writing. The letters will specify an appropriate period within which the deficiency must be corrected (which may be immediate). Failure to correct the deficiency within the

specified period will result in withdrawal of approval from both the premises and the veterinarian.

iv. If the premises no longer satisfies any of the following purposes, namely,

- display of the animals and education of the public;
- conservation of the species;
- basic or applied scientific research or breeding of animals for the purposes of such research.

The RVL/DVM must notify the operator that approval will be withdrawn unless one of the required purposes can be shown to be restored.

7. Withdrawal of Approval

i. Approval will be withdrawn if:

- a GB notifiable disease is confirmed;
- a disease in Annex A of the Directive is confirmed (except where the disease occurs outside the delineated, approved area and the disease is not normally considered to affect the species named in the approval);
- the establishment fails to comply with any of the conditions of Annex C of the Directive the premises no longer fulfils any of the purposes i.e. display of the animals and education of the public, conservation of the species or basic or applied scientific research or breeding of animals for the purposes of such research.

A notice of suspension should normally precede any notice of withdrawal of approval.

ii. The legal instrument in England that implements Directive 92/65/EEC is the Animals and Animal Products (Import and Export) (England) Regulations. Similar legislation applies in Wales and Scotland. The Local Authority is responsible for enforcement of the Directive, but the Secretary of State may choose to assume any of the duties allocated to the Local Authority (Regulation 3). Regulation 9 gives specific powers to the Secretary of State to approve premises under Article 13 of Directive 92/65/EEC, and to suspend, withdraw or restore approvals given in accordance with Article 13 and Annex C of the Directive.

8. Reinstatement of Approval

- i. If approval has been suspended because of a suspicion of a disease on Annex A of the Directive, it may be re-instated as soon as the RVL/DVM is satisfied that all test results are negative and that no such disease exists. The RVL/DVM must be satisfied that all the conditions on Annex C of the Directive are still being observed and may require an inspection visit by a WTVO to confirm this.

- ii. If approval has been suspended because of a suspicion of a GB notifiable disease, it may be re-instated in writing as soon as all legally imposed restrictions on the premises have been lifted and the RVL/DVM is satisfied that all the conditions on Annex C of the Directive are still being observed. An inspection visit by a WTVO may be necessary to confirm this.

- iii. If approval has been withdrawn because of the presence of a disease on Annex A of the Directive, it may be re-instated as soon as the RVL/DVM is satisfied that all appropriate eradication procedures have been completed (including any required under national legislation) and that the disease no longer exists in the premises. The RVL/DVM may require a precautionary empty period or observation period before the premises may be re-stocked, or the remaining stock may be regarded as disease-free. The RVL/DVM must be satisfied that all the conditions on Annex C of the Directive are still being observed and may require an inspection visit by a WTVO to confirm this.

- iv. If approval has been withdrawn because of the presence of a GB notifiable disease, it may be re-instated as soon as the RVL/DVM (in consultation with Veterinary Exotic Notifiable Diseases Unit, Scottish Government and Welsh Assembly Government as appropriate) is satisfied that all the legally required eradication procedures have been completed, including any precautionary empty periods or any surveillance and testing of the remaining animals, and all legally imposed disease control restrictions have been lifted from the premises. The RVL/DVM must be satisfied that all the conditions on Annex C of the Directive are still being observed and may require a WTVO inspection visit to confirm this.

- v. If approval has been withdrawn because of a failure to observe conditions of Annex C of Directive 92/65/EEC, or because the premises no longer fulfils any of the specific purposes defined in the Directive, it can only be re-instated following a new application from the premises, and new inspection by a WTVO with satisfactory results. The RVL/DVM will also obtain a written assurance from the owner/owner's representative that the infringed conditions have been understood and will be observed in the future.

Balai approval and bird imports

Birds of prey and certain other birds being imported into the EU from 3rd Countries for conservation programmes (i.e. not commercially) must be imported into an establishment that meets the conditions of approval. Contact Animal Health Imports Team, Chelmsford for information on structural requirements and minimal conditions which must be met.

For birds of prey centres and similar bodies, the whole premises must be approved, and continuously (not just an on-off quarantine arrangement). If they are licensed as zoos then the Balai Approvals process applies in full.

APPROVED VETERINARIAN PROCEDURE

The premises must appoint a veterinarian who will act as the 'Approved Veterinarian' (AV). The AV is responsible for observing that all the conditions of approval are met and maintained. The nomination must be made at the same time as applying for approval under Annex C of the Directive. His/her duties are:

- to ensure that disease surveillance and control measures are in place;
- to ensure day to day compliance with the animal health requirements of the Directive;
- to ensure day to day compliance with EU rules on animal welfare during transport and on the disposal of animal waste;

Note that the role of AV is not the same as Local Veterinary Inspector (LVI)/Official Veterinarian (OV). The AV is a new concept created for implementation of Regulation EC No. 1282/2002 amending three Annexes of Directive 92/65/EEC.

The AV does not need to be a full-time employee of the premises, but will normally be responsible for all the veterinary work at the premises. The work may on occasions be carried out 'under the direction' of the AV, for example by another member of the same practice when the AV is not available, or when a case is referred to a specialist veterinarian carrying out a specialised procedure. The AV may wish to nominate another member of the same or another practice to act as a deputy. In this case the RVL/DVM must also interview the nominated deputy and ensure that he/she is also familiar with all the above regulations. The AV is solely responsible for ensuring that his/her deputies have the necessary skills and experience to provide deputy services to the approved institution. The deputy will not be required to countersign the checklist at Annex 4, but his /her name will be specified on the Approved Veterinarian's letter of appointment and they will be allowed to sign certification.

The OV/LVI must be on the correct panel to sign an ITAHC or Export health Certificate (EHC).

When a premises applies to the RVL/DVM for approval, it will be asked to nominate a veterinarian whom it wishes to act as its AV. The veterinarian nominated by the approved premises might have his/her practice base in a different animal health office from the approved premises. In this case the RVL/DVM who carries out the approval of the veterinarian should be the RVL/DVM in the area in which the approved premises is located.

The RVL/DVM should arrange to interview the veterinarian who is nominated for approval. The veterinarian must be able to show a reasonable degree of knowledge in the field of animal health as it applies to the relevant species and be able to show that he/she has regularly updated his or her knowledge, especially as regards relevant health regulations. Ideally, he/she should be able to present a training record (e.g. a RCVS Continuing Professional Development Record or, in the case of a veterinarian from another EU Member State, any equivalent in the veterinarian's home Member State). It would also be an advantage (though it is not a requirement) for the veterinarian to have worked at the applicant establishment or a similar establishment for sufficient time to acquire a reasonable level of experience. RVL/DVMs will consider each application on its own merits.

The RVL/DVM must be satisfied that the applicant veterinarian has read and considered the whole of Directive 92/65/EEC, Regulation EC No. 1282/2002 and all the relevant Annexes.

The RVL/DVM should discuss through the checklist in detail and ensure that the veterinarian understands and agrees with each of the requirements. The RVL/DVM should draw attention to the fact that the veterinarian will be required to sign the checklist, in addition to the signature of the owner/manager of the establishment, to confirm agreement with each item in the checklist.

The RVL/DVM must be satisfied that the applicant veterinarian has read and considered the requirements of Article 14(B) of Directive 64/432/EEC.

See paragraph 1(g)(i) of Annex C of the Directive 92/65 EEC(as amended) and paragraph 11 of the checklist.

The RVL/DVM must be satisfied that the applicant veterinarian has read and understood the principal EU legislation on welfare of animals during transport, and disposal of animal waste. The principal welfare legislation is contained in EC Regulation 1/2005 implemented via the Welfare of Animals (Transport) Order. The principal regulations on the disposal of animal waste are contained in Council Regulation 1774/2002. See paragraph 1(g)(v) of Annex C of Directive 92/65 EEC(as amended) and paragraph 15 of the checklist .

If the premises keep animals for scientific research purposes, the RVL/DVM must be satisfied that the applicant veterinarian has read and understood the principal EU legislation on welfare of animals in scientific research establishments. The principal welfare legislation is contained in [Council Directive 86/609/EEC](#) (as amended). See paragraph 1(h) of Annex C of the Directive 92/65 EEC(as amended) and paragraph 16 of the checklist.

The RVL/DVM must be satisfied that the applicant veterinarian is familiar with GB import rabies quarantine requirements (if relevant to the species concerned). The principal legislation is the Rabies (importation of dogs, cats and other mammals) Order 1974 (as amended). If the premises is likely to contain primates, the veterinarian must also be familiar with the recommendations for primate quarantine contained in the OIE International Animal Health Code, chapter 2.10.1. and appendix 3.5.1. A summary of the requirements is given in the “Added animals procedures” and “Isolation conditions for added animals procedures” sections.

If the RVL/DVM is satisfied that all the above requirements have been met, he/she should confirm the approval of the veterinarian in writing.

The approval of the veterinarian applies only to the premises specified in the written confirmation. RVL/DVM should review the approval status and re-interview the veterinarian every 3 years. If the veterinarian moves to a different approved premises, that new premises must make a fresh application to the RVL/DVM, who must carry out a further interview.

If the AV wishes to give up his/her role at the approved establishment, or if the establishment wishes to obtain the services of another approved veterinarian, either party should inform the RVL/DVM in writing. The RVL/DVM should then arrange to interview the new, nominated approved veterinarian as above.

If, however, the RVL/DVM becomes aware of deficiencies in the AV's performance of his/her duties, the RVL/DVM will send a warning letter.

If the deficiencies are not corrected, the RVL/DVM will write to the AV and withdraw approval.