[F1 ANNEX C

CONDITIONS GOVERNING APPROVAL OF BODIES, INSTITUTES OR CENTRES

Textual Amendments

F1 Substituted by Commission Regulation (EC) No 1282/2002 of 15 July 2002 amending Annexes to Council Directive 92/65/EEC laying down 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(1) to Directive 90/425/EEC (Text with EEA relevance).

1. In order to be granted official approval under Article 13(2) of this Directive, a body, institute or centre as defined in Article 2(1)(c) must:

   (a) be clearly demarcated and separated from its surroundings or the animals confined and located so as not to pose a health risk to agricultural holdings whose health status might be jeopardised;

   (b) have adequate means for catching, confining and isolating animals and, have available adequate quarantine facilities and approved procedures for animals coming from non-approved sources;

   (c) be free of the diseases listed in Annex A and the diseases listed in Annex B where the country concerned has a programme pursuant to Article 14. In order that a body, institute or centre is declared free from these diseases, the competent authority shall assess the records on the animal health status kept for at least the previous three years and the results of the clinical and laboratory tests carried out on the animals in the body, institute or centre. However, by way of derogation from this requirement new establishments shall be approved if the animals forming the collection are derived from approved establishments;

   (d) keep up to date records indicating:

      (i) the number and identity (age, sex, species and individual identification where practical) of the animals of each species present in the establishment;

      (ii) the number and identity (age, sex, species and individual identification where practical) of animals arriving in the establishment or leaving it, together with information on their origin or destination, the transport from or to the establishment and the animals health status;

      (iii) the results of blood tests or any other diagnostic procedures;

      (iv) cases of disease and, where appropriate, the treatment administered;

      (v) the results of the post-mortem examinations on animals that have died in the establishment, including still-born animals;

      (vi) observations made during any isolation or quarantine period;

(e) either have an arrangement with a competent laboratory to perform post-mortem examinations, or have one or more appropriate premises where these examinations may be performed by a competent person under the authority of the approved veterinarian;

(f) either have suitable arrangements or on-site facilities for the appropriate disposal of the bodies of animals which die of a disease or are euthanised;

(g) secure, by contract or legal instrument, the services of a veterinarian approved by and under the control of the competent authority, who:

(i) shall comply *mutatis mutandis* with the requirements referred to in Article 14(3)(B) of Directive 64/432/EEC,

(ii) shall ensure that appropriate disease surveillance and control measures in relation to the disease situation of the country concerned are approved by the competent authority and applied in the body, institute or centre. Such measures shall include:

— an annual disease surveillance plan including appropriate zoonoses control of the animals,

— clinical, laboratory and post-mortem testing of animals suspected to be affected by transmissible diseases,

— vaccination of susceptible animals against infectious diseases as appropriate, only in conformity with Community legislation;

(iii) shall ensure that any suspect deaths or the presence of any other symptom suggesting that animals have contracted one or more of the diseases referred to in Annexes A and B is notified without delay to the competent authority, if that particular disease is notifiable in the Member State concerned;

(iv) shall ensure that incoming animals have been isolated as necessary, and in accordance with the requirements of this Directive and the instructions, if any, given by the competent authority;

(v) shall be responsible for the day to day compliance with the animal health requirements of this Directive and of Community legislation on welfare of animals during transport and disposal of animal waste;

(h) if it keeps animals intended for laboratories carrying out experiments, in conformity with the provisions of Article 5 of Directive 86/609/EEC.

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

(a) the premises are under the control of an official veterinarian from the competent authority, who:

(i) shall visit the premises of the body, institute or centre at least once per year;

(ii) shall audit the activity of the approved veterinarian and the implementation of the annual disease surveillance plan;

(iii) shall ensure that the provisions of this Directive are met;

(b) only animals coming from another approved body, institute or centre, are introduced into the establishment, in accordance with the provisions of this Directive;

(c) the official veterinarian verifies that:

— the provisions of this Directive are fulfilled,

— the results of the clinical, post-mortem and laboratory tests on the animals have revealed no occurrence of the diseases referred to in Annexes A and B;

(d) the body, institute or centre keeps the records referred to in point 1(d) after approval, for a period of at least ten years.

3. By way of derogation from Article 5(1) of this Directive and point 2(b) of this Annex, animals including apes (*simiae* and *prosimiae*) having an origin other than an approved body, institute or centre may be introduced in an approved body, institute or centre, provided that these animals undergo a quarantine under official control and in accordance with the instructions given by the competent authority before being added to the collection.

For apes (*simiae and prosimiae*) the quarantine requirements laid down in the OIE International Health Code (Chapter 2.10.1 and Appendix 3.5.1) shall be respected.

For other animals undergoing quarantine in accordance with point 2(b) of this Annex, the quarantine period must be at least 30 days with respect to the diseases listed in Annex A.

4. Animals held in an approved body, institute or centre, shall only leave this establishment if destined to another approved body, institute or centre, in that Member State or another Member State; however, if not destined to an approved body, institute or centre, shall only leave in accordance with the requirements of the competent authority to ensure no risk of possible spread of disease.

5. Where a Member State benefits from additional guarantees under Community legislation it may request appropriate additional requirements and certification for the susceptible species to be added to the approved body, institute or centre.

6. The procedures for partly or completely suspending, withdrawing or restoring approval are the following:

(a) where the competent authority finds that the requirements of point 2 have not been fulfilled or there has been a change of usage which is no longer covered by Article 2 of this Directive the approval shall be suspended or withdrawn;

(b) where notification is given of the suspicion of one of the diseases listed in Annex A or B, the competent authority shall suspend approval of the body, institute or centre, until the suspicion has been officially ruled out. Depending on the disease involved and the risk of disease transmission, the suspension may relate to the establishment as a whole or only to certain categories of animals susceptible to the disease in question. The competent authority shall ensure that the measures necessary to confirm or rule out the suspicion and to avoid any spread of disease are taken, in accordance with Community legislation governing measures to be taken against the disease in question and on trade in animals;

(c) where the suspected disease is confirmed, the body, institute or centre shall again be approved only when, after eradication of the disease and source of infection in the premises, including suitable cleaning and disinfection, the conditions laid down in point 1 of this Annex, with the exception of point 1(c), are again fulfilled;

(d) the competent authority shall inform the Commission of the suspension, withdrawal or restoration of approval of a body, institute or centre.**]**