ANNEX XIV

COMMUNITY ANTIGEN AND VACCINE BANK

1. Conditions for the supply and storage of the concentrated inactivated antigen supplied to the Community antigen and vaccine bank:

(a) each antigen consists of a single homogeneous batch;

(b) each batch is split in order to permit it to be stored at two separate geographical sites under the responsibility of the designated premises of the Community antigen and vaccine bank;

(c) the antigen meets at least the requirements of the European Pharmacopoeia and the relevant provisions of the OIE Manual;

(d) the principles of Good Manufacturing Practise are maintained throughout the production process and this shall include the storage and finishing of the vaccine reconstituted from the antigens in store;

(e) if not otherwise specified in the texts referred to in point (c), the antigen is purified to remove non-structural proteins of the foot-and-mouth disease virus. The purification shall at least ensure that the residual content of non-structural proteins in vaccines reconstituted from such antigen does not induce detectable levels of antibody against non-structural proteins in animals which had received one initial and one subsequent booster vaccination.

2. Conditions for the formulation, finishing, bottling, labelling and delivery of vaccines reconstituted from concentrated inactivated antigen supplied to the Community antigen and vaccine bank:

(a) rapid formulation into vaccine of the antigen referred to in Article 81;

(b) production of a safe, sterile and efficient vaccine with a potency of at least 6 PD_{50} in accordance with the tests prescribed by the European Pharmacopoeia, and suitable for use in case of emergency vaccination of ruminants and pigs;

(c) a capacity to formulate from concentrated inactivated antigen in stock:

  (i) up to one million doses of vaccine within four days of instruction from the Commission;

  (ii) additionally, up to four million doses of vaccine within 10 days of instruction from the Commission;

(d) rapid bottling, labelling and distribution of the vaccine according to the specific needs of the area where vaccination is to be carried out.