

Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC (Text with EEA relevance)

CHAPTER III

**PREVENTATIVE MEASURES**

SECTION 14

**ANTIGEN AND VACCINE BANKS**

*Article 80*

**Community antigen and vaccine bank**

- 1 A Community antigen and vaccine bank shall be established in accordance with the procedure referred to in Article 89(2).
- 2 The Commission shall ensure that Community reserves of concentrated inactivated antigens for the production of foot-and-mouth disease vaccines are maintained on the premises of the Community antigen and vaccine bank. For that purpose, the number of doses and the diversity of strains and subtypes of antigen of foot-and-mouth disease virus and, if necessary, of authorised in accordance with Directive 2001/82/EC vaccines stored in the Community antigen and vaccine bank shall be decided in accordance with the procedure referred to in Article 89(2), taking into account the needs as estimated in the context of the contingency plans provided for in Article 72 and the epidemiological situation, where appropriate after consultation with the Community Reference Laboratory.
- 3 The information on quantities and subtypes of antigens or authorised vaccines stored in the Community antigen and vaccine bank shall be treated as classified information and in particular shall not be published.
- 4 The conditions for the establishment and maintenance of Community reserves of antigen and authorised vaccines at the premises of preferably at least two manufacturing establishments shall be laid down in contracts concluded between the Commission and the manufacturing establishments. Such contracts shall include at least:
  - a conditions for supply of quantities and subtypes of concentrated inactivated antigen;
  - b conditions for secure storage of antigen and authorised vaccines;
  - c guarantees and conditions of rapid formulation, production, bottling, labelling and distribution of vaccines.
- 5 The conditions and guarantees referred to in paragraph 4(a) to (c) may be amended in accordance with the procedure referred to in Article 89(3).