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 79

National antigen and vaccine banks

1 Member States may within the framework of the contingency plan establish or maintain national antigen and vaccine banks for the storage of reserves for emergency vaccination of antigens or vaccines authorised in accordance with Directive 2001/82/EC.

2 Member States may retain establishments for the packaging and storage of vaccines in the case of emergency vaccination.

3 Member States shall ensure that the antigen and formulated vaccine in the national antigen and vaccine banks comply with the minimum standards laid down for the Community antigen and vaccines bank with respect to safety, sterility and content of non-structural proteins.

4 Member States maintaining a national antigen and vaccine bank shall inform the Commission about the antigen and vaccine stocks kept. Such information shall be submitted to the Commission every 12 months as part of the information required by Article 8 of Directive 64/432/EEC. The information on quantities and subtypes of antigens or authorised vaccines stored in the national antigen and vaccine bank shall be treated as classified information and in particular shall not be published.

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).

Article 81

Supply and storage of concentrated inactivated antigen

The Commission shall ensure that the contracted manufacturer of the concentrated inactivated antigen supplied to the Community antigen and vaccine bank, guaranties conditions for the supply and storage of concentrated inactivated antigen of the foot-and-mouth disease virus at least equivalent to those laid down in point 1 of Annex XIV.

Article 82

Formulation, production, bottling, labelling and distribution of vaccine

1 The Commission shall ensure that the contracted manufacturer of the concentrated inactivated antigen supplied to the Community antigen and vaccine bank guaranties conditions for the formulation, finishing, bottling, labelling and delivery of vaccines reconstituted from antigens referred to in Article 81 at least equivalent to those laid down in point 2 of Annex XIV.

2 In case of emergency and with due regard to the epidemiological situation, the Commission shall be authorised to arrange for the immediate production, bottling, labelling, temporary storage and distribution of necessary quantities of vaccines reconstituted from any suitable antigen.

Article 83

Access to the Community antigen and vaccine bank

1 Member States shall have access to the Community antigen and vaccine bank following a request to the Commission.

The Commission shall, within the limits of the Community reserves of antigens and vaccines, immediately arrange for the formulation, production, bottling, labelling

and distribution of the required quantities and subtypes of vaccines, in particular in application of Article 51.

2 Member States that maintain a national antigen and vaccine bank or Member States that are associated to an international antigen and vaccine bank shall have the same rights and obligations to the Community antigen and vaccine bank as other Member States without such reserves.

3 Where it is in the interest of the Community, the Commission may supply or lend to third countries antigens from the Community reserves or vaccines reconstituted from such antigens.

Without prejudice to agreements concluded between the Community and third countries, access of third countries to the Community antigen and vaccine bank shall be authorised in accordance with the procedure referred to in Article 89(2), subject to detailed arrangements between the Commission and the third country concerned on the financial and technical cooperation to be adopted under that procedure.

4 Following the use of the antigen or formulated vaccine from the Community reserves, the Commission shall ensure that the used antigen or vaccine is replaced as soon as possible and according to the epidemiological situation.

Article 84

Testing of foot-and-mouth disease vaccines

1 The Commission shall be responsible for arranging independent testing for potency and innocuity of vaccines reconstituted from antigen stored in the Community antigen and vaccine bank, and of vaccines reconstituted from other antigens and intended for use within the framework of Community assistance to control measures against foot-and-mouth disease in third countries in accordance with Articles 82(2) and 83(3).

2 For the purpose of the testing referred to in paragraph 1 the Commission may employ the services of an independent Community Coordinating Institute.

If necessary, the Community Coordinating Institute shall be designated, and detailed rules on its functions, responsibilities and Community financial contributions shall be adopted, in accordance with the procedure referred to in Article 89(2).

3 Without prejudice to the standards for potency, safety and production procedures provided for in Community legislation, vaccines reconstituted from antigen stored within the Community antigen and vaccine bank shall meet at least the minimum standards for potency, safety and production procedures laid down in the European Pharmacopoeia and the relevant provisions of the OIE Manual.