DECISION OF THE EEA JOINT COMMITTEE

No 111/2008

of 7 November 2008

amending Annex I (Veterinary and phytosanitary matters) to the EEA Agreement

THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area, as amended by the Protocol adjusting the Agreement on the European Economic Area, hereinafter referred to as 'the Agreement', and in particular Article 98 thereof,

Whereas:

(1) Annex I to the Agreement was amended by Decision of the EEA Joint Committee No 95/2008 of 26 September 2008 [1].

(2) Paragraph 6(b) of the Introductory part of Chapter I of Annex I states that without prejudice to financial implications, the Community reserves of foot-and-mouth disease vaccines shall act as reserves for all Contracting Parties.

(3) Paragraph 6(b) of the Introductory part of Chapter I of Annex I foresees that consultations shall take place between the Contracting Parties in order to solve all the problems concerning, in particular, working conditions, financial matters, replacement of antigen, possible use of antigens and on-the-spot inspections.

(4) 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 [2] is incorporated into the Agreement.

(5) The arrangements concerning the access of Norway to the Community foot-and-mouth disease (FMD) antigen and vaccine bank should be set out in relation to Article 83 of Directive 2003/85/EC.

(6) This Decision is not to apply to Iceland and Liechtenstein,

HAS DECIDED AS FOLLOWS:

Article 1

The following shall replace the adaptation text in point 1a (Council Directive 2003/85/EC) in Part 3.1 of Chapter I of Annex I to the Agreement:

'The provisions of the Directive shall, for the purposes of this Agreement, be read with the following adaptations:

(a) Article 83 shall apply with the following adaptations:

1. The Commission will keep the Member States and Norway informed about quantities and qualities of available antigen stocks in the Community antigen bank within the framework of the Standing Committee on the Food Chain and Animal Health.

2. Where FMD control measures are to be supported by emergency vaccination, the central competent authority of Norway may submit a detailed request for the formulation and delivery of vaccines produced from the antigen stocks in the Community antigen bank, specifying the type, amount and presentation of vaccine needed within a specified period.

[1] OJ L 309, 20.11.2008, p. 12.
[2] OJ L 306, 22.11.2003, p. 1.

3. The Commission will, within the limits of the Community reserves of antigens and vaccines and taking into account the epidemiological situation in the Community and Norway, arrange for the immediate or urgent formulation of the appropriate antigens and production, bottling, labelling and delivery of the vaccines, under the terms of existing contracts with the manufacturer of the antigens.

4. Where the request of Norway exceeds 500 000 doses or 50 % of the stocks of one or more antigens, whatever is more, the matter may, in the light of the epidemiological situation, be deferred to consultation with EC Member States in the framework of the Standing Committee on the Food Chain and Animal Health.

5. Norway undertakes to bear the costs for the following actions:

— the transfer of antigens from the place of storage to the establishment of the manufacturer where formulation and finishing of the vaccines is to be carried out,

— the formulation and production of vaccines, including any additional testing that might prove necessary or requested by the recipient,

— the bottling and labelling of the vaccines and their transport to the place of delivery indicated in the request,

— the replacement without delay of any used quantity of antigen by antigens of the same specification (serotype, topotype, Seed Master Strain) and at least the same quality (purification, potency etc.) and origin (manufacturer, marketing authorisation).

The invoice shall be sent by the manufacturer to the respective Norwegian competent authority. It shall detail the cost incurred for each item specified above. A copy of this invoice shall be sent to the Commission in order to verify and ensure compliance with the terms of existing contracts. The Commission will inform Norway about the result of its assessment.

(b) In Annex XI Part A the word "Norway" shall be added to the list of Member States using the services of the Danish Veterinary Institute, Department of Virology, Lindholm in Denmark.'

Article 2

This Decision shall enter into force on 8 November 2008, provided that all the notifications under Article 103(1) of the Agreement have been made to the EEA Joint Committee (*).

Article 3

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

Done at Brussels, 7 November 2008.

For the EEA Joint Committee
The President
H.S.H. Prinz Nikolaus von LIECHTENSTEIN

(*) No constitutional requirements indicated.