EFTA SURVEILLANCE AUTHORITY

Doc. No: 96-6234-I
Ref. No: GOO 465.400.002
Dec. No: 226/96/COL
GEN 857

EFTA SURVEILLANCE AUTHORITY DECISION

of 4 December 1996

replacing the EFTA Surveillance Authority Decision No 31/94/COL[1] of 29 April 1994 concerning additional guarantees relating to Aujeszky´s disease for pigs destined to EFTA States or regions free of the disease as amended by EFTA Surveillance Authority Decision No 75/94/COL[2] of 27 June 1994 approving a programme for the eradication of Aujeszky's disease in Sweden and amending the EFTA Surveillance Authority Decision No 31/94/COL concerning additional guarantees relating to Aujeszky's disease for pigs destined to EFTA States or regions free of the disease, in so far as these Decisions concern Norway

THE EFTA SURVEILLANCE AUTHORITY,

Having regard to the Agreement on the European Economic Area, as adjusted by the Protocol Adjusting the Agreement on the European Economic Area, in particular Article 17 and Protocol 1 (4)(d) thereof,

Having regard to the Act referred to in Point 1 of Chapter I of Annex I to the Agreement on the European Economic Area on animal health problems affecting intra-Community trade in bovine animals and swine (Council Directive 64/432/EEC; hereinafter referred to as the Cattle and Swine Act), and in particular Article 10 thereof,

Having regard to the Agreement between the EFTA States on the establishment of a Surveillance Authority and a Court of Justice, as adjusted by the Protocol Adjusting the Agreement between the EFTA States on the establishment of a Surveillance Authority and a Court of Justice, and in particular Article 5 (2)(d) and Protocol 1, Article 1 (c) thereof,

Whereas Norway, by Decision of the EFTA Surveillance Authority No 75/94/COL of 27 June 1994 amending the EFTA Surveillance Authority Decision No 31/94/COL of 29 April 1994, was granted additional guarantees relating to Aujeszky´s disease;

Whereas these Decisions comprise, in addition to the guarantees thus granted to Norway, similar guarantees granted to Finland and Sweden;

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[1]OJ No L 138, 2.6.1994, p. 43; EEA Supplement to OJ 94/EEA/12/03
[2]OJ No L 247, 22.9.1994, p. 52; EEA Supplement to OJ 94/EEA/35/11

Whereas the Norwegian Government, while confirming that the material situation justifying the EFTA Surveillance Authority Decision No 75/94/COL amending the EFTA Surveillance Authority Decision No 31/94/COL of 29 April 1994 is unchanged, has requested that the Decisions, in so far as they concern the additional guarantees granted to Norway, be replaced by a new decision, covering only the guarantees granted to Norway, alleging this to be necessary for the solution foreseen in ongoing negotiations with the European Union in the veterinary field;

Whereas such a new Decision would not in any way alter the material situation compared to what applies by virtue of the EFTA Surveillance Authority Decision No 31/94/COL of 29 April 1994, as amended by EFTA Surveillance Authority Decision No 75/94/COL of 27 June 1994;

Whereas there is accordingly no obstacle in granting the request made by the Norwegian Government;

Whereas the measures provided for in this Decision are in accordance with the opinion of the EFTA Veterinary Committee assisting the EFTA Surveillance Authority,

HAS ADOPTED THIS DECISION:

1. The EFTA Surveillance Authority Decision No 31/94/COL of 29 April 1994 concerning additional guarantees relating to Aujeszky´s disease for pigs destined to EFTA States or regions free of the disease as amended by EFTA Surveillance Authority Decision No 75/94/COL of 27 June 1994 approving a programme for the eradication of Aujeszky's disease in Sweden and amending the EFTA Surveillance Authority Decision No 31/94/COL of 29 April 1994 concerning additional guarantees relating to Aujeszky's disease for pigs destined to EFTA States or regions free of the disease shall be replaced by the text at Annex, in so far as these Decisions concern Norway.

2. This Decision shall enter into force on 9 December 1996.

3. This Decision is addressed to the EFTA States.

4. This Decision shall be authentic in the English language.

Done at Brussels, 4 December 1996

For the EFTA Surveillance Authority

Björn Friðfinnsson
College Member

Håkan Berglin
Director

Annex

1. Pigs intended for breeding coming from other EFTA States or EC Member States or regions thereof and destined for EFTA States or regions thereof where vaccination for AD is not permitted, listed in Annex I, must fulfil the following conditions:

   1.1 AD must be compulsorily notifiable in the EFTA State and the EC Member State of origin;

   1.2 no clinical, pathological or serological evidence of AD must have been recorded in the herd of origin for the past 12 months;

   1.3 if vaccine for AD has been used on the herd of origin, only a g1 deleted vaccine shall have been used for the past 12 months;

   1.4 the pigs must have been held in isolation in accommodation approved by the competent authority such that no direct or indirect contact with other pigs shall have been possible for at least 30 days prior to movement;

   1.5 the pigs must not have been vaccinated;

   1.6 the pigs must have been subjected to an Elisa test for the presence of g1 antibodies in accordance with Annex II of this Decision, on sera taken at least 21 days after entry into isolation, with negative results. All animals in isolation must also have given negative results to this test. In the case of pigs aged over four months the test used shall be the whole virus Elisa;

   1.7 the pigs must have remained on the herd of origin since birth or the pigs must have remained in the consigning herd for three months and in others of equivalent status since birth;

   1.8 the pigs must not come into contact with pigs which do not fulfil the conditions set out in Points 1.1 - 1.7 during transport from the site of origin to the farm of destination.

2. Pigs intended for production coming from other EFTA States or EC Member States or regions thereof and destined for EFTA States or regions thereof where vaccination for AD is not permitted, listed in Annex I, must fulfil the following conditions:

   2.1 AD must be compulsorily noticeable in the EFTA State or the EC Member State of origin;

   2.2 no clinical, pathological or serological evidence of AD must have been recorded in the herd of origin for the past 12 months;

   2.3 the pigs must not have been vaccinated;

2.4 no pre-movement testing shall be necessary if the herd of origin is part of an official monitoring programme where at least 15% of the breeding animals (or 25 animals, whichever is the greater) are tested over the course of each year. Such testing shall be split into at least three approximately equal divisions, each being separated by at least two months; movement into such herds shall only be from herds of equivalent or superior status and no clinical case of AD shall have been recorded within 2 km of the herd of origin for the previous 60 days;

2.5 if the herd of origin is not part of such a monitoring programme the pigs must have been segregated prior to movement and the pigs must have been sampled in accordance with Annex III within 10 days prior to movement and subjected to a test in accordance with Annex II. All animals tested must have passed the test;

2.6 the pigs must have remained in the herd of origin since birth or the pigs must have remained in the herd of origin for three months and in herds of equivalent status since birth;

2.7 the pigs must not come into contact with pigs which do not fulfil the conditions set out in Points 2.1 - 2.6 during transport from the site of origin to the farm of destination.

3. The animals referred to in Point 2 shall be transported directly to the farm of destination and shall remain there until slaughter unless otherwise authorised by the competent authority in the EFTA State of destination. The competent authority of the EFTA State of destination may require that the pigs go directly to slaughter.

4. Pigs intended for slaughter coming from other EFTA States or EC Member States or regions thereof and destined for EFTA States or regions thereof, listed in Annex I, must fulfil the following conditions:

4.1 the pigs must be transported directly to the slaughterhouse of destination;

4.2 if such pigs have been vaccinated, only a g1 deleted vaccine shall have been used;

4.3 no clinical, pathological or serological evidence of AD must have been recorded in the herd of origin for the past three months;

4.4 the pigs must have remained in the herd of origin for the previous 60 days or since birth;

4.5 AD must be compulsorily noticeable in the EFTA State or EC Member State of origin;

4.6 the pigs must not come into contact with pigs which do not fulfil the conditions set out in Points 4.1 - 4.5 during transport from the site of origin to the slaughterhouse.

5. The health certificate referred to as Model III in Annex F to the Cattle and Swine Act must be completed by the following for pigs destined for an EFTA State or region thereof, listed in Annex I, and coming from an EFTA State or EC Member State or region thereof;

> "pigs in accordance with EFTA Surveillance Authority Decision 226/96/COL of 4 December 1996 concerning Aujeszky´s disease. In the case of pigs for breeding the test used was the whole virus ELISA/ELISA for g1 antibodies. (Delete where applicable)".

6. The conditions laid down in Points 1 to 5 shall not apply to the introduction of pigs into an EFTA State or region thereof, listed in Annex I, from an EFTA State or region thereof which under Article 10 of the Cattle and Swine Act has been granted additional guarantees corresponding to those provided for in this Decision.

7. An EFTA State listed in Annex I shall submit annual reports on the monitoring and findings concerning AD. This report shall be submitted to the EFTA Surveillance Authority at the latest by 1 April, the following year.

ANNEX I

Regions free of Aujeszky's disease which do not permit vaccination

Norway: All regions

ANNEX II

Protocol for enzyme linked immunosorbent assay (Elisa) for detecting antibodies to Aujeszky's disease virus glycoprotein 1 (ADV-g1) in serum

1. The institutions listed in paragraph 2 (d) shall evaluate Elisa g1-tests and kits against the criteria in paragraph 2 (a), 2 (b), 2 (c). The competent authority in each EFTA State shall ensure that only Elisa g 1-kits that meet these standards shall be registered. The examinations listed in 2 (a) and 2 (b) must be carried out prior to approval of the test and the examination in 2 (c), at least, must thereafter be carried out on each batch.

2. Standardisation, sensitivity and specificity of the test.

   (a) The sensitivity of the test must be of such a level that the following Community Reference sera[3] are scored positive:

   Community Reference serum ADV1 at 1 : 8 dilution,
   Community Reference serum ADV-g1 A ,
   Community Reference serum ADV-g1 B ,
   Community Reference serum ADV-g1 C ,
   Community Reference serum ADV-g1 D ,
   Community Reference serum ADV-g1 E ,
   Community Reference serum ADV-g1 F .

   (b) The specificity of the test must be of such a level that the following Community Reference sera[3] are scored negative:

   Community Reference serum ADV-g1 G ,
   Community Reference serum ADV-g1 H ,
   Community Reference serum ADV-g1 J ,
   Community Reference serum ADV-g1 K ,
   Community Reference serum ADV-g1 L ,
   Community Reference serum ADV-g1 M
   Community Reference serum ADV-g1 N ,

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[3] as laid down in "Report of Sub- Committee of Scientific Veterinary Committee on Aujeszky's disease", reference no VI/2556/92-EN (PVET/EN/1374), which can be obtained from the EFTA Surveillance Authority.

Community Reference serum ADV-g1 O ,
Community Reference serum ADV-g1 P ,
Community Reference serum ADV-g1 Q .

(c) For batch control, the EC Reference serum ADV1 must be scored positive at a dilution of 1 : 8 and the EC Reference serum ADV-g1 K must be scored negative.

(d) The institute listed below will, in addition, be responsible for checking the quality of the Elisa method in each EFTA State, and in particular for producing and standardising national reference sera according to the EC Reference sera .

1. Veterinærinstituttet, Oslo, Norway;

(e) The Community Reference sera will be supplied by those institutes listed in paragraph 2 (d) above.

ANNEX III

Population	Number to be sampled
under 25	All
25-100	25
100 -	30