COMMISSION DECISION

of 23 July 2001

on additional guarantees in intra-Community trade of pigs relating to Aujeszky's disease, criteria to provide information on this disease and repealing Decisions 93/24/EEC and 93/244/EEC

(notified under document number C(2001) 2236)

(Text with EEA relevance)

(2001/618/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 64/432/EEC of 26 June 1964, on animal health problems affecting intra-Community trade in bovine animals and swine [1], as last amended and updated by Directive 2000/20/EC [2], and in particular Article 8, Article 9(2) and Article 10(2) thereof,

Whereas:

(1) Commission Decision 93/24/EEC [3] establishes additional guarantees relating to Aujeszky's disease for pigs destined for Member States or regions free of the disease.

(2) Commission Decision 93/244/EEC [4] establishes additional guarantees relating to Aujeszky's disease for pigs destined for certain parts of the territory of the Community where approved programmes are in place for the eradication of this disease.

(3) The International Office of Epizootic Diseases (OIE) is the international organisation designated under the Agreement on the Application of Sanitary and Phytosanitary Measures in application of GATT 1994 which is responsible for the establishment of international animal health rules for trade in animals and animal products. These rules are published in the International Animal Health Code.

(4) The chapter of the International Animal Health Code on Aujeszky's disease has recently been substantially amended.

(5) It is appropriate to modify the additional guarantees required in intra-Community trade of pigs in relation to Aujeszky's disease in order to ensure their consistency with the international rules on this disease and better control in the Community.

(6) Criteria must be established on the information to be provided by the Member States on Aujeszky's disease, in accordance with Article 8 of Directive 64/432/EEC.

(7) For the sake of clarity Decisions 93/24/EEC and 93/244/EEC should be repealed and a single Decision should be adopted concerning additional guarantees in intra-Community trade of pigs relating to Aujeszky's disease and on criteria to provide information on this disease.

(8) The measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION:

Article 1

The dispatching of pigs intended for breeding or production destined for the Member States or regions free of Aujeszky's disease listed in Annex I and coming from any other Member State or region not listed in that Annex is authorised subject to the following conditions:

(a) Aujeszky's disease must be compulsorily notifiable in the Member State of origin;

(b) a plan for the control and eradication of Aujeszky's disease, fulfilling the criteria laid down in Article 9(1) of Directive 64/432/EEC, must be in place in the Member State or regions of origin under the supervision of the competent authority. Appropriate measures on pig transport and movements must be in place according to this plan for preventing a spread of disease between holdings of a different status;

(c) with regard to the holding of origin of the pigs:

— no clinical, pathological or serological evidence of Aujeszky's disease has been recorded in the previous 12 months in the holding in question,

— no clinical, pathological or serological evidence of Aujeszky's disease has been recorded in the previous 12 months in the holdings located in an area of 5 km surrounding the holding of origin of the pigs; however, this provision shall not apply if, in these latter holdings, disease monitoring and eradication measures have been regularly applied under the supervision of the competent authority and in accordance with the eradication plan referred to in point (b), and these measures have effectively prevented any spread of disease to the holding in question,

[1] OJ 121, 29.7.1964, p. 1977/64.
[2] OJ L 163, 4.7.2000, p. 35.
[3] OJ L 16, 25.1.1993, p. 18.
[4] OJ L 111, 5.5.1993, p. 21.

— vaccination against Aujeszky's disease has not been carried out for at least 12 months,

— the pigs have been subjected on at least two occasions at a distance of at least four months to a serological survey for the presence of ADV-gE or ADV-gB or ADV-gD antibody or to the whole Aujeszky's disease virus. This survey must have shown the absence of Aujeszky's disease and that vaccinated pigs have been free from gE antibodies,

— no pigs have been introduced from holdings of a lower animal health status as regards Aujeszky's disease in the previous 12 months, unless they have been tested for Aujeszky's disease with negative results;

(d) the pigs to be moved:

— have not been vaccinated,

— have been kept isolated in accommodation approved by the competent authority, during the 30 days prior to movement, and in such a way that any risk of spreading Aujeszky's disease to these pigs is prevented,

— must have lived in the holding of origin or in a holding of an equivalent status since birth, and have remained in the holding of origin for at least:

(i) 30 days, in the case of pigs intended for production;

(ii) 90 days, in the case of pigs intended for breeding,

— have been subjected with negative results to at least two serological tests for ADV-gB or ADV-gD or the whole Aujeszky's disease virus, at a distance of at least 30 days between each test. However, in case of pigs less than four months old, the serological test for ADV-gE may also be used. Sampling for the last test must be performed within 15 days prior to shipment. The number of pigs tested in the isolation unit must be sufficient to detect:

(i) 2 % seroprevalence with 95 % confidence in the isolation unit in case of pigs intended for production;

(ii) 0,1 % seroprevalence with 95 % confidence in the isolation unit in case of pigs intended for breeding.

However, the first of the two tests shall not be necessary if:

(i) in the framework of the plan referred to in point (b), a serological survey has been carried out in the holding of origin between 45 and 17 days prior to shipment, demonstrating the absence of Aujeszky's disease antibodies and that vaccinated pigs have been free from gE antibodies;

(ii) the pigs to be moved have lived in the holding of origin since birth;

(iii) no pigs have moved on to the holding of origin while the pigs to be moved have been kept in isolation.

Article 2

The dispatching of pigs intended for slaughter destined for the Member States or regions free of Aujeszky's disease listed in Annex I and coming from any other Member State or region not listed in that Annex, is authorised subject to the following conditions:

(a) Aujeszky's disease must be compulsorily notifiable in the Member State of origin;

(b) a plan for the control and eradication of Aujeszky's disease is in place in the Member State or regions of origin of the pigs, fulfilling the criteria laid down in Article 1(b);

(c) all the pigs in question must be transported directly to the slaughterhouse of destination and either:

— they come from a holding which fulfils the conditions laid down in Article 1(c), or

— they have been vaccinated against Aujeszky's disease at least 15 days prior to their shipment and come from a holding of origin where:

(i) in the framework of the plan referred to in point (b), Aujeszky's disease monitoring and eradication measures have been regularly applied under the supervision of the competent authority for the previous 12 months;

(ii) they had remained for at least 30 days before dispatch and where no clinical or pathological evidence of this disease has been detected at the moment of completion of the health certificate referred to in Article 7, or

— they have not been vaccinated and they proceed from a holding where:

(i) in the framework of the plan referred to in point (b), Aujeszky's disease monitoring and eradication measures have been regularly applied under the supervision of the competent authority in the previous 12 months and no clinical, pathological or serological evidence of Aujeszky's disease has been recorded in the previous six months;

(ii) vaccination against Aujeszky's disease and introduction of vaccinated pigs have been forbidden by the competent authority, since the holding is in the process of reaching the highest status as regards Aujeszky's disease in accordance to the plan referred to in point (b);

(iii) they have lived for at least 90 days before dispatch.

Article 3

Pigs intended for breeding destined for the Member States or regions listed in Annex II, where approved Aujeszky's disease eradication programmes are in place, must either:

(a) come from Member States or regions listed in Annex I, or

(b) come from:

— Member States or regions listed in Annex II, and

— a holding which fulfils the requirements of Article 1(c); or

(c) fulfil the following conditions:

— Aujeszky's disease must be compulsorily notifiable in the Member State of origin,

— a plan for the control and eradication of Aujeszky's disease is in place in the Member States or region of origin, which fulfils the criteria laid down in Article 1(b),

— no clinical, pathological or serological evidence of Aujeszky's disease has been recorded in the previous 12 months in the holding of origin of the pigs in question,

— the pigs must have been isolated in accommodation approved by the competent authority for the 30 days immediately prior to movement and kept isolated in such a way that any risk of spreading of Aujeszky's disease is prevented,

— the pigs must have been subjected, with negative results, to a serological test for the presence of gE antibodies. Sampling for the last test must be performed within 15 days prior to shipment. The number of pigs tested must be sufficient to detect 2 % seroprevalence with 95 % confidence in these pigs,

— the pigs must lave lived in the bolding of origin or in a holding of an equivalent status since birth, and have remained in the holding of origin for at least 90 days.

Article 4

Pigs intended for production destined for the Member States or regions listed in Annex II, where approved Aujeszky's disease eradication programmes are in place, must either:

(a) come from Member States or regions listed in Annex I, or

(b) come from:

— Member States or regions listed in Annex II, and

— a holding which fulfils the requirements of Article 1(c); or

(c) fulfil the following conditions:

— Aujeszky's disease must be compulsorily notifiable in the Member State of origin,

— a plan for the control and eradication of Aujeszky's disease is in place in the Member States or region of origin, which fulfils the criteria laid down in Article 1(b),

— no clinical, pathological or serological evidence of Aujeszky's disease has been recorded in the previous 12 months in the holding of origin of the pigs in question,

— a serological survey for Aujeszky's disease, demonstrating its absence and that vaccinated pigs have been free from gE antibodies, has been carried out in the holding of origin and between 45 and 170 days prior to shipment,

— the pigs must either have lived in the holding of origin since birth or have remained in such holdings for at least 30 days after introduction from a holding of an equivalent status, where a serological survey equivalent to the one referred to in the fourth indent above has been carried out.

Article 5

The serological tests carried out to monitor or detect Aujeszky's disease in pigs in accordance with this Decision must meet the standards laid down in Annex III.

Article 6

Without prejudice to Article 10(3) of Directive 64/432/EEC, information of the occurrence of Aujeszky's disease, including details of the monitoring and eradication programmes in operation in the Member States listed in Annex II and in the other Member States or regions not listed in that Annex where monitoring and eradication prorammes are in place, must be provided at least annually by each Member State in accordance with the uniform criteria laid down in Annex IV.

Article 7

1. Without prejudice to the provisions laid down in Community legislation concerning health certificates, before the completion, for animals of the porcine species destined for Member States or regions listed in Annex I or II, of section C of the health certificate required by Directive 64/432/EC, the official veterinarian shall ascertain:

(a) the status of the holding and of the Member State or region of origin of the pigs in question as regards Aujeszky's disease;

(b) in case the pigs are not originating from a Member State or a region free of the disease, the status of the holding and of the Member State or regions of destination for the pigs in question as regards Aujeszky's disease;

(c) the compliance of the pigs in question with the conditions laid down in this Decision.

2. For animals of the porcine species destined for Member States or regions listed in Annex I or II, the certification under paragraph 4 of Section C of the health certificate referred to in paragraph 1 shall be completed and supplemented as follows:

(a) in the first indent, after the word 'disease:' the word 'Aujeszky' must be added;

(b) in the second indent, reference shall be made to this Decision. In the same line, the number of the Article of this Decision, which is relevant for the pigs in question, shall be quoted between brackets.

Article 8

Member States must ensure that when pigs destined for Member States or regions listed in Annex I or II are transported, they shall not come in contact with pigs of different or unknown status, as regards Aujeszky's disease, during transport or transit.

Article 9

Decisions 93/24/EEC and 93/244/EEC are repealed as from the date laid down in Article 10.

Article 10

This Decision shall apply from 1 July 2002.

Article 11

This Decision is addressed to the Member States.

Done at Brussels, 23 July 2001

For the Commission

David BYRNE

Member of the Commission

ANNEX I

Member States or regions thereof free of Aujeszky's disease and where vaccination is prohibited

Denmark:	all regions
United Kingdom:	all regions in England, Scotland and Wales
France:	the Departements of Aisne, Allier, Ardennes, Ariège, Aube, Aude, Aveyron, Bas-Rhin, Bouches-du-Rhône, Calvados, Cantal, Charente, Charente-Maritime, Cher, Corrèze, Côte d'Or, Creuse, Deux-Sèvres, Dordogne, Doubs, Eure, Eure-et-Loir, Gard, Gers, Gironde, Haute-Garonne, Haute-Loire, Haute-Marne, Haute-Pyrénées, Haut-Rhin, Haute-Saône, Indre, Indre-et-Loire, Jura, Landes, Loire, Loire-Atlantique, Loir-et-Cher, Loiret, Lot, Lot-et-Garonne, Lozère, Maine-et-Loire, Marne, Meurthe-et-Moselle, Meuse, Moselle, Nièvre, Oise, Pyrénées-Atlantiques, Puy-de-Dôme, Rhône, Sarthe, Saône-et-Loire, Savoie, Seine-Maritime, Somme, Vaucluse, Tarn, Tarn-et-Garonne, Territoire de Belfort, Vendée, Vienne, Vosges and Yonne
Finland:	all regions
Germany:	the *Länder* of Thuringia, Saxony, Brandenburg, Mecklenburg-Western Pomerania, Saxony-Anhalt, Rheinland-Pfalz and Baden-Württemberg
Austria:	all regions
Sweden:	all regions
Luxembourg:	whole territory.

ANNEX II

Member States or regions thereof where approved Aujeszky's disease control programmes are in place

Germany: all regions except the *Länder* of Thuringia, Saxony, Brandenburg, Mecklenburg-Western Pomerania, Saxony-Anhalt, Rheinland-Pfalz, Baden-Württemberg

ANNEX III

Standards for Aujeszky's disease serological tests — Protocol for the enzyme linked immunosorbent assay (ELISA) for detecting antibodies to Aujeszky's disease virus (whole virus), to glycoprotein B (ADV-gB), to glycoprotein D (ADV-gD) or to glycoprotein E (ADV-gE)

1. The institutes listed in paragraph 2(d) shall evaluate Elisa ADV-gE tests and kits against the criteria in paragraph 2(a), (b) and (c). The competent authority in each Member State shall ensure that only Elisa ADV-gE kits that meet these standards shall be registered. The examinations listed in 2(a) and (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 are scored positive:
   — Community reference serum ADV 1 at 1:8 dilution,
   — Community reference serum ADV-gE A,
   — Community reference serum ADV-gE B,
   — Community reference serum ADV-gE C,
   — Community reference serum ADV-gE D,
   — Community reference serum ADV-gE E,
   — Community reference serum ADV-gE F.

   (b) The specificity of the test must be of such a level that the following Community reference sera are scored negative:
   — Community reference serum ADV-gE G,
   — Community reference serum ADV-gE H,
   — Community reference serum ADV-gE J,
   — Community reference serum ADV-gE K,
   — Community reference serum ADV-gE L,
   — Community reference serum ADV-gE M,
   — Community reference serum ADV-gE N,
   — Community reference serum ADV-gE O,
   — Community reference serum ADV-gE P,
   — Community reference serum ADV-gE Q.

   (c) For batch control, Community reference serum ADV 1 must be scored positive at 1:8 dilution and one of the Community reference serum sera from ADV-gE G to ADV-gE Q, as listed in point (b), must be scored negative.

   For batch control of ADV-gB and ADV-gD kits, Community reference serum ADV 1 must be scored positive at the dilution of 1:2 and Community reference serum Q referred to in (b) should be scored negative.

   (d) The institutes listed below will, in addition, be responsible for checking the quality of the ELISA method in each Member State, and in particular for producing and standardising national reference sera according to the Community reference sera.
   — Belgium — Centre de Recherches vétérinaires et agrochimiques, 1180 Bruxelles;
   — Denmark — Statens veterinære Institut for Virusforsknig, Lindholm, 4771 Kalvehave;
   — Germany — Bundesforschungsanstalt für Viruskrankheiten der Tiere, 16868 Wusterhausen,
   — Greece — Veterinary Institute of Infectious and Parasitic Diseases, 15310 Ag. Paraskevi,
   — Spain — Laboratorio Central de Veterinaria de Algete, Madrid,
   — France — École nationale vétérinaire, Alfort, 94704 Maisons-Alfort,
   — Ireland — Veterinary Research Laboratory, Abbotstown, Castleknock, Dublin 15,
   — Italy — Istituto Zooprofilattico Sperimentale della Lombardia a dell'Emilia-Romagna, Brescia,
   — Luxembourg — Laboratoire de Médecine Vétérinaire de l'État, 1020 Luxembourg,
   — The Netherlands — Instituut voor Veehouderij en Diergezondheid (ID-DLO), 8200 AB Lelystad,
   — Austria — Bundesanstalt für veterinärmedizinische Untersuchungen in Mödling, 2,40 Modling,
   — Portugal — Laboratório Nacional de Investigaão Veterinária, 1500 Lisboa,
   — Finland — Eläinlääkintä- ja elintarviketutkimuslaitos, 00581 Helsinki,
   — Sweden — Statens veterinarmedicinska anstalt, 75189 Uppsala,
   — United Kingdom — Veterinary Laboratory Agency, New Haw, Weybridge, Surrey KT15 3NB.

ANNEX IV

Criteria on the information to be provided on the occurrence of Aujeszky's disease (AD) and on plans for the monitoring and eradication of this disease, to be provided in accordance with Article 8 of Council Directive 64/432/EEC

1. Member State: .....

2. Date: .....

3. Reporting period: .....

4. Number of holdings where AD has been detected by means of clinical, serological or virological investigations: .....

5. Information on AD vaccination, serological investigations and categorisation of holdings (please complete the attached table):

Region	Number of pig holdings	Number of pig holdings under an AD-programme (1)	Number of AD not-infected pig holdings (with vaccination) (2)	Number of AD free pig holdings (without vaccination) (3)
Total				

(1) Programme under the supervision of the competent authority.
(2) Pig holdings where serological tests for AD have been carried out with negative results in accordance with an official AD programme and where vaccination has been applied during the previous 12 months.
(3) Pig holdings which fulfil the conditions of Article 1(c).

6. Further information on serological monitoring in Artificial Insemination Centres, for export purposes, in the framework of other surveillance schemes, etc.: .....

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