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Final

Guidance to Commission Decision 2008/185/EC

**regarding additional guarantees in intra-Community trade of pigs
related to Aujeszky's disease and criteria for listing a Member
State or a region thereof as free from Aujeszky's disease or as
having an approved disease control programme**

1. Introduction

Commission Decision 2008/185/EC of 21 February 2008 on additional guarantees in intra-Community trade of pigs relating to Aujeszky's disease (AD) and criteria to provide information on this disease¹ lays down the additional guarantees for movements of pigs between Member States. These guarantees are linked to the classification of Member States into three classes:

- (1) Member States or regions which are free of AD and where vaccination is prohibited (Annex I),
- (2) Member States or regions where disease control programmes are in place and which are in an advanced stage of eradication of AD (Annex II) and
- (3) Member States or regions not listed in Annex I or Annex II

The purpose of listing a Member State or a region as free from AD or as having an approved control programme is to grant additional guarantees for the intra-community trade of pigs to the concerned Member State in order not to jeopardize the level of control and eradication reached in its territory.

In principle pigs can be dispatched from any Member State to any other if the conditions laid down in Decision 2008/185/EC are respected. **These conditions are under the control of the Member State of origin and are more stringent for movements of pigs to a Member State with a higher animal health status. Therefore the Member State of origin has to provide additional guarantees if necessary.**

The objective of this paper is to explain the principles of the additional guarantees as regards AD and to provide guidelines on the procedures to list a Member State or a region in Annex I or in Annex II of Decision 2008/185/EC. The guidelines are based on the requirements of Articles 9 and 10 of Council Directive 64/432/EEC² and the International Animal Health Code on AD³ of the World Organisation for Animal Health (OIE).

This document is a follow up to the working document SANCO/10346/2004 "*Guidance to COMMISSION DECISION 2001/618/EC of 23 July 2001 on additional guarantees in intra-Community trade of pigs relating to Aujeszky's disease*" of 27.05.2004.

The following guidelines are only indicative!

¹ OJ L 59, 4.3.2008, p. 19.

² Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine

³ Terrestrial Animal Health Code (2007), Chapter 2.2.2., Aujeszky's Disease

2. Procedures for listing a Member State or a region in Annex I of Decision 2008/185/EC

2.1. *Considering a Member State or a region free of AD*

As a general rule, AD is notifiable in the whole country and all clinical cases suggestive for AD have to be subject to field and laboratory investigations.

A Member State that considers its territory or part of its territory free from AD shall according to Article 10 of Directive 64/432/EEC present to the Commission a substantial and comprehensive dossier with supporting documentation. The format of Annex I of Commission Decision 2008/425/EC⁴ can be used as a model for submission. The requested information is not restrictive and the documentation must at least comprise:

- the history of the occurrence of AD in its territory (figures on the number of herds according category, the number of pigs, the evolution of the incidence and prevalence of the disease);
- the results of surveillance testing based on serological, virological, pathological or epidemiological investigation and on the fact that the disease must by law be notified to the competent authorities;
- the period over which the surveillance was carried out (figures on the number of tested herds and animals, the nature of the tests, the testing scheme, the results, ...);
- where applicable, the period during which vaccination against the disease has been prohibited and the geographical area concerned by the prohibition;
- the arrangements for verifying the absence of the disease.

The Commission examines the evidence presented by the Member States and presents the assessment for an opinion to the Member States through the Standing Committee on the Food Chain and Animal Health (SCFCAH).

A Member State or a region may be considered free from AD if:

- no vaccination against the disease has been carried out or vaccination against AD has been banned for all domestic pigs for at least 1 year;
- infection is not known to be established in feral pigs, or measures have been implemented to prevent any transmission of the AD virus from feral pigs to domestic pigs;
- AD has never been reported in the Member State or region, serological surveys, with negative results, have been conducted on a representative sample of all pig holdings no more than 3 years prior to qualification; the serological surveys should be directed at the detection of antibodies against the whole virus, and based on the breeding pig population and, for holdings that contain no breeding pigs, on a comparable number of fattening pigs; or
- AD has been reported in the past in the Member State or region, a surveillance and control programme has been put in place to detect every infected holding and eradicate AD from it; **the surveillance programme should demonstrate that no holding within the Member State or**

⁴ Commission Decision 2008/425/EC of 25 April 2008 laying down standard requirements for the submission by Member States of national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses for Community financing

region have had any clinical, virological or serological (gE-positive) evidence of AD for at least 1 year.

In order for a country to reach free status, all of its regions must have reached AD free status.

2.2. Maintenance of free status

In order to maintain its free status, a Member State or a region should comply with the following requirements:

- the ban on AD vaccination remains in force;
- measures aimed at preventing the transmission of the AD virus from feral pigs to domestic pigs remain in force.
- additional targeted serological and clinical investigations of holdings which present a high risk of AD virus introduction;
- serological surveys directed at the detection of antibodies to the whole AD virus on a statistically significant number of holdings every year.

Member States or regions having successfully eradicated the disease in the recent past should serologically demonstrate the absence of infection (gE-negative) but should aim to eliminate vaccinated animals (gB-positive/gE-negative) as soon as possible. The minimum number of holdings to be tested should allow the detection of infected holdings at a prevalence sufficiently low to reinforce the confidence of the free status of the territory, with a confidence of 95 %. The threshold of 0.2% has been used in several countries which succeeded in eradicating the disease and can be used. The minimum number of blood samples to be taken in a holding must allow the detection of 20% seroprevalence with 95% confidence in breeding animals. However, in the case of holdings that contain no breeding pigs, the minimum number of samples to be taken must allow the detection of 10% seroprevalence with 95% confidence. If full traceability is given, samples can be taken at the slaughterhouse.

Alternative serological surveys have proven to be successful in some Member States. The sampling models applied are:

- a) the minimum number of holdings to be tested should allow the detection of infected holdings at a prevalence of 0.05% with a confidence of 95%, the minimum number of blood samples to be taken in a holding must allow the detection of 20% seroprevalence with 95% confidence. This sampling model may be recommended for Member States and regions thereof which recently became free of AD.
- b) the minimum number of holdings to be tested should allow the detection of infected holdings at a prevalence of 0.2% with a confidence of 95% and the minimum number of blood samples to be taken in a holding must allow the detection of 20% seroprevalence with 95% confidence if the holding is tested every three months.

2.3. Recovery of free status

Should an AD outbreak occur in a holding of a free Member State or region, the free status may be restored if:

1. following an emergency plan, all pigs in the affected holding were slaughtered and,

2. during and after the application of this measure, an epidemiological investigation including clinical examination and serological and/or virological testing has been carried out in:
 - (a) all pig holdings which have directly or indirectly come into contact with the infected holding and
 - (b) in all pig holdings located within a 5 kilometre radius of the outbreak, demonstrating that these holdings are not infected. The minimum number of blood samples to be taken in a holding must allow the detection of <5% prevalence with 95% confidence in breeding animals. However, in the case of holdings that contain no breeding pigs, the minimum number of samples to be taken must allow the detection of <10% prevalence with 95% confidence.
3. within this period of investigation the movement of pigs from these holdings is banned except to a slaughterhouse for immediate slaughter but not before laboratory investigations demonstrate the absence of infection.

Alternatively the free status may also be restored if:

1. all the pigs in the affected holding have been slaughtered;
2. all pigs within at least 5 kilometre radius of the outbreak are vaccinated with deleted virus strains according to the recommendations of the manufactures and a serological testing procedure (differential ELISA) has been applied twice 30 days apart to demonstrate the absence of infection (gE-negative). However, depending on the epidemiological situation and the pig density, the vaccination radius can be increased to 10 kilometers;
3. within this period of investigation, the movement of pigs from these holdings is banned except to a slaughterhouse for immediate slaughter, but not before laboratory investigations demonstrate the absence of infection;
4. during and after the application of the measures described above, a thorough epidemiological investigation including clinical examination and serological and/or virological testing has been carried out in all pig holdings which have directly or indirectly come into contact with the infected holding.

During the application of the measures mentioned above, the status of AD free region or Member State is suspended.

The Member State concerned shall notify the Commission of any changes as regards AD, in particular regarding any new outbreaks of the disease.

3. Procedures for the approval of a programme and listing a Member State or a region in Annex II of Decision 2008/185/EC

The programme which qualifies a Member State or regions thereof to be listed in Annex II of Decision 2008/185/EC **should not be confused** with the programmes for the eradication, control and monitoring of AD submitted by the Member States for Community financing according to Decisions 90/424 and 2008/425/EC. **If a programme was approved for Community financing, it does not mean that the programme is also approved in the framework of additional guarantees and the Member State or region thereof will be automatically listed in Annex II of Commission Decision 2008/185/EC.**

If a Member State with an AD programme wishes to be listed in Annex II of Decision 2008/185/EC, it has to submit to the Commission a well documented request for examination according to Article 9 of Directive 64/432/EEC. The list of requested information is not restrictive and a substantial and comprehensive dossier is needed. The format of Annex I of Decision 2008/425/EC is a useful tool as regards the presentation of the submitted information. The documentation must at least comprise:

- the distribution of the disease in the Member State (figures on the number of herds according category, the number of pigs, the evolution of the incidence and prevalence of the disease);
- the reasons for the programme, taking into consideration the importance of the disease and the programme's likely benefit in relation to its cost,
- the geographical area in which the programme will be implemented;
- the status categories to be applied to the pig herds, the standards which must be attained in each category, and the test procedures to be used;
- the programme monitoring procedures, the results of which must be supplied at least annually to the Commission (according Art. 8 of Directive 64/432/EEC);
- the action to be taken if, for any reason, an establishment loses its status;
- the measures to be taken if the results of the tests carried out in accordance with the provisions of the programme are positive.

The Commission examines the evidence presented by the Member States and presents the assessment for an opinion to all Member States in the framework of the SCFCAH. For approving the control programme three different aspects will be considered:

- a) the quality of the programme according to the requirements of Art. 9 of Directive 64/432/EEC,
- b) the epidemiological situation of AD in the Member State or region,
- c) the progress made towards eradicating AD during the past five years.

The basic criteria for approving a programme are:

- the programme must be compulsory and supervised by the competent authority;
- all pig herds of the area of implementation are included in the programme;
- the design of the programme should lead to AD-freedom;
- a classification of all herds has been made into at least the categories
 - (i) infected,
 - (ii) free with vaccination (holdings which may vaccinate) and
 - (iii) free without vaccination (holdings where vaccination is specifically prohibited);
- at the time of application at least 80% of the holdings belong to the categories free with vaccination and free without vaccination, or alternatively the programme has proved that the number of infected herds has decreased during the last five years with 5-10% per year
- the classification of herds is recorded and kept up-to-date;
- the registration and the identification of pig herds must meet EU legislation;
- appropriate measures on pig transport and movements must be in place for preventing the spread of AD virus between holdings of a different status;
- if vaccination is part of the programme, then only vaccines with deleted virus strains according the recommendations of the manufactures are used;
- regular serological surveillance is implemented to detect infected herds.

- the minimum number of pigs tested in a herd must be statistically based on at least a 95% confidence level to detect <10% prevalence in breeding animals and <5% prevalence in holdings that contain no breeding pigs;
- for qualifying a herd as AD-free two negative herd tests 3 to 12 months apart are needed. However, if the sampling was designed as such to detect 2 % seroprevalence with 95 % confidence one negative herd test might be sufficient;
- the serological tests are conducted according the standards of Annex III to Decision 2008/185/EC.
- infection is not known to be established in feral pigs, or measures have been implemented to prevent any transmission of the AD virus from feral pigs to domestic pigs.

Less intense programmes or programmes carried out on a voluntary basis, as well as programmes in Member State with an unfavorable epidemiological situation of AD would not qualify for approval in the framework of Decision 2008/185/EC.

If a programme has been approved, the Member State concerned shall notify the Commission of any changes in the programme, in particular regarding any new outbreaks of the disease.

4. Information to be provided by Member States as regards Aujeszky's disease

Each Member State shall forward to the Commission by **31 May each year**, details of the occurrence of diseases listed in Annex E (I) of Directive 64/432/EEC and of any other disease covered by the additional guarantees provided for by Community legislation as is the case for AD.

The criteria on the information to be provided for AD as well as the required format are laid down in **Annex IV of Decision 2008/185/EC**. The information has to cover the whole territory of the MS in the previous calendar year including details of the monitoring and eradication programmes in operation.

The Commission compiles the information from the Member States and presents it in the framework of the SCFCAH.

This provision applies without prejudice to Article 10(3) of Directive 64/432/EEC where Member States, recognised as free of AD, shall notify the Commission of any new outbreaks of the disease.

5. The additional guarantees as regards Aujeszky's disease

5.1. Principles

Additional guarantees for the movement of pigs are granted to regions or Member States that are listed in Annex I and Annex II of Decision 2008/185/EC (Member States or regions free of AD and Member States where approved AD control programmes are in place).

The additional guarantees are more stringent for movements of pigs to a region or a Member State with a 'higher' status. Otherwise, the guarantees for pigs destined for slaughter, production or breeding become increasingly stringent. **It is important however to note that trade in pigs is authorised from any region or Member States to any other as long as the conditions laid down in Decision 2008/185/EC are respected. As a general principle, the Member State of origin has to provide to the Member State of destination the information regarding its AD status (as laid down in Decision 2008/185/EC.)**

The following generic rules apply:

- For animals of the porcine species destined for Member States or regions listed in Annex I or II, the certification of Annex F, Model II, under paragraph 4 of Section C of the health certificate required by Directive 64/432/EC, 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 Decision 2008/185/EC and the number of the Article which is relevant for the pigs in question, shall be quoted between brackets.
- Member States must ensure that when pigs destined for Member States or regions listed in Annex I or II are transported, they do not come into contact with pigs of different or unknown status, as regards AD, during transport or transit.
- Slaughter pigs destined for Member States or regions free of AD and coming from any other Member State or region must be transported directly to the slaughterhouse of destination.

5.2. The additional guarantees

The additional guarantees for the intra-community movements of pigs are summarized below. Please note that Figure 1 also diagrammatically explains the possible movements of pig categories from regions or Member States with a certain AD status to other regions or Member States and highlights when additional guarantees are needed.

Movements of pigs:

1. **From a free region to a non-free region:** no additional guarantees are required
2. **From a free region to another free region:** no additional guarantees are required. However, in the health certificate reference should be made to Article 1 or Article 2 of Decision 2008/185/EC.
3. **To a free region from a non-free region:** additional guarantees are required for production and breeding pigs and for pigs destined for slaughter.
4. **To a region with an approved programme:**
 - additional guarantees are required for production and breeding pigs from any other region or Member State except from a free region (However, in the health certificate it should be confirmed that the pigs originate from a free area.). Please also note that additional guarantees need to be provided by other regions or Member States with an approved programme;
 - no additional guarantees are required for pigs destined for slaughter.
5. **From a region without an approved programme to another similar region:** no additional guarantees are required.

The specific additional guarantees are related to:

- the MS (or region) of origin;

- the holding of origin;
- the pigs to be moved;
- the testing of the pigs to be moved.

5.3. ***Specific requirements for a Member State or region not listed in Annex I or II***

The prior conditions for movements of pigs from a Member State or region that has no approved programme to a region or Member State with an approved programme (for production and breeding pigs) or recognised as free (for slaughter, production and breeding pigs) is that:

- AD must be compulsorily notifiable in the Member State of origin;
- a plan for the control and eradication of AD according the condition of 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.

5.4. ***Certification of the pigs***

As regards the **certification of the pigs** destined for Member States or regions listed in Annex I or II of Decision 2008/185/EC, **the official veterinarian, before he completes the required health certificate, shall determine:**

- the status of the holding and of the Member State or region of origin of the pigs in question as regards AD;
- the status of the holding and of the Member State or regions of destination for the pigs in question as regards AD;
- the compliance of the pigs in question with the conditions laid down in Decision 2008/185/EC.

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

ISO code	Member State	Regions
AT	Austria	All regions
CY	Cyprus	All regions
CZ	Czech Republic	All regions
DE	Germany	All regions
DK	Denmark	All regions
FI	Finland	All regions
FR	France	The departments of Ain, Aisne, Allier, Alpes-de-Haute-Provence, Alpes-Maritimes, Ardèche, Ardennes, Ariège, Aube, Aude, Aveyron, Bas-Rhin, Bouches-du-Rhône, Calvados, Cantal, Charente, Charente-Maritime, Cher, Corrèze, Côte-d'Or, Côte-d'Armor, Creuse, Deux-Sèvres, Dordogne, Doubs, Drôme, Essonne, Eure, Eure-et-Loir, Finistère, Gard, Gers, Gironde, Hautes-Alpes, Hauts-de-Seine, Haute Garonne, Haute-Loire, Haute-Marne, Hautes-Pyrénées, Haut-Rhin, Haute-Saône, Haute-Savoie, Haute-Vienne, Hérault, Indre, Ille-et-Vilaine, Indre, Indre-et-Loire, Isère, Jura, Landes, Loire, Loire-Atlantique, Loir-et-Cher, Loiret, Lot, Lot-et-Garonne, Lozère, Maine-et-Loire, Manche, Marne, Mayenne, Meurthe-et-Moselle, Meuse, Morbihan, Moselle, Nièvre, Nord, Oise, Orne, Paris, Pas-de-Calais, Pyrénées-Atlantiques, Pyrénées-Orientales, Puy-de-Dôme, Réunion, Rhône, Sarthe, Saône-et-Loire, Savoie, Seine-et-Marne, Seine-Maritime, Seine-Saint-Denis, Somme, Tarn, Tarn-et-Garonne, Territoire de Belfort, Val-de-Marne, Val-d'Oise, Var, Vaucluse, Vendée, Vienne, Vosges, Yonne, Yvelines
LU	Luxembourg	All regions
NL	The Netherlands	All regions
SK	Slovakia	All regions
SE	Sweden	All regions
UK	United Kingdom	All regions in England, Scotland and Wales

Note: Norway, which belongs to the European Economic Area (EEA) is also recognised as an AD-free country. Switzerland is also recognized as an AD-free country in accordance with the Agreement between the European Union and the Swiss Confederation on trade in agricultural products

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

ISO code	Member State	Regions
BE	Belgium	All regions
ES	Spain	The territory of the Autonomous Communities of Galicia, País Vasco, Asturias, Cantabria, Navarra, La Rioja The territory of the provinces of León, Zamora, Palencia, Burgos, Valladolid and Ávila in the Autonomous Community of Castilla y León. The territory of the province of Las Palmas in the Canary Islands
HU	Hungary	All regions
IT	Italy	The province of Bolzano
IE	Ireland	All regions
UK	United Kingdom	All regions in Northern Ireland

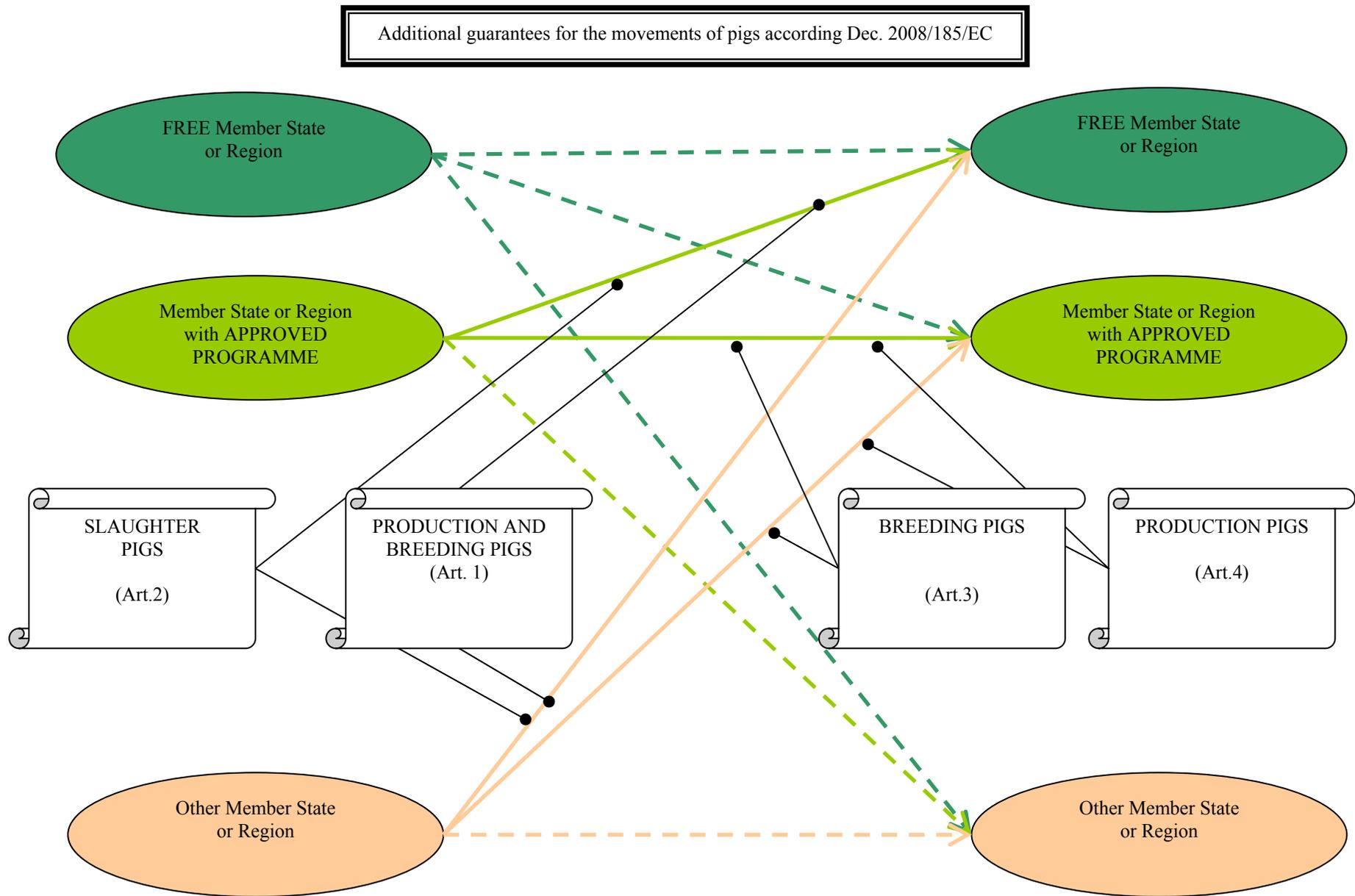


Figure 1: Diagram illustrating the additional guarantees for the movements of pigs between different Member States or regions of the EU as regards AD
 (—▶ additional guarantees -----▶ no additional guarantees)