Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC

CHAPTER I

General provisions

Article 1

This Directive lays down the animal health and public health requirements governing trade in and imports into the Community of products of animal origin (including trade samples taken from such products) not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC[(1)] and, as regards pathogenic agents, to Directive 90/425/EEC.

This Directive shall be without prejudice to the adoption of more detailed rules on animal health in the framework of the aforesaid specific rules nor the maintenance of restrictions on trade or imports of products covered by the specific rules referred to in the first paragraph based on the rules of public health.

Article 2

1 For the purposes of this Directive:

a *trade means trade as defined by Article 2 (2) of Directive 89/662/EEC*;

b *trade sample means a sample of no commercial value, taken on behalf of the owner or the person responsible for an establishment, which is representative of a given product of animal origin produced by that establishment, or constitutes a specimen of a product of animal origin the manufacture of which is contemplated, and which, for the purposes of subsequent examination, must bear a reference to the type of product, its composition and the species of animal from which it was obtained*;

c *serious transmissible disease means all diseases covered by Directive 82/894/EEC*[(2)]

d *pathogenic agents jmeans any collection or culture of organisms or any derivative, present either alone or in the form of a manipulated combination of such a collection or culture of organisms capable of causing disease in any living being (other than man) and any modified derivatives of these organisms, which can carry or transmit an animal pathogen, or the tissue, cell culture, secretions or excreta by which or by means of which an animal pathogen can be carried or transmitted; this definition does not include the immunological veterinary medicinal products authorized pursuant to Directive 90/677/EEC*[(3)];

[[F1]e processed animal protein intended for animal consumption means animal protein which has been treated so as to render it suitable for direct use as a feedingstuff or as an ingredient in a feedingstuff for animals. It includes fishmeal, meatmeal, bonemeal, hoofmeal, hornmeal, bloodmeal, feathermeal, dry greaves and other similar products including mixtures containing these products;**]**

f *processed animal protein intended for human consumption means greaves, meatmeal and pork-rind powder referred to in Article 2 (b) of Directive 77/99/EEC*[(4)]**[**[F2]**.]**

[[F1]g apiculture product means honey, beeswax, royal jelly, propolis or pollen, not intended for human consumption or for industrial use.**]**

2 In addition, the definitions contained in Article 2 of Directives 89/662/EEC, 90/425/EEC and 90/675/EEC shall apply *mutatis mutandis*.

Textual Amendments

F1 Deleted by Directive 2002/33/EC of the European Parliament and of the Council of 21 October 2002 amending Council Directives 90/425/EEC and 92/118/EEC as regards health requirements for animal by-products.

F2 Substituted by Directive 2002/33/EC of the European Parliament and of the Council of 21 October 2002 amending Council Directives 90/425/EEC and 92/118/EEC as regards health requirements for animal by-products.

Article 3

Member States shall ensure that:

— trade in and imports of products of animal origin referred to in Article 1 **[**[F1]together with gelatins not intended for human consumption **]**are not prohibited or restricted for animal health or public health reasons other than those arising from the application of this Directive or from Community legislation, and in particular any safeguard measures taken,

— **[**[F2]any new product of animal origin intended for human consumption whose placing on the market in a Member State is authorised after the date provided for in Article 20 may not be the subject of trade or importation until a decision has been taken in accordance with the first paragraph of Article 15 after evaluation, if appropriate in the light of the opinion of the Scientific Veterinary Committee set up by Decision 81/651/EEC, of the real risk of the spread of serious transmissible diseases which could result from movement of the product, not only for the species from which the product originates but also for other species which could carry the disease, become a focus of disease or a risk to human health,**]**

— the other products of animal origin referred to in Article 2 (b) of Directive 77/99/EEC may not be the subject of trade or importation from third countries unless they meet the requirements of that Directive and the relevant requirements of this Directive.

Textual Amendments

F1 Deleted by Directive 2002/33/EC of the European Parliament and of the Council of 21 October 2002 amending Council Directives 90/425/EEC and 92/118/EEC as regards health requirements for animal by-products.

F2 Substituted by Directive 2002/33/EC of the European Parliament and of the Council of 21 October 2002 amending Council Directives 90/425/EEC and 92/118/EEC as regards health requirements for animal by-products.

CHAPTER II

Provisions applicable to trade

Article 4

Member States shall take the necessary measures to ensure that, for the purposes of applying Article 4 (1) of Directive 89/662/EEC and Article 4 (1) (a) of Directive 90/425/EEC, the products of animal origin referred to in **[**F3**[**X1Annex I**]** and the second and third indents of Article 3 of this Directive may, without prejudice to the particular provisions to be adopted in implementation of Articles 10 (3) and 11, be the subject of trade only if they satisfy the following requirements:

1. they must meet the requirements of Article 5 and the specific requirements laid down in Annex I as regards animal health aspects**[**F4**[**X1 and Annex II as regards public health aspects**]]**,

2. they must come from establishments which:

   (a) undertake, in the light of the specific requirements laid down in **[**X1Annex I**]]** for the products the establishment produces, to:

   — comply with the specific production requirements set out in this Directive,

   — establish and implement methods of monitoring and checking the critical points on the basis of the processes used,

   — depending on the products, take samples for analysis in a laboratory recognized by the competent authority for the purpose of checking compliance with the standards established by this Directive,

   — keep a record, whether written or otherwise recorded, of the information obtained pursuant to the preceding indents for presentation to the competent authority. The results of the various checks and tests in particular shall be kept for at least two years,

   — guarantee the administration of marking and labelling,

   — should the result of the laboratory examination or any other information available to them reveal the existence of a serious animal health or public health hazard, inform the competent authority,

   — consign, for purposes of trade, only products accompanied by a commercial document indicating the nature of the product, the name and, where appropriate, the veterinary approval number of the establishment of production;

   (b) they are under supervision by the competent authority to ensure that the operator or manager of the establishment complies with the requirements of this Directive;

   (c) they were registered by the competent authority on the basis of assurances from the establishment guaranteeing compliance with the requirements of this Directive.

Editorial Information

X1 Substituted by Corrigendum to Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC (Official Journal of the European Union L 157 of 30 April 2004).

Textual Amendments

F3 Substituted by Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC.

F4 Deleted by Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC.

Article 5

Member States shall ensure that every necessary measure is taken to guarantee that products of animal origin referred to in **[**[F3]**[**[X1]Annex I**]]** are not dispatched for purposes of trade from any holding, situated in a zone subject to restrictions because of the occurrence of a disease to which the species from which the product is derived is susceptible or from any establishment or zone from which movements or trade would constitute a risk to the animal health status of the Member States except where products are heat-treated in accordance with Community legislation.

Particular assurances permitting, by way of derogation from the first paragraph, the movement of certain products may be adopted under the procedure laid down in Article 18 within the framework of safeguard measures.

Editorial Information

X1 Substituted by Corrigendum to Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC (Official Journal of the European Union L 157 of 30 April 2004).

Textual Amendments

F3 Substituted by Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC.

Article 6

Member States shall ensure that trade in pathogenic agents is subject to strict rules to be defined under the procedure laid down in Article 18.

Article 7

1 The rules on checks established by Directive 89/662/EEC and, as regards pathogenic agents, by Directive 90/425/EEC shall apply, in particular as regards the organization of and follow-up to the checks to be carried out, to the products covered by this Directive.

2 Article 10 of Directive 90/425/EEC shall apply to the products covered by this Directive.

3 For the purposes of trade, the provisions of Article 12 of Directive 90/425/EEC shall be extended to establishments supplying products of animal origin covered by this Directive.

4 Without prejudice to the specific provisions of this Directive, the competent authority shall carry out any checks it may deem appropriate where it is suspected that this Directive is not being complied with.

5 Member States shall take the appropriate administrative or penal measures to penalize any infringement of this Directive, in particular where it is found that the certificates or documents drawn up do not correspond to the actual state of the products referred to in **[**[F3]**[**[X1]Annex I**]]**, or that the products in question do not satisfy the requirements of this Directive or have not undergone the checks provided for therein.

Editorial Information

X1 Substituted by Corrigendum to Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC (Official Journal of the European Union L 157 of 30 April 2004).

Textual Amendments

F3 Substituted by Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC.

Article 8

In Chapter 1 (1) of Annex A to Directive 92/46/EEC[(5)] the following subparagraph is added:

Milk and milk products must not come from a surveillance zone defined in accordance with Directive 85/511/EEC unless the milk has undergone pasteurization (71,7 °C for 15 seconds) under the supervision of the competent authority.

CHAPTER III

Provisions applicable to imports into the Community

Article 9

The requirements applicable to imports of products covered by this Directive must offer at least the guarantees provided for in Chapter II, including those established in

implementation of Article 6, and those laid down in the second and third indents of Article 3.

Article 10

1 For the purposes of uniform application of Article 9, the following provisions shall apply.

2 The products referred to in **[**F3**[**X1Annex I**]]** and in the second and third indents of Article 3 may be imported into the Community only if they satisfy the following requirements:

a unless otherwise specified in **[**F3**[**X1Annex I**]]**, they must come from a third country or part of a third country on a list to be drawn up and updated in accordance with the procedure provided for in Article 18;

[F2b unless otherwise specified in **[**F3**[**X1Annex I**]]**, products must come from establishments on a Community list to be drawn up in accordance with the procedure laid down in Article 18;**]**

c in the cases specifically provided for in **[**F3**[**X1Annex I**]]** and in the second and third indents of Article 3, they must be accompanied by an animal health or public health certificate corresponding to a specimen to be drawn up under the procedure provided for in Article 18, certifying that the products meet the additional conditions or offer the equivalent guarantees referred to in paragraph 3 (a) and come from establishments offering such guarantees, and signed by an official veterinarian or, as appropriate, by any other competent authority recognized under the same procedure.

3 Under the procedure provided for in Article 18:

a specific requirements shall be established — in particular for the protection of the Community from certain exotic diseases or diseases transmissible to man — or guarantees equivalent to those conditions.

The specific requirements and equivalent guarantees established for third countries may not be more favourable than those laid down in **[**F3**[**X1Annex I**]]** and in the second and third indents of Article 3**[**F5.**]**

[F6Pending the fixing of the detailed rules of application provided for in the fourth and fifth indents of Chapter 2 of Annex II, Member States shall ensure that imports of products referred to therein are subject to compliance with the minimum guarantees laid down in the said indents;**]**

[F7b a Community list shall be drawn up of third country establishments which satisfy the requirements of paragraph 2 (b);**]**

c the nature of any treatment or the measures to be taken to avoid recontamination of animal casings, eggs and egg products shall be established.

4 The decisions provided for in paragraphs 2 and 3 must be taken on the basis of evaluation and, if appropriate, the opinion of the Scientific Veterinary Committee, of the real risk of the spread of serious transmissible diseases or of diseases transmissible to man which could result from movement of the product, not only for the species from which the product originates but also for other species which could carry the disease or become a focus of disease or a risk to public health.

5 Experts from the Commission and the Member States shall carry out on-the-spot inspections to verify whether the guarantees given by the third country regarding the conditions of production and placing on the market can be considered equivalent to those applied in the Community.

The experts from the Member States responsible for these inspections shall be appointed by the Commission, acting on proposals from the Member States.

These inspections shall be made on behalf of the Community, which shall bear the cost of any expenditure involved.

Pending organization of the inspections referred to in the first subparagraph, national rules applicable to inspection in third countries shall continue to apply, subject to notification, through the Standing Veterinary Committee, of any failure to comply with the guarantees offered in accordance with paragraph 3 found during these inspections.

6 Pending compilation of the lists provided for **[**F5in paragraph 2 (a) and (b) second indent**]**, Member States are authorized to maintain the controls provided for in Article 11 (2) of Directive 90/675/EEC and the national certificate required by products imported under existing national rules.

Editorial Information

X1 Substituted by Corrigendum to Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC (Official Journal of the European Union L 157 of 30 April 2004).

Textual Amendments

F2 Substituted by Directive 2002/33/EC of the European Parliament and of the Council of 21 October 2002 amending Council Directives 90/425/EEC and 92/118/EEC as regards health requirements for animal by-products.

F3 Substituted by Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC.

F5 Substituted by Council Directive 96/90/EC of 17 December 1996 amending Directive 92/118/EEC laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC.

F6 Inserted by Council Directive 96/90/EC of 17 December 1996 amending Directive 92/118/EEC laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC.

F7 Deleted by Council Directive 96/90/EC of 17 December 1996 amending Directive 92/118/EEC laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC.

Article 11

The procedure provided for in Article 18 shall be used to stipulate specific animal health requirements for imports into the Community and the nature and content of accompanying documents for products referred to in Annex I intended for experimental laboratories.

Article 12

1 The principles and rules laid down in Directives 90/675/EEC and 91/496/EEC[(6)] shall apply, with particular reference to the organization of and follow-up to the inspections to be carried out by the Member States and the safeguard measures to be implemented.

However, for certain types of product of animal origin, derogations may be adopted in accordance with the procedure laid down in Article 18, from the physical check provided for in **[**[F8]Article 4(4)(b) of Directive 97/78/EC**]**.

[F9]2 . . . . . .

Textual Amendments

F8 Substituted by Council Directive 97/79/EC of 18 December 1997 amending Directives 71/118/EEC, 72/462/EEC, 85/73/EEC, 91/67/EEC, 91/492/EEC, 91/493/EEC, 92/45/EEC and 92/118/EEC as regards the organisation of veterinary checks on products entering the Community from third countries.

F9 Deleted by Council Directive 97/79/EC of 18 December 1997 amending Directives 71/118/EEC, 72/462/EEC, 85/73/EEC, 91/67/EEC, 91/492/EEC, 91/493/EEC, 92/45/EEC and 92/118/EEC as regards the organisation of veterinary checks on products entering the Community from third countries.

Article 13

1 Member States may, by issuing an appropriate licence, permit the importation from third countries of products of animal origin referred to in **[**[F3]**[**[X1]Annex I**]]** in the form of trade samples.

2 The licence mentioned in paragraph 1 must accompany the consignment and contain full details of the specific conditions under which the consignment may be imported, including any derogations from the checks provided for by Directive 90/675/EEC.

3 Where the consignment enters one Member State for onward transmission to a second Member State, the first Member State shall ensure that the consignment is accompanied by the appropriate licence. Movement shall take place in accordance with the provisions of Article 11 (2) of Directive 90/675/EEC. The responsibility for ensuring that the consignment complies with the conditions of the licence (and whether entry into its territory should be permitted) shall rest with the Member State which issues the licence.

Editorial Information

X1 Substituted by Corrigendum to Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC (Official Journal of the European Union L 157 of 30 April 2004).

Textual Amendments

F3 Substituted by Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC.

CHAPTER IV

Common final provisions

Article 14

1 Article 3 (d) of Directive 72/461/EEC[(7)] shall be deleted.

Commission Decisions 92/183/EEC[(8)] and 92/187/EEC[(9)] shall continue to apply for the requirements of this Directive, without prejudice to any amendments to be made to them under the procedure provided for in Article 18.

2 Directive 90/667/EEC is hereby amended as follows:

a in Article 13 the following paragraph shall be added:

2. With a view to ensuring that the controls provided for in paragraph 1 are followed up:

a processed products obtained from low-risk or high-risk materials must satisfy the requirements of Chapter 6 of Annex I to Directive 92/118/EEC[(10)];

b low-risk materials, high-risk materials intended for processing in a plant designated in another Member State in accordance with the second sentence of Article 4 (1) and processed products obtained from high-risk or low-risk materials must be accompanied:

— if they come from a plant approved in accordance with Article 4 or 5, by a commercial document specifying;

— if appropriate, the nature of the treatment,

— whether the product contains ruminant proteins,

— if they come from another plant, by a certificate issued and signed by an official veterinarian indicating:

— the methods of treatment used on the consignment,

— the result of the salmonella tests,

— whether the product contains ruminant proteins.;

b in Article 6, ‘shall be established under the procedure laid down in Article 19’ shall be replaced by ‘are laid down under Chapter 10 of Annex I to Directive 92/118/EEC’;

c in Article 14 the first paragraph shall be deleted.

Article 15

The Council, acting by a qualified majority on a proposal from the Commission, shall adopt any new Annex laying down specific requirements for other products capable of presenting a real risk of spreading serious transmissible diseases or a real risk to human health.

The Annexes shall, where the need arises, be amended under the procedure provided for in Article 18 in compliance with the general principles set out in the second indent of Article 3.

Article 16

1 Member States shall be authorized to make the entry into their territory of products of animal origin referred to in **[**[F3]**[**[X1]Annex I**]]** and in the second and third indents of Article 3 which were produced in the territory of a Member State and have passed through the territory of a third country subject to production of an animal health or public health certificate certifying compliance with the requirements of this Directive.

2 Member States which have recourse to the possibility laid down in paragraph 1 shall so inform the Commission and the other Member States within the Standing Veterinary Committee set up by Decision 68/361/EEC[(11)].

Editorial Information

X1 Substituted by Corrigendum to Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC (Official Journal of the European Union L 157 of 30 April 2004).

Textual Amendments

F3 Substituted by Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC.

Article 17

1 Annexes A and B to Directives 89/662/EEC and 90/425/EEC shall be replaced by the texts set out in Annex III to this Directive.

2 Directive 77/99/EEC is hereby amended as follows:

— in Article 2 (b), point (iv) shall be deleted and points (v) and (vi) shall become (iv) and (v) respectively;

— Article 6 (2) shall read:

2. Under the procedure laid down in Article 20, additional conditions may be set for the other products of animal origin so as to ensure the protection of public health.

Article 18

Where reference is made to the procedure provided for in this Article, the Standing Veterinary Committee shall act in accordance with the rules laid down in Article 17 of Directive 89/662/EEC.

Article 19

Under the procedure provided for in Article 18, transitional measures may be adopted for a period of up to three years beginning on 1 July 1993 to facilitate the transition to the new arrangements established by this Directive.

Article 20

1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with Articles 12 (2) and 17 by 1 January 1993 and with the other requirements of this Directive before 1 January 1994. They shall forthwith inform the Commission thereof.

When these measures are adopted by the Member States, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

2 Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in the field governed by this Directive.

3 The setting of the deadline for transposition into national law at 1 January 1994 shall be without prejudice to the abolition of veterinary checks at frontiers provided for by Directives 89/662/EEC and 90/425/EEC.

Article 21

This Directive is addressed to the Member States.

(**1**) OJ No L 395, 30. 12. 1989, p. 13. Directive as last amended by Directive 91/496/EEC (OJ No L 268, 24. 9. 1991, p. 56).

(**2**) OJ No L 378, 31. 12. 1982, p. 58. Directive as last amended by Decision 90/134/EEC (OJ No L 76, 22. 3. 1990, p. 23).

(**3**) OJ No L 373, 31. 12. 1990, p. 26

(**4**) OJ No L 26, 31. 1. 1977, p. 85. Directive updated by Directive 92/5/EEC (OJ No L 57, 2. 3. 1992, p. 1), and last amended by Directive 92/45/EEC (OJ No L 268, 14. 9. 1992, p. 35)

(**5**) OJ No L 268, 14. 9. 1992, p. 1.

(**6**) OJ No L 268, 24. 9. 1991, p. 56.

(**7**) OJ No L 302, 31. 12. 1972, p. 24. Directive as last amended by Directive 91/687/EEC (OJ No L 377, 31. 12. 1991, p. 16).

(**8**) OJ No L 84, 31. 3. 1992, p. 33.

(**9**) OJ No L 87, 2. 4. 1992, p. 20.

(**10**) OJ No L 62, 15. 3. 1993, p. 49.’

(**11**) OJ No L 255, 18. 10. 1968, p. 23.