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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

(OJ L 62, 15.3.1993, p. 49)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Decision 94/466/EC of 13 July 1994	L 190	26	26.7.1994
►**M2**	Commission Decision 94/723/EC of 26 October 1994	L 288	48	9.11.1994
►**M3**	Commission Decision 95/338/EC of 26 July 1995	L 200	35	24.8.1995
►**M4**	Commission Decision 95/339/EC of 27 July 1995	L 200	36	24.8.1995
►**M5**	Commission Decision 96/103/EC of 25 January 1996	L 24	28	31.1.1996
►**M6**	Commission Decision 96/340/EC of 10 May 1996	L 129	35	30.5.1996
►**M7**	Commission Decision 96/405/EC of 21 June 1996	L 165	40	4.7.1996
►**M8**	Council Directive 96/90/EC of 17 December 1996	L 13	24	16.1.1997
►**M9**	Council Directive 97/79/EC of 18 December 1997	L 24	31	30.1.1998
►**M10**	Commission Decision 1999/724/EC of 28 October 1999	L 290	32	12.11.1999
►**M11**	Commission Decision 2001/7/EC of 19 December 2000	L 2	27	5.1.2001

Amended by:

►**A1**	Act of Accession of Austria, Sweden and Finland	C 241	21	29.8.1994
	(adapted by Council Decision 95/1/EC, Euratom, ECSC)	L 1	1	1.1.1995

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COUNCIL DIRECTIVE 92/118/EEC

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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

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof,

Having regard to the proposals from the Commission ([1]),

Having regard to the opinions of the European Parliament ([2]),

Having regard to the opinions of the Economic and Social Committee ([3]),

Whereas products of animal origin are included in the list of products in Annex II to the Treaty; whereas the placing on the market of such products constitutes an important source of income for part of the farming population;

Whereas in order to ensure rational development in this sector and increase productivity, animal health and public health rules for the products in question should be laid down at Community level;

Whereas the Community must adopt the measures intended progressively to establish the internal market consisting of an area without internal frontiers, over a period expiring on 31 December 1992;

Whereas in view of the abovementioned objectives the Council has laid down animal health rules applicable to fresh meat, poultrymeat, meat products, game meat, rabbit meat and milk products;

Whereas, save where otherwise provided, trade in products of animal origin must be liberalized, without prejudice to recourse to possible safeguard measures;

Whereas, given the significant risk of the spread of diseases to which animals are exposed, for certain products of animal origin particular requirements should be specified to be imposed when they are placed on the market for the purposes of trade, particularly when intended for regions with a high health status;

Whereas, when Directive 92/65/EEC was adopted, the Commission agreed to disassociate the animal health aspects applicable to animals from those applicable to products;

Whereas, so as to allow checks at borders between Member States to be abolished on 1 January 1993, animal health and public health rules should be fixed to apply to all products subject to such checks trade in and imports of which have not yet been harmonized at Community level;

Whereas, to achieve this objective, certain existing rules should be adapted for the adoption of the aforesaid measures;

Whereas a system of approval should be introduced for the third countries and establishments which meet the requirements laid down by this Directive, together with a Community inspection procedure to ensure that the conditions for such approval are observed;

Whereas the accompanying document for products is the best way of satisfying the competent authority of the place of destination that a consignment complies with the provisions of this Directive; whereas

([1]) OJ No C 327, 30. 12. 1989, p. 29; and OJ No C 84, 2.4. 1990, p 102.
([2]) OJ No C 113, 7. 5. 1990, p. 205; and OJ No C 149, 18. 6. 1990, p. 259.
([3]) OJ No C 124, 21. 5. 1990, p. 15; and OJ No C 182, 23. 7. 1990, p. 250.

▼B

the public health or animal health certificate should be maintained for the purposes of verifying the destination of certain imported products;

Whereas the rules, principles and safeguard measures established by Council Directive 90/675/EEC of 10 December 1990 laying down the principles governing the organization of veterinary checks on products entering the Community from third countries [1] should apply here;

Whereas, in the context of intra-Community trade, the rules laid down in Directive 89/662/EEC should also be applied;

Whereas the Commission should be entrusted with the task of adopting certain measures for implementing this Directive; whereas, to that end, procedures should be laid down establishing close and effective cooperation between the Commission and the Member States within the Standing Veterinary Committee;

Whereas, in view of the particular supply difficulties arising from its geographical situation, special derogations should be permitted for the Hellenic Republic;

Whereas the adoption of specific rules for the products covered by this Directive is without prejudice to the adoption of rules on food hygiene and safety in general, on which the Commission has submitted a proposal for a framework Directive,

HAS ADOPTED THIS DIRECTIVE:

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 [2] 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 [3]

[1] OJ No L 373, 31. 12. 1990, p. 1.
[2] 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).
[3] 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).

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(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 ([1]);

(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 ([2]);

(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*.

Article 3

Member States shall ensure that:

— trade in and imports of products of animal origin referred to in Article 1 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,

— any new product of animal origin whose placing on the market in a Member State is authorized 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 and, if appropriate, the opinion of the Scientific Veterinary Committee set up by Decision 81/651/EEC ([3]), 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.

([1]) OJ No L 373, 31. 12. 1990, p. 26
([2]) 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)
([3]) OJ No L 233, 19. 8. 1981, p. 32.

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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 Annexes I and II 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 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 Annexes I and II 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.

Article 5

Member States shall ensure that every necessary measure is taken to guarantee that products of animal origin referred to in Annexes I and II 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.

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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 Annexes I and II, or that the products in question do not satisfy the requirements of this Directive or have not undergone the checks provided for therein.

Article 8

In Chapter 1 (1) of Annex A to Directive 92/46/EEC [1] 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 ºC 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 Annexes I and II 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 Annexes I and II, 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;

▼M8

(b) unless otherwise specified in Annex II,

— the products referred to in Chapters 3, 5 (B), 12, 13, 14 (I) (unprocessed slurry) and 15 of Annex I and honey must come

[1] OJ No L 268, 14. 9. 1992, p. 1.

▼M8

from an establishment that has been registered by the competent authority of the third country;

— products other than those referred to in the first indent must come from establishments on a Community list to be drawn up in accordance with the procedure laid down in Article 18;

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(c) in the cases specifically provided for in Annexes I and II 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 Annexes I and II and in the second and third indents of Article 3.

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Pending 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;

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(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 ►M8 in 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

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and the national certificate required by products imported under existing national rules.

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 ([1]) 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 ►M9 Article 4(4)(b) of Directive 97/78/EC ◄.

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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 Annexes I and II 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.

CHAPTER IV

Common final provisions

Article 14

1. Article 3 (d) of Directive 72/461/EEC ([2]) shall be deleted.

Commission Decisions 92/183/EEC ([3]) and 92/187/EEC ([4]) 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:

([1]) OJ No L 268, 24. 9. 1991, p. 56.
([2]) 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).
([3]) OJ No L 84, 31. 3. 1992, p. 33.
([4]) OJ No L 87, 2. 4. 1992, p. 20.

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‘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 (*);

(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.

(*) OJ No L 62, 15. 3. 1993, p. 49.’;

(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 Annexes I and II 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 ([1]).

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:

([1]) OJ No L 255, 18. 10. 1968, p. 23.

▼B

‘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.

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ANNEX I

SPECIFIC ANIMAL HEALTH REQUIREMENTS

▼M4

CHAPTER I

Milk, milk products and colostrum not intended for human consumption

Intra-Community trade in and imports of milk, milk products and colostrum not intended for human consumption are subject to the following conditions:

1. any container in which the product is transported must be marked to indicate the nature of the product;
2. each consignment must be accompanied, as appropriate, by a commercial document as referred to in the last indent of Article 4 (2) (a) or a health certificate as referred to in Article 10 (2) (c), bearing the name and the registration number of the processing or treatment plant; the document or certificate must be kept by the consignee for at least one year;
3. the documents and certificates referred to in paragraph 2 must show:
   (a) in the case of raw milk or colostrum, that it has been produced under conditions offering adequate guarantees as regards animal health. Such conditions must be established in accordance with the procedure laid down in Article 18;
   (b) in the case of milk or treated or processed milk products, the milk or the milk product has been subjected to a heat treatment of at least 72ºC for at least 15 seconds or any combination of temperature and time having at least an equivalent heat effect and producing a negative reaction to the phosphatase test, followed by:
      (i) in the case of dried milk or dried milk products, a drying process;
      (ii) in the case of an acidified milk product, a process by which the pH is reduced and kept for at least one hour at a level below 6,0;
   (c) in the case of dried milk or dried milk products, the following requirements have been met:
      (i) after completion of the drying process, every precaution has been taken to prevent contamination of the product;
      (ii) the final product has been packed in new containers;
   (d) in the case of bulk containers, before the milk, milk product or colostrum was loaded into any vehicle or container for conveyance to its destination, the said vehicle or container was disinfected using a product approved by the competent authorities.
4. In addition to the requirements set out in points 1, 2 and 3, imports of milk, milk products and colostrum not intended for human consumption may be authorized only from third countries or parts of third countries included on the lists provided for in Article 23 of Directive 92/46/EEC and meeting the conditions set out in Article 26 of that Directive. Where a risk of introduction of an exotic disease or any other risk to animal health is identified, additional conditions for the protection of animal health may be established in accordance with the procedure laid down in Article 18.

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CHAPTER 2

Animal casings

A. *Trade*

Trade in animal casings is subject to production of a document specifying the plant of origin which must be:

— where the casings are salted or dried at the point of origin and where salted or dried casings are subsequently handled for other purposes, a plant approved by the competent authority,

— in other cases, a plant approved in accordance with Directive 64/433/EEC ([1]), provided the casings are transported in such a way as to avoid contamination.

([1]) OJ No 121, 29. 7. 1964, p. 2012/64. Directive as last amended by Directive 91/497/EEC (OJ No L 268, 24. 9. 1991, p. 69).

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B. *Imports from third countries*

Imports of animal casings from any third country are subject to production of the certificate referred to in Article 10 (2) (c), issued and signed by an official veterinarian of the exporting third country, stating that:

(i) the casings come from plants approved by the competent authority of the exporting country;

(ii) the casings have been cleaned, scraped and then either salted or bleached (or as an alternative to salting or bleaching, that they have been dried after scraping);

(iii) after the treatment in (ii), effective steps were taken to prevent the recontamination of the casings.

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CHAPTER 3

Hides and skins of ungulates [1] **not covered by Directive 64/433/EEC or 72/462/EEC and which have not undergone certain tanning processes**

I. A. The provisions of this chapter do not apply to:

— hides or skins of ungulates covered by Directive 64/433/EEC or 72/462/EEC,

— hides or skins having undergone the complete process of tanning,

— 'wet blue',

— 'pickled pelts',

— 'limed hides' (treated with lime and in brine at a pH of 12 to 13 for at least eight hours).

B. Within the scope defined in A, the provisions of this chapter apply to fresh, chilled and treated hides and skins.

For the purpose of this Decision, 'treated hides and skins' means hides and skins which have been:

— dried, or

— dry-salted or wet-salted for at least 14 days prior to dispatch, or

— salted for seven days in sea salt with the addition of sodium carbonate to 2 %, or

— drying for 42 days at a temperature of at least 20 ºC, or

— preserved by a process other than tanning, to be determined in accordance with the procedure laid down in Article 18.

II. *Intra-Community trade*

A. Trade in fresh or chilled hides and skins is subject to the same animal health conditions as those applicable to fresh meat pursuant to Directive 72/461/EEC.

B. Trade in treated hides and skins is authorized on condition that each consignment is accompanied by a commercial document as provided for in the last indent of Article 4 (2) (a) certifying that:

— the hides and skins have been treated in accordance with point I.B, and

— the consignment has not been in contact with any other animal product or live animals presenting a risk of spreading a serious transmissible disease.

III. *Importations*

A. Fresh or chilled hides and skins may only be imported from third countries or a part of a third country from which imports of all categories of fresh meat of the corresponding species are authorized pursuant to Community legislation.

B. Imports of fresh or chilled hides and skins must meet animal health conditions to be determined in accordance with the procedure laid down in Article 18 and must be accompanied by an animal health certificate as provided for in Article 10 (2) (c).

C. Imports of treated hides or skins from the third countries listed in Part 1 of the Annex to Decision 79/542/EEC [2] are authorized on condition that each consignment is accompanied by a certificate of a model to be

[1] 'Hides and skins of ungulates' means the integuments of ungulates.

[2] OJ No L 146, 14. 06. 1979, p. 15. Decision as last amended by Commission Decision 94/59/EC (OJ No L 27, 1. 2. 1994, p. 53).

▼M2

determined by the Commission in accordance with the procedure laid down in Article 18, to the effect that:

(a) either where the hides or skins come from animals originating in a region of a third country or in a third country not subject, pursuant to Community regulations, to restrictions as a result of an outbreak of a serious transmissible disease to which the animals of the species concerned are susceptible, they have been treated in accordance with point I.B;

or

where the hides or skins come from other regions of a third country or other third countries, they are treated as laid down in point I.B, third and fourth indents;

and

(b) the consignment has not been in contact with any other animal product or with live animals presenting a risk of spreading a serious transmissible disease.

D. However, in the case of imports from any third country of hides or skins of ruminants treated in accordance with point I.B and which have been kept separate for 21 days or have undergone transport for 21 uninterrupted days, the certificate provided for in point C is replaced by a declaration to the effect that or proving that those requirements have been met, of a model to be determined by the Commission in accordance with the procedure laid down in Article 18.

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CHAPTER 4

Pet food containing low-risk materials within the meaning of Directive 90/667/EEC

1. Each consignment of petfood in hermetically sealed containers must be accompanied by a certificate issued and signed by an official veterinarian of the country of origin stating that the product has been subjected to heat treatment to a minimum Fc value of 3,0.

2. Each consignment of semi-moist petfood must be accompanied either by the commercial document or by the certificate provided for in Article 13 (2) (b) of Directive 90/667/EEC stating that:

   (i) the raw materials of animal origin from which the petfood was manufactured were obtained solely from healthy slaughtered animals, the meat from which had been passed as fit for human consumption;

   (ii) the ingredients of animal origin have been subjected to a heat treatment of at least 90 ºC throughout their substance;

   (iii) after processing, effective steps were taken to ensure that the consignment was not exposed to recontamination.

3. Dried petfood must satisfy the following requirements:

   (a) the raw materials from which the petfood was manufactured were low-risk materials in accordance with Articles 2, 5 and 17 of Directive 90/667/EEC;

   (b) each consignment is accompanied by a commercial document or certificate provided for in Article 13 (2) (b) of Directive 90/667/EEC stating that:

      (i) the dried petfood consisted of products of slaughtered animals heat-treated so as to achieve a temperature throughout their substance of at least 90 ºC, on the understanding that the treatment was not necessary for finished products the ingredients of which had undergone such treatment;

      (ii) after heat treatment, every precaution was taken to ensure that the product was not contaminated in any way prior to shipment;

      (iii) the product is packed in new containers (bags or sacks);

      (iv) the production process has been tested, with satisfactory results, in accordance with Chapter III (2) of Annex II to Directive 90/667/EEC.

4. Each consignment of products manufactured from processed hides must be accompanied by a commercial document or certificate provided for in Article 13 (2) (b) of Directive 90/667/EEC stating that the products have been subjected to a heat treatment during processing sufficient to destroy pathogenic organisms (including salmonella) and that effective steps were taken after processing to prevent contamination of the products.

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CHAPTER 5

Bones and bone products (excluding bone meal), horns and horn products (excluding horn meal) and hooves and hoof products (excluding hoof meal)

Trade in and imports of the products in question are subject to the following conditions:

A. where they are intended for human or animal consumption:

1. where trade is concerned, bones, horns and hooves are subject to the animal health requirements laid down in Directive 72/461/EEC;
2. where trade is concerned, bone products, horn products and hoof products are subject to the animal health requirements provided for in Directive 80/215/EEC ([1]);
3. where imports are concerned, bones, bone products, horns, horn products, hooves and hoof products are subject to the requirements of Directive 72/462/EEC ([2]);

B. where they are intended for uses other than human or animal consumption, including those intended to be processed with a view to the manufacture of gelatins:

1. Member States shall authorize the importation of bone and bone products (excluding bone meal), horns and horn products (excluding horn meal) and hooves and hoof products (exluding hoof meal) provided that:
   (i) the products are dried before export and not chilled or frozen;
   (ii) the products are conveyed only by land and sea from their country of origin direct to a border inspection post in the Community and are not transhipped at any port or place outside the Community;
   (iii) following the document checks provided for in Directive 90/675/EEC, the products are conveyed directly to the manufacturing plant;
2. each consignment must be accompanied by an undertaking from the importer that products imported under this chapter will not be diverted for direct use in human or animal food.

   A declaration to this effect must be presented to the official veterinarian at the border inspection post at first point of entry of the goods into the Community and be annotated by him, and thereafter shall accompany the consignment to its destination.
3. under the procedure provided for in Article 18 of this Directive, in the light of the animal health situations and guarantees as regards controls on origin offered by a third country, derogations from some of these requirements may be permitted.

CHAPTER 6

Processed animal protein

I. Without prejudice to any restrictions imposed as regards BSE or to the restrictions on the feedings of ruminant protein to ruminants, trade in and imports of processed animal protein are subject:

A. as regards trade:

— in processed animal protein intended for human foodstuffs, to the production of the document or certificate provided for in Directive 77/99/EEC stating that the requirements of that Directive have been complied with,

— in processed animal proteins intended for animal feedingstuffs, to the production of the document or certificate provided for in Article 13 of Directive 90/667/EEC;

B. as regards imports:

1. to production of a health certificate as provided for in Article 10 (2) (c), signed by the official veterinarian of the country of origin and stating that:

   (a) the product:

      (i) where it is intended for animal consumption, has undergone appropriate heat treatment with the result that it complies

([1]) OJ No L 47, 21. 2. 1980, p. 4. Directive as last amended by Directive 91/687/EEC (OJ No L 377, 31. 12. 1991, p. 16).
([2]) OJ No L 302, 31. 12. 1972, p. 28. Directive as last amended by Directive 91/688/EEC (OJ No L 377, 31. 12. 1991, p. 18).

▼B

with the biological standards laid down in Annex II, Chapter III to Directive 90/667/EEC;

(ii) where it is intended for human consumption, fulfils the requirements of Directive 80/215/EEC;

(b) every precaution has been taken after treatment to prevent contamination of the product treated;

(c) samples have been taken and tested for salmonella when the consignment left the country of origin;

(d) the results of these tests are negative;

2. following document checks of the certificate referred to in 1, to sampling by the competent authority at the border inspection post without prejudice to point II:

(i) of each consignment of products submitted in bulk;

(ii) at random of consignments of products packaged in the manufacturing plant;

3. for release for free circulation in Community territory of consignments of processed animal protein, to prove that the results of the sampling carried out pursuant to B (1) (c) have proved negative, if necessary after reprocessing;

C. national rules existing on the date of notification of this Directive concerning the requirements applicable as regards BSE and scrapie for animal proteins may be maintained pending a decision on the type of heat treatment capable of destroying the agent responsible.

Trade in and imports of meat meal and bone meal remain subject to Article 5 (2) of Directive 89/662/EEC and Article 11 (2) of Directive 90/675/EEC.

II. Member States may carry out random sampling of bulk consignments originating in a third country from which the last six consecutive tests have proved negative. Where during one of these checks a result has proved positive, the competent authority of the country of origin must be informed so that it can take appropriate measures to remedy the situation. These measures must be brought to the attention of thecompetent authority responsible for the import checks. In the event of a further positive result from the same source, further tests must be carried out on all consignments from the same source until the requirements laid down in the first sentence are again satisfied.

III. Member States must keep records of the results of sampling carried out on all consignments which have undergone sampling.

IV. In accordance with Article 3 (3) of Directive 89/662/EEC, transhipment of consignments is permitted only through ports which have been approved under the procedure laid down in Article 18, provided that a bilateral agreement has been reached between Member States to allow checking of the consignments to be deferred until they reach the border inspection post of the Member State of final destination.

V. Where a consignment proves to be positive for salmonella, it is either:

(a) re-exported from the Community;

(b) used for purposes other than animal feeds. In this case, the consignment may leave the port or storage depot only on condition that it is not incorporated into animal feedingstuffs;

(c) re-processed in a treatment plant approved pursuant to Directive 90/667/EEC or any plant approved for decontamination. Movement from the port or storage depot shall be controlled by permit from the competent authority and the consignment shall not be released until it has been treated, tested for salmonella by the competent authority in accordance with Annex II, Chapter III, to Directive 90/667/EEC and a negative result obtained.

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CHAPTER 7

Blood and blood products of ungulates and poultry

(with the exception of serum from equidae)

I. *Fresh blood and blood products intended for human consumption*

A. Trade

1. Trade in fresh blood of ungulates and poultry intended for human consumption is subject to the animal health conditions applicable to trade in fresh

▼M7

meat pursuant to Council Directives 72/461/EEC ([1]), 91/494/EEC ([2]) or 91/495/EEC ([3]).

2. Trade in blood products intended for human consumption is subject to the animal health conditions laid down in Chapter 11 of this Directive.

B. Imports

1. Imports of fresh blood of domestic ungulates intended for human consumption are prohibited pursuant to Council Directive 72/462/EEC ([4]).

   Imports of fresh blood of domestic poultry intended for human consumption are subject to the animal health conditions laid down in Directive 91/494/EEC.

   Imports of fresh blood of reared game intended for human consumption are subject to the animal health conditions laid down in Chapter 11 of this Annex.

2. Imports of blood products for human consumption, including those referred to in Council Directive 77/99/EEC ([5]), are subject to the animal health conditions applicable to meat products pursuant to Directive 72/462/EEC and this Directive, without prejudice to the rules on blood-based processed animal protein products referred to in Chapter 6 of this Annex.

II. *Fresh blood and blood products not intended for human consumption*

A. Definitions

For the purposes of this point, the following definitions shall apply

blood:

— whole blood defined as 'low-risk material' within the meaning of Directive 90/667/EEC;

blood products:

— fractions of blood which may have undergone treatment other than that provided for in Directive 90/667/EEC,

  or

— blood which has undergone treatment other than that provided for in Directive 90/667/EEC;

products used for in vitro diagnosis:

— a packaged product, ready for use by the end user, containing a blood product, and used as a reagent, reagent product, calibrator, kit or any other system, whether used alone or in combination, intended to be used *in vitro* for the examination of samples of human or animal origin, with the exception of donated organs or blood, solely or principally with a view to the diagnosis of a physiological state, state of health, disease or genetic abnormality or to determine safety and compatibility with reagents;

laboratory reagent:

— a packaged product, ready for use by the end user, containing a blood product, and intended for laboratory use as a reagent or reagent product, whether used alone or in combination;

full treatment:

— heat treatment at a temperature of 65 ºC for at least three hours, followed by an effectiveness check,

  or

— irradiation at 2,5 megarads or by gamma rays, followed by an effectiveness check,

  or

— change in pH to pH 5 for two hours, followed by an effectiveness check,

  or

— the treatment provided for in Chapter 4 of this Annex,

  or

— any other treatment or process to be laid down in accordance with the procedure laid down in Article 18.

([1]) OJ No L 302, 31. 12. 1972, p. 24.
([2]) OJ No L 268, 24. 9. 1991, p. 35.
([3]) OJ No L 268, 24. 9. 1991, p. 41.
([4]) OJ No L 302, 31. 12. 1972, p. 28.
([5]) OJ No L 26, 31. 1. 1977, p. 85.

▼M7

B. Trade

Trade in blood and blood products is subject to the animal health conditions laid down in Chapter II of this Directive and to the conditions laid down in Directive 90/667/EEC.

C. Imports

1. Imports of blood are subject to the animal health conditions laid down in Chapter 10 of this Annex.

2. (a) Imports of blood products are authorized provided that each consignment is accompanied by a certificate, the form of which is to be fixed pursuant to the procedure laid down in Article 18, certifying that:

— the products originate in a third country in which no case of foot-and-mouth disease has been recorded within at least 24 months and no case of vesicular stomatitis, swine vesicular disease, rinderpest, peste des petits ruminants, Rift Valley fever, blue tongue, African horse sickness, classical swine fever, African swine fever, Newcastle disease or avian influenza has been recorded for 12 months in the susceptible species and in which vaccination has not been carried out against those diseases for at least 12 months. The health certificate may be made out according to the species of animal from which the blood products are derived,

or

— in the case of blood products derived from bovine animals, they originate in an area of a third country fulfilling the conditions set out in the first indent from which imports of bovine animals, their fresh meat or their sperm are authorized pursuant to Community legislation. The blood from which such products are manufactured must be from bovine animals from that area of the third country and must have been collected:

— in slaughterhouses approved in accordance with Community legislation,

or

— in slaughterhouses approved and supervised by the competent authorities of the third country. The Commission and Member States must be notified of the address and approval number of such slaughterhouses,

or

— in the case of blood products derived from bovine animals, they have undergone full treatment guaranteeing the absence of pathogens of the bovine diseases referred to in the first indent,

or

— in the case of blood products derived from bovine animals, they fulfil the conditions laid down in Chapter 10 of this Annex. In such cases, the packaging may not be opened during storage and the processing undertaking must carry out full treatment of the products concerned.

(b) The specific conditions relating to imports of products for use in *in vitro* diagnosis and laboratory reagents shall be established, where necessary, in accordance with the procedure laid down in Article 18.

III. *General provisions*

The detailed rules for the application of this Chapter are to be adopted, where necessary, in accordance with the procedure laid down in Article 18.

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CHAPTER 8

Serum from equidae

1. In order to be the subject of trade, serum must come from equidae which show none of the serious transmissible diseases referred to in Directive 90/426/EEC ([1]) or of the serious transmissible diseases to which equidae are susceptible and have been obtained in bodies or centres not subject to health restrictions pursuant to that Directive.

2. Serum from equidae may be imported only if it comes from equidae born and raised in a third country from which the importation of horses for slaughter is

([1]) OJ No L 224, 18. 8. 1990, p. 42. Directive as last amended by Decision 92/130/EEC (OJ No L 47, 22. 2. 1992, p. 26).

▼B

authorized and was obtained, processed and dispatched in conditions to be specified under the procedure laid down in Article 18.

CHAPTER 9

Lard and rendered fats

1. Member States shall authorize the importation into the Community of lard and rendered fats from third countries appearing on the list annexed to Decision 79/542/EEC from which the importation of fresh meat of the species concerned is permitted.

2. Where there has been an outbreak of a serious transmissible disease in the previous 12 months before export in a country mentioned in paragraph 1, each consignment of lard or rendered fats must be accompanied by a certificate referred to in Article 10 (2) of this Directive stating that:

   A. the lard or rendered fats have been subjected to one of the following heat treatment processes:

      (i) at least 70 ºC for at least 30 minutes; or

      (ii) at least 90 ºC for at least 15 minutes; or

      (iii) a minimum temperature of 80 ºC in a continuous rendering system;

   B. where the lard of rendered fats are packaged, they have been packed in new containers and all precautions have been taken to prevent their recontamination;

   C. where bulk transport of the product is intended, the pipes, pumps and bulk tank and any other bulk container tanks or bulk road tanker used in the transportation of the products from the manufacturing plant either directly on to the ship or into shore tanks or direct to establishments were inspected and found to be clean before use.

CHAPTER 10

Raw material for the manufacture of animal feedingstuffs and pharmaceutical or technical products

1. Raw material means fresh meat, glands, organs and other offal as well as intestinal mucuses which are not intended for human consumption. Raw material shall be regarded as fresh if it has only undergone refrigeration or other treatment not resulting in sufficiently safe destruction of pathogenic agents. The substances involved may only be low-risk substances within the meaning of Directive 90/667/EEC.

2. Raw material must be accompanied by a commercial document or certificate, provided for in Article 13 (2) of Directive 90/667/EEC, or a certificate complying with the model to be laid down under the procedure provided for in Article 18 and must satisfy the requirements of Decision 92/183/EEC.

3. In trade the original of the health certificate or commercial document must be submitted to the veterinary authorities responsible for the processing plant and the intermediate storage warehouse — cold storage facility — or sorting facility; in the case of imports into the Community, it must be submitted to the border control authority.

4. The raw material must be transported directly to approved or registered processing plants which meet the conditions laid down in Directive 90/667/EEC or to cold-storage facilities approved for intermediate storage. Prior to processing, raw material for manufacturing pharmaceuticals may also be sorted and stored in facilities specially approved for the purpose by the Member States. Member States shall inform the Commission of the approval of such sorting facilities.

5. The raw material may be transported to the processing plant only in watertight and properly sealed containers or vehicles. The legend ‘Only for the manufacture of petfood’ or ‘Only for the manufacture of pharmaceuticals or technical products’ must appear on the recipients and accompanying documents, depending on the intended purpose. The name and address of the consignee undertaking must appear on the containers and accompanying papers.

6. The vehicles and containers used to transport the goods, together with all items of equipment or appliances which have come into contact with the untreated raw material, must be cleaned and disinfected. Packaging material must be incinerated or disposed of by some other means in accordance with instructions from the official veterinarian.

7. Intermediate storage of the raw material shall be permissible only in cold storage facilities approved for the purpose, subject to authorization and

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under the supervision of the official veterinarian. The raw material must be stored separately from other goods and in such a way as to prevent any propagation of epizootic diseases.

8. At the processing plant the raw material shall be treated in such a way as to kill any pathogenic agents and rule out any danger to domestic herds. Removal of raw material from the plant for safe disposal in processing plants approved or registered for the purpose in accordance with Directive 90/667/EEC shall be permissible only in exceptional cases and with the authorization of the official veterinarian. The provisions of points 5, 6 and 9 shall apply correspondingly to the transportation of the raw material and to the notification of the official veterinarian responsible for the processing plant.

9. When the raw material is transported from the plant of origin, or beyond the Community's external border:

   — the official veterinarian responsible for the plant of origin in the case of intra-Community trade, or

   — the border inspection authority in the case of imports into the Community

   shall notify the official veterinarian responsible for the processing plant, intermediate storage warehouse or sorting facility of that fact by means of the 'Animo system', by telex or by fax.

10. Imports into the Community are also subject to the following provisions:

   (a) Member States shall authorize the importation of raw material into the Community only from third countries which appear on the list laid down in Council Decision 79/542/EEC or in a special Commission Decision on a specific raw material;

   (b) following the border check the raw materials shall, under the supervision of the competent veterinary authority, be transported either directly to an approved or registered processing plant which is under the constant supervision of an official veterinarian and has given a guarantee that the raw materials will be used only for the permitted purpose and that they will not leave the plant untreated, or to an approved intermediate storage or approved sorting facility;

   (c) the health certificate bearing the file mark of the border inspection authority or a certified copy of that certificate must accompany the goods until they reach the destination plant.

CHAPTER 11

Rabbit meat and farmed game meat

Member States shall ensure that rabbit meat and farmed game meat are imported only if:

(a) they come from third countries included:

   (i) for furred farm game, on the list of countries from which fresh meat of the corresponding species may be imported pursuant to Directive 72/462/EEC;

   (ii) for feather farmed game, on the list of countries from which fresh poultrymeat may be imported pursuant to Directive 91/494/EEC ([1]);

   (iii) for rabbit meat, on a list to be drawn up under the procedure laid down in Article 18;

(b) they satisfy at least the requirements laid down in Chapters II and III respectively of Directive 91/495/EEC ([2]);

(c) they come from establishments offering the guarantees provided for in (b) and recognized under the procedure provided for in Article 18 or, pending the list referred to in (a) (iii), from establishments approved by the competent authorities;

(d) each batch of meat is accompanied by the health certificate provided for in Article 10 (2) (c).

([1]) OJ No L 268, 24. 9. 1991, p. 25.
([2]) OJ No L 268, 24. 9. 1991, p. 41.

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CHAPTER 12

Apiculture products

1. Apiculture products intended exclusively for use in apiculture:

   (a) must not come from an area which is the subject of a prohibition order associated with an occurrence of American foulbrood or acarioasis, if in the case of acarioasis the Member State of destination has obtained additional guarantees in accordance with Article 14 (2) of Directive 92/65/EEC ([1]);

   (b) must meet the requirements imposed by Article 8 (a) of Directive 92/65/EEC.

2. Any derogations must be established, as necessary, under the procedure laid down in Article 18 of this Directive.

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CHAPTER 13

Game trophies

A. Without prejudice to the measures adopted pursuant to Regulation (EEC) 3626/82 ([2]), trade in and imports of game trophies:

   (i) of ungulates and birds having undergone a complete taxidermy treatment ensuring their preservation at ambient temperatures;

   (ii) of species other than ungulates and birds;

   shall not be subject to any ban or restriction for reasons of animal health.

B. Without prejudice to the measures adopted pursuant to Regulation (EEC) No 3626/82, trade in and imports of game trophies of ungulates and birds not having undergone the treatment mentioned in A (I) shall be subject to the following conditions:

   1. with regard to trade:

      game trophies must either:

      — come from animals originating in an area not subject to restrictions as a result of the presence of serious transmissible diseases to which animals of the species concerned are susceptible,

      or:

      — comply with the conditions laid down in 2 (b) or (c) if they come from animals originating in an area subject to restrictions as a result of the presence of serious transmissible diseases to which animals of the species concerned are susceptible;

   2. with regard to imports:

      (a) in respect of game trophies consisting of entire anatomical parts not having been treated in any way:

      the trophies must:

      — come from animals in respect of which the import into the Community of all categories of fresh meat of the species concerned which has not undergone any form of treatment is authorized pursuant to Community rules,

      — be packaged immediately, without being in contact with other products of animal origin likely to contaminate them, in individual, transparent and closed packages so as to avoid any subsequent contamination,

      — be accompanied by a veterinary certificate certifying that the above conditions have been met.

      Furthermore, during the taxidermy treatment, the waste which is not part of the trophy must be destroyed;

      (b) in respect of game trophies consisting solely of bone, horns, hooves, claws, antlers or teeth:

      the trophies must:

      — have been immersed in boiling water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed,

([1]) OJ No L 268, 14. 9. 1992, p. 54.
([2]) OJ No L 384, 31. 12. 1982, p. 1.

▼M1

— have been disinfected with a product authorized by the competent authority in the country of dispatch, in particular with hydrogen peroxide where parts consisting of bone are concerned,

— be packaged, immediately after treatment, without being in contact with other products of animal origin likely to contaminate them, in individual, transparent and closed packages so as to avoid any subsequent contamination,

— be accompanied by a document or certificate certifying that the above conditions have been met;

(c) in respect of game trophies consisting solely of hide or skin:

— the trophies must:

— have been either:

(i) dried;

or:

(ii) dry- or wet-salted for a minimum of 14 days before dispatch;

or:

(iii) preserved by a treatment other than tanning to be fixed according to the procedure provided for in Article 18,

— be packaged, immediately after treatment, without being in contact with other products of animal origin likely to contaminate them, in individual, transparent and closed packages so as to avoid any subsequent contamination,

— be accompanied by a document or certificate certifying that the above conditions have been met.

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CHAPTER 14

Manure

For the purposes of this Chapter manure means any excrement and/or urine of cloven-hoofed animals, equidae and/or poultry, with or without litter, and guano.

I. Unprocessed manure

A. *Trade in unprocessed manure*

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1. (a) Trade in unprocessed manure of species other than poultry or equidae is prohibited, except for manure:

from an area or holding which is not subject to restrictions by virtue of a serious transmissible disease,

and

intended for spreading under the control of the competent authorities on land forming part of or belonging to the same holding, whether separated or not, located on both sides of the frontier between Member States and within a distance of approximately 20 kilometres. Records should be kept by the owner of the holding concerning these cross-frontier movements in order to be approved. The competent authority shall keep a register of such approved holdings.

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(b) However, in derogation to (a), a Member State may grant specific approval for the introduction onto its territory:

— of manure intended for processing in an establishment specifically approved for that purpose by the competent authorities with a view to the manufacture of the products referred to under II below. When such establishments are being approved, account is to be taken of the origin of the manure, or

— of manure intended for spreading on a holding. Such trade can only occur with the consent of the competent authorities of both the Member State of origin and of destination. When giving consent, account is to be taken in particular of the origin of the manure, its destination and animal health and safety considerations.

In such cases the manure is to be accompanied by a health certificate that conforms to the model laid down in the procedure provided for in Article 18.

2. Trade in unprocessed poultry manure is subject to the following conditions:

(a) the manure must originate in an area which is not subject to restrictions by virtue of Newcastle disease or avian influenza;

▼M5

(b) in addition, unprocessed, manure from poultry flocks vaccinated against Newcastle disease must not be dispatched to a region which has obtained Newcastle disease non-vaccinating status pursuant to Article 12 (2) of Directive 90/539/EEC;

(c) the manure is to be accompanied by a health certificate that conforms to the model laid down in the procedure provided for in Article 18.

3. Trade in unprocessed manure of equidae is not subject to any animal health conditions.

B. *Imports of unprocessed manure*

Imports of unprocessed manure are subject to the following conditions:

1. the manure must satisfy, according to the species concerned, the requirements under A (1) (a) above;

2. the manure must be accompanied by a certificate as provided for in Article 10.

II. Processed manure and processed manure products

All organic fertilizers must have been treated to ensure that the product is pathogen-free.

A. Trade in processed manure and processed manure products is subject to the following conditions:

1. they must come from an establishment approved by the competent authorities;

2. they must:

— be free from salmonella (no salmonella in 25 g treated product),

— be free from enterobacteriaceae (based on the aerobic bacteria count: < 1 000 cfu per gram of treated product),

— have been subjected to reduction in spore-forming bacteria and toxin formation;

3. they must be stored in such a way that, once processed, contamination or secondary infection and dampness is impossible.

They must therefore be stored in:

— well-sealed and insulated silos, or

— properly sealed packs (plastic bags or ‘big bags’).

B. Imports of processed manure and processed manure products are subject to the following conditions:

1. they must satisfy the requirements under A above;

2. they must be accompanied by a certificate as provided for in Article 10.

III. Guano

Trade in and imports of ‘guano’ are not subject to any animal health conditions.

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CHAPTER 15

Unprocessed wool, hair, bristles, feathers and parts of feathers

1. Sheep's wool, ruminant hair and pig bristles shall be considered to be ‘unprocessed’ if they have not undergone factory washing or been obtained from tanning, and feathers and parts of feathers shall be considered ‘unprocessed’ if they have not been treated with a steam current or by some other method ensuring that no pathogens are transmitted.

2. Unprocessed sheep's wool, ruminant hair, pig bristles, feathers and parts of feathers (the goods) may only be traded in or imported if they are securely enclosed in packaging and dry. However, trade in and imports of pig bristles from countries or regions in which African swine fever is endemic are prohibited except for pig bristles which:

(a) have been boiled, dyed or bleached; or

(b) have undergone some other form of treatment which is certain to kill pathogenic agents, provided that evidence to this effect is submitted in the form of a certificate from the veterinarian responsible for the place of origin. Factory washing shall not be regarded as a form of treatment for the purposes of this provision.

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3. The provisions of this chapter shall not apply to trade or imports of decorative feathers or feathers:

   (a) carried by travellers for their private use; or

   (b) which are the subject of trade in or imports into the Community in the form of consignments sent to private individuals for non-industrial purposes.

4. The goods must be sent directly to the plant of destination or the warehouse for storage in conditions such that any spread of pathogenic agents is avoided.

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ANNEX II

SPECIFIC PUBLIC HEALTH CONDITIONS

CHAPTER 1

Imports from third countries of meat products obtained from poultrymeat, farmed game meat, wild game meat and rabbit meat

Member States shall ensure that meat products obtained from poultrymeat, farmed game meat, wild game meat and rabbit meat are not imported unless:

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(a) either they come from a third country listed in accordance with:

(i) Article 9 of Directive 91/494/EEC for poultrymeat;

(ii) Article 16 of Directive 92/45/EEC for wild game meat;

(iii) Chapter 2 of Annex I to this Directive for rabbit meat and farmed game meat,

either they come from a third country listed in the Annex, Part I of Decision 79/542/EEC. In this case they must have undergone a heat treatment in a sealed container, the F^o value being equal or over 3,00. However for meat products made from species other than swine, this treatment may be replaced by a heat treatment which brings the internal temperature to at least 70 ºC.

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(b) the fresh meat used meets the appropriate requirements of Article 14 of Directive 71/118/EEC for poultrymeat, Article 16 of Directive 92/45/EEC for wild game meat, Article 3 of Directive 91/495/EEC for rabbit meat and Article 6 of that Directive for farmed-game meat;

(c) they come from an establishment offering the same guarantees as those referred to in Directive 77/99/EEC and approved in accordance with the procedure provided for in Article 18 or, pending the adoption of such a decision, by the competent authority of the Member State with imports of these products remaining subject to the rules in Article 11 (2) of Directive 90/675/EEC;

(d) they are prepared, checked and handled in accordance with the appropriate requirements provided for in Directive 77/99/EEC;

(e) each consignment of meat products is accompanied by a health certificate established in accordance with the procedure provided for in Article 18.

CHAPTER 2

►M8 Before 1 July 1997 ◄, the health conditions applicable to the following shall be established in accordance with the procedure laid down in Article 18:

— putting on the market in and imports of eggs and imports of egg products intended for human consumption, without prejudice to the rules laid down within the framework of the common organization of the market.

▼A1

In respect of salmonella and pending the adoption of Community provisions, the following rules shall apply for eggs intended for Finland and Sweden:

(a) consignments of eggs may be subject to additional general or limited guarantees defined by the Commission following the procedure provided for in Article 18;

(b) the guarantees provided for in (a) shall not be carried out for eggs originating in an establishment subject to a programme recognized as equivalent to that referred to in (c), pursuant to the procedure provided for in Article 18;

(c) the guarantees provided for in (a) shall apply only after approval by the Commission of an operational programme to be presented by Finland and Sweden. The Commission decisions must be taken before the date of entry into force of the Accession Treaty in order for the operational programmes and the guarantees provided for in (a) to be applicable as from the date of entry into force of the Accession Treaty,

▼M10

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▼B

— trade in and import of honey ►M6 ——————— ◄ intended for human consumption,

▼M8

— trade in and imports of milk and milk-based products intended for human consumption, obtained from species not covered by Directive 92/46/EEC; depending on the species, specific requirements may be laid down as regards:

  — animal health and the health status of dairy herds, in particular with regard to tuberculosis and brucellosis;

  — hygiene in respect of

    — milking,

    — the collection, transport, treatment and processing of milk,

    — staff,

  — testing for residues of pharmacologically and/or hormonally active substances, antibiotics, pesticides or other harmful substances in milk or milk products,

  — criteria applicable to raw milk as a raw material,

  — microbiological criteria applicable to finished products,

— the production, placing on the market and importation of meat of species not covered by specific requirements, and in particular reptile meat and products thereof, intended for human consumption.

  Depending on the species, specific requirements may be laid down as regards:

  — microbiological and parasitological criteria,

  — hygiene during slaughter,

  — testing for residues.

▼M6

CHAPTER 3

I. **Specific public health conditions applicable to trade in and imports of snails intended for human consumption**

A. Without prejudice to Community, national or international provisions on the protection of wildlife, for the purpose of this Chapter, 'snails' means terrestrial gastropods of the species *Helix pomatia Linné, Helix aspersa Muller, Helix lucorum* and species of the family of *Achatinidae*.

B. Member States must ensure that shelled, cooked and prepared or preserved snails are traded for human consumption only if they meet the following conditions:

(1) They must come from establishments:

  — which meet the requirements of Article 4 (2) of this Directive,

  — which are approved by the competent authority in accordance with the requirements of Chapters III and IV of the Annex to Directive 91/493/EEC,

  — which undergo monitoring by the competent authority of production conditions and health checks in accordance with Chapter V (I) (3) and (5) and (II), (3) and (4) of Directive 91/493/EEC,

  — which conduct own checks in accordance with the provisions of Commission Decision 94/356/EC.

(2) They must be subjected to organoleptic checks carried out by sampling. If the organoleptic examination reveals that the snails are not fit for human consumption, measures must be taken to withdraw them from the market and denature in such a way that they cannot be re-used for human consumption.

(3) For the preparation of shelled snailmeat,

  (a) depending on the scale of the operation, establishments must set aside special rooms or areas for:

    — the storage of packaging and wrapping materials,

    — the reception and storage of live snails,

    — washing, blanching or boiling, shelling and trimming,

    — the storage and, where necessary, cleaning and treatment of shells,

    — the heat treatment of the snailmeat, where necessary,

    — the wrapping or packaging of the snailmeat,

    — the storage of the finished product in cold stores;

  (b) the snails must be checked before being boiled. Dead snails must not be prepared for human consumption;

  (c) following shelling, the hepatopancreas removed during trimming must not be used for human consumption.

▼**M6**

(4) *Canned snails*

Establishments must satisfy the conditions laid down in Chapter IV (IV) (4) of the Annex to Directive 91/493/EEC.

(5) *Cooked and prepared snails*

(a) Depending on the scale of the operation, establishments must set aside special rooms or areas for:

— the storage of shelled snailmeat in cold stores,

— the storage of clean shells,

— the storage of breading products,

— the preparation of stuffing,

— cooking and cooling,

— the filling of the shells with snailmeat and stuffing, and packaging in a controlled-temperature room,

— where applicable, freezing,

— the storage of finished products in cold stores;

Products must satisfy the relevant conditions set out in Chapter IX of Annex B to Directive 77/99/EEC.

(b) Snailmeat used to fill shells prior to cooking must satisfy the conditions laid down in respect of shelled snailmeat.

(6) In accordance with the procedure laid down in Article 18 of this Directive, microbiological criteria, including sampling plans and methods of analysis, may be laid down when there is a need to protect public health.

(7) The snails must be put up, packaged, stored and transported under the appropriate hygiene conditions laid down in Chapters VI and VIII of the Annex to Directive 91/493/EEC.

(8) The packaging and wrapping of snails must bear an identification mark containing the following particulars:

the name of the consigning country in capitals or the initial letter or letters of the consigning country in printed capitals, i.e.: AT, B, DK, D, EL, E, F, FI, IRL, I, L, NL, P, SE, UK followed by the approval number of the establishment, and one of the following sets of initials: CE, EC, EF, EG, EK, EY.

C. For imports:

(1) the packaging and wrapping of shelled, cooked and prepared or preserved snails must carry the name or ISO code of the country of origin and the approval number of the production establishment in indelible print;

(2) the following is an example of the specimen health certificate laid down in Article 10 (2) (c) of this Directive, which must accompany every consignment of shelled, cooked and prepared or preserved snails originating in third countries.

▼M6

SPECIMEN HEALTH CERTIFICATE FOR SHELLED, COOKED, PREPARED OR PRESERVED SNAILS ORIGINATING IN THIRD COUNTRIES AND INTENDED FOR THE EUROPEAN COMMUNITY

Note to the importer: this certificate is for veterinary purposes only and must accompany the consignment until it reaches the border inspection point.

Reference No: .....

Country of dispatch:

Competent authority:

I. **Identification of snails**

Description of product:

— species (scientific names): .....

— state (1) and nature of treatment: .....

Code No (as appropriate): .....

Type of packaging: .....

Number of packages: .....

Net weight: .....

Required storage and transportation temperature: .....

II. **Origin of snails**

Name(s) and official approval number(s) of establishment(s) approved by the competent authority for export to the European Community:

.....

.....

.....

.....

.....

III. **Destination of products**

The snails are dispatched from:

.....

(place of dispatch)

to: .....

(country and place of destination)

by the following means of transport (2): .....

Name and address of consignor: .....

.....

.....

Name of consignee and address of the place of destination: .....

.....

(1) Chilled, frozen, shelled, cooked, prepared, preserved.

(2) Registration number of lorries, railway wagons or container, flight number or name of ship.

▼M6

IV. **Health attestation**

The undersigned official inspector hereby certifies that the snails described above:

(1) have been handled and, where appropriate, shelled, cooked, prepared, preserved, frozen, packaged and stored in a hygienic manner in accordance with the requirements of Chapter 3 (I) of Annex II to Directive 92/118/EEC;

(2) have been the subject of an own check programme drawn up and implemented by the person responsible for the establishment in accordance with Directive 94/356/EC;

(3) have undergone an official health check in accordance with Chapter V of the Annex to Directive 91/493/EEC.

The undersigned official inspector hereby declares that he is aware of the provisions of Chapter 3, Part I, of Annex II to Council Directive 92/118/EEC, of the provisions of Chapters III, IV, V, VI and VII of Directive 91/493/EEC of the provisions of Chapter IX of Annex B to Directive 77/99/EEC and of the provisions of Decision 94/356/EC.

Done at ....., ...
(date)

Official stamp (1)

Name in capital letters and signature of official inspector (1)

(1) The colour of the stamp and signature must be different from that of the other particulars in the certificate.

▼M6

II. **Specific public health conditions applicable to trade in and imports of frogs' legs intended for human consumption**

A. Without prejudice to Community, national or international provisions on the protection of wildlife, for the purposes of this Chapter, 'Frogs' legs' means the back part of the body divided by a transversal cut behind the front limbs, eviscerated and skinned, of the species *Rana* spp. (family *Ranidae*), presented fresh, frozen or processed.

B. Member States must ensure that frogs' legs are traded for human consumption only if they meet the following conditions:

(1) The frogs must have been slaughtered, bled, prepared and, where appropriate, chilled, frozen, processed, packaged and stored in establishments which:

— meet the requirements of Article 4, point 2 of this Directive,

— are approved by the competent authority in accordance with the requirements of Chapters III and IV of the Annex to Directive 91/493/EEC,

— undergo monitoring by the competent authority of production conditions and health checks in accordance with Chapter V (I) (3) and (5) and (II) (3) and (4) of the Annex to Directive 91/493/EEC,

— conduct own checks in accordance with the provisions of Decision 94/356/EC.

(2) The frogs legs must be subjected to organoleptic checks carried out by sampling. If the organoleptic examination reveals that the frogs legs are not fit for human consumption, measures must be taken to withdraw them from the market and denature in such a way that they cannot be re-used for human consumption.

(3) In addition, a special room must be set aside for the storage and washing of live frogs, and for their slaughter and bleeding. The death of frogs must only be carried out by slaughter in an approved establishment. Frogs which are found to be dead prior to slaughter must not be prepared for human consumption. The special room must meet the requirements of Chapter III, paragraph I, point 2 of the Annex to Directive 91/493/EEC and must be physically separated from the preparation room.

(4) Immediately following preparation, the frogs' legs must be washed very fully in running drinking water and immediately chilled at the temperature of melting ice, frozen at a temperature of at least − 18 ºC or processed.

(5) Where the frogs' legs are processed, this must be carried out in accordance with the rules laid down in Chapter IV of the Annex to Directive 91/493/EEC.

(6) *Microbiological controls*

In accordance with the procedure laid down in Article 18 of this Directive, microbiological criteria, including sampling plans and methods of analysis, may be laid down when there is a need to protect public health.

(7) The frogs' legs must be put up, packaged, stored and transported under the appropriate hygiene conditions laid down in Chapters VI and VIII of Directive 91/493/EEC.

(8) The packaging and containers of frogs' legs must bear an identification mark containing the following particulars:

The name of the consigning country in capitals, or the initial letter or letters of the consigning country in printed capitals, i. e.: AT, B, DK, D, EL, E, F, FI, IRL, I, L, NL, P, SE, UK followed by the approval number of the establishment, and, one of the following sets of initials: CE, EC, EF, EG, EK, EY.

C. For imports:

(1) The packaging and wrapping of frogs' legs must carry the name or ISO code of the country of origin and the approval number of the production establishment in indelible print.

(2) The following is an example of the specimen health certificate laid down in Article 10 (2) (c) of this Directive, which must accompany every consignment of frogs' legs originating in third countries:

▼M6

SPECIMEN HEALTH CERTIFICATE FOR CHILLED, FROZEN OR PREPARED FROGS' LEGS ORIGINATING IN THIRD COUNTRIES AND INTENDED FOR THE EUROPEAN COMMUNITY

Note to the importer: This certificate is for veterinary purposes only and must accompany the consignment until it reaches the border inspection point.

Reference No: .....

Country of dispatch:

Competent authority:

I. **Identification of frogs' legs**

Description of product:

— species (scientific names): .....

— state (1) and nature of treatment: .....

Code No (as appropriate): .....

Type of packaging: .....

Number of packages: .....

Net weight: .....

Required storage and transportation temperature: .....

II. **Origin of frogs' legs**

Name(s) and official approval number(s) of establishment(s) approved by the competent authority for export to the European Community:

.....

.....

.....

.....

.....

III. **Destination of products**

The frogs' legs are dispatched from:

.....

(Place of dispatch)

to: .....

(Country and place of destination)

by the following means of transport (2): .....

Name and address of consignor: .....

.....

.....

Name of consignee and address of the place of destination: .....

.....

(1) Chilled, frozen, processed.

(2) Registration number of lorries, railway wagons or container, flight number or name of ship.

▼M6

IV. **Health attestation**

The undersigned official inspector hereby certifies that the frogs' legs described above:

(1) originate from frogs that have been bled, prepared and, where appropriate, chilled, frozen or processed, packaged and stored in a hygienic manner in accordance with the requirements of Chapter 3 (II) of Annex II to Directive 92/118/EEC;

(2) have been the subject of an own check programme drawn up and implemented by the person responsible for the establishment in accordance with Decision 94/356/EC;

(3) have undergone an official health check in accordance with the relevant provisions of Chapter V of the Annex to Directive 91/493/EEC.

The undersigned official inspector hereby declares that he is aware of the provisions of Chapter 3, Part II, of Annex II to Directive 92/118/EEC, of the provisions of Chapters II, IV, V, VI and VII of Directive 91/493/EEC and of the provisions of Decision 94/356/EC.

Done at ....., ...
(date)

Official stamp (1)

Name in capital letters and signature of official inspector (1)

(1) The colour of the stamp and signature must be different from that of the other particulars in the certificate.

▼M10

CHAPTER 4

SPECIFIC HEALTH CONDITIONS FOR THE GELATINE INTENDED FOR HUMAN CONSUMPTION

This chapter lays down the health conditions applicable to putting on the market and for imports of gelatine intended for human consumption, but excluding gelatine destined to pharmaceutical, cosmetic or other technical use and medical devices.

For the purpose of this chapter, the following definitions apply:

— gelatine: natural, soluble protein, gelling or non-gelling, obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals (including fish and poultry),

— hides and skins: all cutaneous and subcutaneous tissues,

— tanning: the hardening of hides, using vegetable tanning agents, chromium salts or other substances such as aluminium salts, ferric salts, silicic salts, aldehydes and quinones, or other synthetic hardening agents,

— category 1 country or region: country or region classified as BSE free in accordance with Community legislation,

— category 2 country or region: country or region classified as provisionally BSE free with accordance to Community legislation,

— category 3 country or region: country or region classified as low BSE risk in accordance with Community legislation,

— category 4 country or region: country or region classified as high BSE risk in accordance with Community legislation.

Gelatine intended for human consumption shall comply with the following conditions:

I. **Conditions for establishments producing gelatine**

Gelatine intended for human consumption shall come from establishments which:

1. comply with the conditions laid down in Chapters I, II, V, VI, VII, VIII, IX and X of the Annex to Directive 93/43/EEC;
2. are authorised and registered in accordance with Article 11 of Directive 77/99/EEC;
3. are subject to supervision of production conditions by the competent authority in accordance with Chapter IV of Annex B to Directive 77/99/EEC as appropriate;
4. carry out an own-checks programme in accordance with Article 7(1) and (3) of Directive 77/99/EEC;
5. keep records for two years on the sources of all incoming raw material and on all outgoing products;
6. introduce and implement a system that makes it possible to link each production batch dispatched, the incoming raw material consignments, the production conditions and the time of production.

II. **Requirements for raw materials to be used for the production of gelatine**

1. For the production of gelatine intended for human consumption, the following raw materials may be used:
   — bones,
   — hides and skins of farmed ruminant animals,
   — pig skins,
   — poultry skin,
   — tendons and sinews,
   — wild game hides and skins,
   — fish skin and bones.
2. The use of bones obtained from ruminant animals born, reared or slaughtered in category 4 countries or regions is prohibited.
3. The use of hides and skins submitted to tanning processes is prohibited.
4. Raw materials listed in the first five indents of paragraph 1 shall be derived from animals which have been slaughtered in a slaughterhouse and whose carcases have been found fit for human consumption following ante and post mortem inspection.
5. Raw material listed in the sixth indent of paragraph 1 shall be derived from killed animals whose carcases have been found fit for human consumption

▼M10

following the inspections laid down in Article 3 of Council Directive 92/45/EEC ([1]).

6. Raw materials listed in the first six indents of paragraph 1 shall come from slaughterhouses, cutting plants, meat processing establishments, wild game processing plants, bone degreasing plants, tanneries, collection centres, retail shops, or premises adjacent to sales points where the cutting and the storage of meat and poultrymeat is performed for the sole purpose of supplying the final consumer directly.

7. Raw material listed in the last indent of paragraph 1 shall come from plants manufacturing fish products for human consumption approved or registered in accordance with Council Directive 91/493/EEC ([2]).

8. The collection centres and tanneries which intend to supply raw material for the production of gelatine intended for human consumption shal be specifically authorised for this purpose and registered by the competent authorities and fulfil the following requirements:

   (a) they must have storage rooms with hard floors and smooth walls which are easy to clean and disinfect;

   (b) where appropriate, they must be provided with refrigeration facilities;

   (c) the storage rooms must be kept in a satisfactory state of cleanliness and repair, so that they do not consitute a source of contamination for the raw materials;

   (d) if raw material not in conformity to this part is stored and/or processed in these premises, it must be segregated throughout the period of receipt, storage, processing and dispatch from raw material in conformity to this part;

   (e) they must be inspected by the competent authority at regular intervals in order to ensure that this chapter is being complied with and to check accounting documents and/or health certificates which enable the origin of the raw material to be traced.

9. Imports into the Community of raw material destined to the production of gelatine intended for human consumption are subject to the following provisions:

   — Member States shall authorise the importation of this raw material only from third countries which appear on the list laid down in Council Decision 79/542/EEC ([3]) or in Commission Decision 94/85/EC ([4]) or in Commission Decision 97/296/EC ([5]) or in Decision 94/86/EC ([6]), as appropriate,

   — each consignment is accompanied by a certificate that conforms to the model laid down in accordance with the procedure provided for in Article 18 of this Directive.

III. **Transport and storage of raw materials**

1. Transports of raw materials destined to the production of gelatine must be carried out under clean conditions using appropriate means of transport.

   During transportation, at the time of delivery in the collection centre and in the tannery and in the gelatine processing establishment, raw materials must be accompanied by a commercial document in conformity with the model laid down in Part VIII of this chapter.

2. Raw materials must be transported and stored chilled or frozen, unless they are processed within 24 hours after their departure.

   By way of derogation from the preceding subparagraph, degreased and dried bones or ossein, salted, dried and limed hides and skins and hides and skins treated with alkali or acid may be transported and stored at ambient temperature.

3. The storage rooms must be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the raw materials.

([1]) OJ L 268, 14.9.1992, p. 35.
([2]) OJ L 268, 24.9.1991, p. 15.
([3]) OJ L 146, 14.6.1979, p. 15.
([4]) OJ L 44, 17.2.1994, p. 31.
([5]) OJ L 122, 14.5.1997, p. 21.
([6]) OJ L 44, 17.2.1994, p. 33.

▼M10

IV. **Conditions to be complied with for the manufacture of gelatine**

1. Gelatine must be produced by a process which ensures that:

   — all ruminant bone material which is derived from animals born, reared and slaughtered in category 3 countries or regions is subjected to a process which ensures that all bone material is finely crushed and degreased with hot water and treated with dilute hydrochloric acid (at minimum concentration of 4 % and pH < 1,5) over a period of at least two days, followed by an alkaline treatment of saturated lime solution (pH > 12,5) for a period of at least 20 days with a sterilisation step of 138-140 ºC during four seconds or by an equivalent process approved by the Commission after consultation of the appropriate Scientific Committee,

   — other raw material is subjected to a treatment with acid or alkali, followed by one or more rinses. The pH must be adjusted subsequently. Gelatine must be extracted by heating one or several times in succession, followed by purification by means of filtration and sterilisation.

2. After having been subjected to the processes listed in paragraph 1, gelatine may undergo a drying process and, where appropriate, a process of pulverisation or lamination.

3. The use of preservatives, other than sulphur dioxide and hydrogen peroxide, is prohibited.

4. Provided the requirements for gelatine not intended for human consumption are exactly the same as for gelatine intended for human consumption, production and storage may be undertaken in the same establishment.

V. **Requirements for finished products**

Each production batch of gelatine shall be subjected to tests to ensure that it meets the following criteria:

1. *Microbiological criteria*

Microbiological parameters	Limit
Total aerobic bacteria	10^3/g
Coliforms (30 ºC)	0/g
Coliforms (44,5 ºC)	0/10 g
Anaerobic sulphite-reducing bacteria (no gas production)	10/g
Clostridium perfringens	0/g
Staphylococcus aureus	0/g
Salmonella	0/25 g

2. *Residues*

Elements	Limit
As	1 ppm
Pb	5 ppm
Cd	0,5 ppm
Hg	0,15 ppm
Cr	10 ppm
Cu	30 ppm
Zn	50 ppm
Moisture (105 ºC)	15 %
Ash (550 ºC)	2 %
SO_2 (Reith Williems)	50 ppm
H_2O_2 (European Pharmacopia 1986 (V_2O_2))	10 ppm

▼**M10**

VI. **Packaging, storage and transport**

1. Gelatine intended for human consumption must be wrapped, packaged, stored and transported under satisfactory hygiene conditions, in particular:
   — a room must be provided for storing, wrapping and packaging materials,
   — wrapping and packaging must take place in a room or in a place intended for that purpose.
2. Wrappings and packages containing gelatine must:
   — bear an identification mark giving the following particulars:

     the name or initial letter or letters of the consigning country in printed capitals, i.e.: AT-B-DK-D-EL-E-F-FI-IRL-I-L-NL-P-SE-UK, followed by the registration number of the establishment and one of the following sets of initials: CE-EC-EF-EG-EK-EY

     and
   — carry the words ‘Gelatine for human consumption’.
3. Gelatine must be accompanied during transportation by a commercial document, in accordance with Article 3(A)(9)(a) of Directive 77/99/EEC, which must bear the words ‘Gelatine for human consumption’ and the date of preparation.

VII. **Importation of gelatine from third countries**

A. Member States shall ensure that gelatine destined to human consumption is imported only if:
   — it comes from third countries which appear on the list of Part XIII of the Annex to Commission Decision 94/278/EC [1],
   — it comes from establishments meeting the conditions laid down in Part I of this chapter,
   — it has been produced from raw material which met the requirements of Parts II and III of this chapter,
   — it has been manufactured in compliance with the conditions set out in Part IV of this chapter,
   — it satisfies the criteria of Part V and the requirements of part VI.1 of this chapter,
   — it bears on its wrappings and packages an identification mark giving the following particulars:

     the ISO Code reference of the country of origin followed by the registration number of the establishment

     and
   — it is accompanied by a certificate that conforms to the model laid down in accordance with the procedure provided for in Article 18 of this Directive.

B. In accordance with the procedure of Article 18 of this Directive, the Commission may recognise the health measures applied by a third country to the production of gelatine for human consumption, as offering guarantees equivalent to those applied for putting on the market in the Community, if the third country supplies objective proof in this respect.

   When the Commission recognises such equivalence of the health measures of a third country, it shall adopt in accordance with the same procedure, the conditions governing the importation of gelatine for human consumption including the health certificate which must accompany the product.

[1] OJ L 120, 11.5.1994, p. 44.

▼M10

VIII. **Model of commercial document for raw material destined to the production of gelatine for human consumption**

COMMERCIAL DOCUMENT

For raw material destined to the production of gelatine for human consumption

Number of the commercial document: .....

I. **Identification of the raw material**

Nature of the raw material: .....

Raw material derived from the following animal species: .....

.....

Net weight: .....

Identification mark (pallet or container): .....

II. **Origin of the raw material** [1]**:**

Slaughterhouse

Address of the establishment: .....

Veterinary approval/registration number: .....

Cutting plant

Address of the establishment: .....

Veterinary approval/registration number: .....

Meat products plant

Address of the establishment: .....

Veterinary approval/registration number: .....

Other animal products plant

Address of the establishment: .....

Veterinary registration number: .....

Wild game processing establishment

Address of the establishment: .....

Veterinary approval number: .....

Fish products plants

Address of the establishment: .....

Veterinary approval/registration number: .....

Centres of collection

Address of the establishment: .....

Veterinary registration number: .....

Tannery

Address of the establishment: .....

Veterinary registration number: .....

Retailshop

Address: .....

[1] Delete as appropriate.

▼**M10**

Premises adjacent to sales points, where the cutting and the storage of meat and poultrymeat is performed for the sole purpose of supplying the final consumer directly

Address: .....

III. **Destination of the raw material**

The raw material will be sent to the following establishment (centre of collection/tannery/gelatine plant) [1]:

Name: .....

Address: .....

IV. **Declaration**

I, the undersigned, declare that I read and understood the provisions of Part II and III of Chapter 4 of Annex II to Directive 92/118/EEC and that [1]:

— hides and skins from farmed ruminant animals, bones, pig skins, poultry skin and tendons and sinews described above are derived from animals which have been slaughtered in a slaughterhouse and whose carcases have been found fit for human consumption following ante and post mortem inspection

and/or

— hides and skins from wild game described above are derived from killed animals whose carcases have been found fit for human consumption following the inspections laid down in Article 3 of Directive 92/45/EEC

and/or

— fish skin and bones described above come from plants manufacturing fish products for human consumption or registered in accordance with Directive 91/493/EEC.

Done at ....., on .....

.....

(Signature of the owner of the plant or its representatives)

[1] Delete as appropriate.

▼B

ANNEX III

I

CONSOLIDATED VERSION OF ANNEXES A AND B TO DIRECTIVE 89/662/EEC

'ANNEX A

VETERINARY LEGISLATION

CHAPTER I

— Council Directive 64/433/EEC of 26 June 1964 on health problems affecting intra-Community trade in fresh meat (OJ No 121, 29. 7. 1964, p. 2012/64).

— Council Directive 71/118/EEC of 15 February 1971 on health problems affecting trade in fresh poultrymeat (OJ No L 55, 8. 3. 1971, p. 23).

— Council Directive 72/461/EEC of 12 December 1972 on health problems affecting intra-Community trade in fresh meat (OJ No L 302, 31. 12. 1972, p. 24).

— Council Directive 77/99/EEC of 21 December 1976 on health problems affecting intra-Community trade in meat products (OJ No L 26, 31. 1. 1977, p. 85).

— Council Directive 80/215/EEC of 22 January 1980 on animal health problems affecting intra-Community trade in meat products (OJ No L 47, 21. 2. 1980, p. 4).

— Council Directive 88/657/EEC of 14 December 1988 laying down the requirements for the production of, and trade in, minced meat, meat in pieces of less than 100 grams and meat preparations (OJ No L 382, 31. 12. 1988, p. 3).

— Council Directive 89/437/EEC of 20 June 1989 on hygiene and health problems affecting the production and the placing on the market of egg products (OJ No L 212, 22. 7. 1989, p. 87).

— Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products (OJ No L 46, 19. 2. 1991, p. 1).

— Council Directive 91/492/EEC of 15 July 1991 laying down the health conditions for the production and the placing on the market of live bivalve molluscs (OJ No L 268, 24. 9. 1991, p. 1).

— Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and the placing on the market of fishery products (OJ No L 268, 24. 9. 1991, p. 15).

— Council Directive 91/494/EEC of 26 June 1991 on animal health conditions governing intra-Community trade in and imports from third countries of fresh poultrymeat (OJ No L 268, 24. 9. 1991, p. 35).

— Council Directive 91/495/EEC of 27 November 1991 concerning public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat (OJ No L 268, 24. 9. 1991, p. 41).

— Council Directive 92/45/EEC of 16 June 1992 on public health and animal health problems relating to the killing of wild game and the placing on the market of wild-game meat (OJ No L 268, 14. 9. 1992, p. 35).

— Council Directive 92/46/EEC of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products (OJ No L 268, 14. 9. 1992, p. 1).

CHAPTER II

— 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 (with the exception of pathogens).

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ANNEX B

PRODUCTS NOT SUBJECT TO COMMUNITY HARMONIZATION, BUT TRADE IN WHICH WOULD BE SUBJECT TO THE CHECKS PROVIDED FOR BY THIS DIRECTIVE

Other products of animal origin included neither in Annex B to this Directive nor in the Annex to Directive 90/425/EEC: these products will be defined under the procedure laid down in Article 18.'

II

CONSOLIDATED VERSION OF ANNEXES A AND B TO DIRECTIVE 90/425/EEC

'ANNEX A

CHAPTER I

VETERINARY LEGISLATION

Section 1

— Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ No 121, 29. 7. 1964, p. 1977/64).

— Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra-Community trade in and imports of deep-frozen semen of domestic animals of the bovine species (OJ No L 194, 22. 7. 1988, p. 10).

— Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of embyros of domestic animals of the bovine species (OJ No L 302, 19. 10. 1989, p. 1).

— Council Directive 90/426/EEC of 26 June 1990 on the health policy conditions governing the movement of equidae and their import from third countries (OJ No L 224, 18. 8. 1990, p. 42).

— Council Directive 90/429/EEC of 26 June 1990 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species (OJ No L 224, 18. 8. 1990, p. 62).

— Council Directive 90/539/EEC of 15 October 1990 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs (OJ No L 303, 31. 10. 1990, p. 6).

— Council Directive 90/667/EEC of 27 November 1990 laying down the veterinary rules for the disposal and processing of animal waste, for its placing on the market and for the prevention of pathogens in feedstuffs of animal or fish origin and amending Directive 90/425/EEC (OJ No L 363, 27. 12. 1990, p. 51).

— Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products (OJ No L 46, 19. 2. 1991, p. 1).

— Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals (OJ No L 46, 19. 2. 1991, p. 19).

— Council Directive 91/628/EEC of 19 November 1991 on the protection of animals during transport and amending Directives 90/425/EEC and 91/496/EEC (OJ No L 340, 11. 12. 1991, p. 17).

Section 2

Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) (1) to Directive 90/425/EEC (OJ No L 268, 14. 9. 1992, p. 54).

— For pathogens:

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

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Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC.

CHAPTER II

ZOOTECHNICAL LEGISLATION

— Council Directive 77/504/EEC of 25 July 1977 on pure-bred breeding animals of the bovine species (OJ No L 206, 12. 8. 1977, p. 8).

— Council Directive 88/661/EEC of 19 December 1988 on the zootechnical standards applicable to breeding animals of the porcine species (OJ No L 382, 31. 12. 1988, p. 36).

— Council Directive 89/361/EEC of 30 May 1989 concerning pure-bred breeding sheep and goats (OJ No L 153, 8. 6. 1989, p. 30).

— Council Directive 90/427/EEC of 26 June 1990 on the zootechnical and genealogical conditions governing intra-Community trade in equidae (OJ No L 224, 18. 8. 1990, p. 55).

— Council Directive 91/174/EEC of 25 March 1991 laying down zootechnical and pedigree requirements for the marketing of pure-bred animals (OJ No L 85, 5. 4. 1991, p. 37).

▼B

ANNEX B

ANIMALS AND PRODUCTS NOT SUBJECT TO HARMONIZATION BUT TRADE IN WHICH WILL BE SUBJECT TO THE CHECKS PROVIDED FOR IN THIS DIRECTIVE

CHAPTER I

Veterinary legislation — other live animals not listed in Annex A, Chapter I.

CHAPTER II

Veterinary legislation — semen, ova and embryos not listed in Annex A, Chapter I.'