ANNEX VIII

REQUIREMENTS FOR THE PLACING ON THE MARKET OF PETFOOD, DOGCHEWS AND TECHNICAL PRODUCTS

CHAPTER I

Requirements for the approval of petfood and technical plants

Plants producing petfood, dogchews and technical products, other than organic fertilizers, soil improvers and fat derivatives derived from Category 2 material, must fulfil the following requirements:

1. they must have adequate facilities for storing and treating incoming material in complete safety; and

2. they must have adequate facilities for disposing of unused animal by-products remaining after the production of the products in accordance with this Regulation, or this material must be sent to a processing plant or to an incineration or co-incineration plant in accordance with this Regulation.

CHAPTER II

Requirements for petfood and dogchews

A. Raw material

[F1 1. The only animal by-products that may be used to produce petfood and dogchews are those referred to in Article 6(1)(a) to (j). However, raw petfood may only be manufactured from animal by-products referred to in Article 6(1)(a) or Article 6(1)(b).]

Textual Amendments

F1 Substituted by Commission Regulation (EC) No 829/2007 of 28 June 2007 amending Annexes I, II, VII, VIII, X and XI to Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards the placing on the market of certain animal by-products (Text with EEA relevance).

B. Processing standards

2. Canned petfood must be subjected to heat treatment to a minimum Fc value of 3.

3. Processed petfood other than canned petfood must be subjected to a heat treatment of at least 90 ^{o}C throughout its substance. After treatment, every precaution must be taken to ensure that the product is not exposed to contamination. The product must be packed in new packaging.

[F1 4. Dogchews must be subjected to a treatment during processing sufficient to destroy pathogenic organisms, including salmonella. After that treatment, every precaution must be taken to ensure that such dogchews are not exposed to contamination. The dogchews must be packed in new packaging.]

5. Raw petfood must be packed in new packaging preventing any leakage. Effective steps must be taken to ensure that the product is not exposed to contamination throughout the production chain and up to the point of sale. The wording 'petfood only' must be visibly and legibly displayed on the packaging.

[F2 6. Random samples must be taken during production and/or during storage (before dispatch) to verify compliance with the following standards:

Salmonella: absence in 25 g, n = 5, c = 0, m = 0, M = 0.

Enterobacteriaceae: n = 5, c = 2, m = 10, M = 300 in 1 g

Where:

n	=	number of samples to be tested;
m	=	threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not exceed m;
M	=	maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more samples is M or more; and
c	=	number of samples the bacterial count of which may be between m and M, the sample still being considered acceptable if the bacterial count of the other samples is m or less.

However, for canned petfood that has undergone the heat treatment referred to in paragraph 2, sampling and testing for *Salmonella* and *Enterobacteriaceae* may not be necessary.]

Textual Amendments

F2 Substituted by Commission Regulation (EC) No 808/2003 of 12 May 2003 amending Regulation (EC) No 1774/2002 of the European Parliament and of the Council laying down health rules concerning animal by-products not intended for human consumption (Text with EEA relevance).

C. Importation

7. Member States must authorise importation of petfood and dogchews if they:

(a) come from third countries that appear on the list in Part X of Annex XI;

(b) come from petfood plants approved by the competent authority of the third country meeting the specific conditions laid down in this Regulation;

(c) have been produced in accordance with this Regulation;

(d) are accompanied:

(i) in the case of canned petfood, by a certificate that conforms to the model laid down in Chapter 3(A) of Annex X,

(ii) in the case of processed petfood other than canned petfood, by a certificate that conforms to the model laid down in Chapter 3(B) of Annex X,

(iii) in the case of dogchews, by a certificate that conforms to the model laid down in Chapter 3(C) of Annex X, or

(iv) in the case of raw petfood, by a certificate that conforms to the model laid down in Chapter 3(D) of Annex X.

CHAPTER III

Requirements for manure, processed manure and processed manure products

I. Unprocessed manure

A. Trade

1.

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

(i) from an area which is not subject to restrictions by virtue of a serious transmissible disease, and

(ii) intended for application, under the supervision of the competent authorities, to land forming part of a single holding located on both sides of the border of two Member States.

(b) However, the competent authority may grant specific approval for the introduction on to its territory of:

(i) manure intended for processing in a technical plant or a biogas plant or in a composting plant approved by the competent authority in accordance with this Regulation with a view to the manufacture of the products referred to under Section II below. The competent authority must take account of the origin of the manure when approving such plants; or

(ii) manure intended for applying to land on a holding. Such trade can only occur with the consent of the competent authorities of both the Member States of origin and destination. When considering giving consent, the competent authorities must have particular regard to the origin of the manure, its destination and animal health and safety considerations.

A health certificate conforming to a model laid down under the procedure referred to in Article 33(2) must accompany the manure in such cases.

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;

(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 15(2) of Directive 90/539/EEC[(1)]; and

(c) a health certificate conforming to a model laid down under the procedure referred to in Article 33(2) must accompany the manure.

[[F1]3. Unprocessed manure of equidae which is traded must not originate from a holding subject to animal health restrictions pertaining to glanders, vesicular stomatitis, anthrax or rabies in accordance with Article 4 (5) of Directive 90/426/EEC.**]**

B. Importation

[[F1]4. The importation of unprocessed manure is prohibited.**]**

II. Processed manure and processed manure products

A. Placing on the market

[F3 5. The placing on the market of processed manure and processed manure products shall be subject to the following conditions set out in points (a) to (e):

(a) They must come from a technical plant, a biogas plant or a composting plant approved by the competent authority in accordance with this Regulation.

(b) They must have been subjected to a heat treatment process of at least 70 °C for at least 60 minutes and they must have been subjected to reduction in spore-forming bacteria and toxic formation.**]**

(c) **[**F3 However, the competent authority may authorise the use of other standardised process parameters than those described in (b) provided an applicant demonstrates that such parameters ensure minimising of biological risks. This demonstration shall include a validation, which shall be carried out as follows:

(i) Identification and analysis of possible hazards including the impact of input material, based on a full definition of the processing conditions, and a risk assessment, which evaluates how the specific processing conditions are achieved in practice under normal and atypical situations.

(ii) Validation of the intended process

by measuring the reduction of viability/infectivity of endogenous indicator organisms during the process, where the indicator is:

— consistently present in the raw material in high numbers,

— not less heat resistant to the lethal aspects of the treatment process, but also not significantly more resistant than the pathogens for which it is being used to monitor,

— relatively easy to quantify and relatively easy to identify and confirm;

or

by measuring the reduction of viability/infectivity, during exposure, of a well-characterised test organism or virus introduced in a suitable test body into the starting material.

(iii) The validation referred to in point (ii) must demonstrate that the process achieves the following overall risk reduction:

— for thermal and chemical processes by reduction of *Enterococcus faecalis* by at least 5 log10 and by reduction of infectivity titre of thermo resistant viruses such as *parvovirus*, where they are identified as a relevant hazard, by at least 3 log10,

— for chemical processes also by reduction of resistant parasites such as eggs of *ascaris sp.* by at least 99,9 % (3 log10) of viable stages.

(iv) Designing a complete control programme including procedures for monitoring the process.

(v) Measures ensuring continuous monitoring and supervision of the relevant process parameters fixed in the control programme when operating the plant.

Details on the relevant process parameters used in a plant as well as other critical control points must be recorded and maintained so that the owner, operator or their

representative and the competent authority can monitor the operation of the plant. Records must be made available to the competent authority on request.

Information relating to a process authorised under this point must be made available to the Commission on request.**]**

(d) **[**[F3]Representative samples of the manure taken during or immediately after processing at the plant in order to monitor the process must comply with the following standards:

Escherichia coli: n = 5, c = 5, m = 0, M = 1 000 in 1 g;

or

Enterococaceae: n = 5, c = 5, m = 0, M = 1 000 in 1 g;

and

Representative samples of the manure taken during or on withdrawal from storage at the technical, biogas or composting plant must comply with the following standards:

Salmonella: absence in 25 g: n = 5; c = 0; m = 0; M = 0

where:

n	=	number of samples to be tested;
m	=	threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not exceed m;
M	=	maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more samples is M or more; and
c	=	number of samples the bacterial count of which may be between m and M, the sample still being considered acceptable if the bacterial count of the other samples is m or less.

Processed manure or processed manure products not complying with the above requirements shall be regarded as unprocessed;

(e) They must be stored in such a way that once processed contamination or secondary infection and dampness is minimised. They must therefore be stored in:

(i) well-sealed and insulated silos, or

(ii) properly sealed packs (plastic bags or ‘big bags’).**]**

Textual Amendments

F3 Substituted by Commission Regulation (EC) No 208/2006 of 7 February 2006 amending Annexes VI and VIII to Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards processing standards for biogas and composting plants and requirements for manure (Text with EEA relevance).

B. Importation

6. Member States must authorise importation of processed manure and processed manure products if they:

(a) come from third countries that appear on the list in Part IX of Annex XI;

(b) come from a plant approved by the competent authority of the third country meeting the specific conditions laid down in this Regulation;

(c) satisfy the requirements of paragraph 5 above; and

(d) **[**[F1]are accompanied by a health certificate that conforms to the model laid down in Chapter 17 of Annex X.**]**

III. Guano

7. The placing on the market of 'guano' is not subject to any animal health conditions.

[[F4]CHAPTER IV

[[F5]Requirements for blood and blood products used for technical purposes, excluding the serum of equidae and excluding intermediate products as referred to in Article 1 of Commission Regulation (EC) No 2007/2006**]**

A. Importation

1. Imports of blood are subject to the requirements laid down in Chapter XI.

2. Member States must authorise importation of blood products if they:

(a) come from third countries that appear on the list in part VI of Annex XI;

(b) come from a plant approved by the competent authority of the third country meeting the specific conditions laid down in this Regulation; and

(c) are accompanied by a health certificate that conforms to the model set out in Chapter 4 C of Annex X; and

3. Member States must authorise importation of blood products if they originate in a third country or regions thereof where:
either:

(a) in the case of blood products derived from ruminant animals:

(i) the animals and the products come from a region where no case of foot-and-mouth disease, vesicular stomatitis, rinderpest, peste des petits ruminants, Rift Valley fever, African horse sickness and bluetongue[(2)] has been recorded for 12 months and in which vaccination has not been carried out against those diseases for at least 12 months in the susceptible species and from which imports of ruminant animals of the specified species are authorised pursuant to Community legislation. The blood from which such products are manufactured must have been collected:

— in slaughterhouses approved in accordance with Community legislation,

— from live animals in facilities approved in accordance with Community legislation; or

— in slaughterhouses approved and supervised by the competent authority of the third country. In this case, the

Commission and Member States must be notified of the address and approval number of such slaughterhouse or the certificate shall indicate this information;

or

(ii) the products have undergone one of the following treatments guaranteeing the absence of pathogens of the ruminant diseases referred to in subparagraph (i):

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

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

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

— heat treatment of at least 90 °C throughout their substance, followed by an effectiveness check, or

— any other treatment provided for in accordance with the procedure referred to in Article 33(2);

(iii) by way of derogation from point (ii) above, a Member State may allow import from countries where sero-positive bluetongue animals are present, of blood and blood products intended for technical purposes including pharmaceuticals, *in vitro* diagnosis and laboratory reagents, provided that the approved technical plant of final destination is situated in the same Member State; the consignment must go directly to that plant and all precautions including safe disposal of waste, unused or surplus material must be taken to avoid risks of spreading diseases to animals or humans;

or

(b) in the case of blood products derived from animals belonging to the taxa Proboscidae and Artiodactyla, and their crossbreeds, other than ruminants:

(i) the animals and the products come from a region where no case of foot-and-mouth disease, swine vesicular disease, African horse sickness, classical swine fever, African swine fever, rinderpest, peste des petits ruminants, 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;

or

(ii) the products have undergone one of the following treatments guaranteeing the absence of pathogens of the diseases referred to in subparagraph (i):

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

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

— heat treatment of at least 90 °C throughout their substance, followed by an effectiveness check, or

— any other treatment provided for in accordance with the procedure referred to in Article 33(2).

4. The specific conditions relating to imports of products for use *in vitro* diagnosis and laboratory reagents may be laid down, where necessary, under the procedure referred to in Article 33(2).**]**

Textual Amendments

F4 Substituted by Commission Regulation (EC) No 668/2004 of 10 March 2004 amending certain Annexes to Regulation (EC) No 1774/2002 of the European Parliament and of the Council, as regards the importation from third countries of animal by-products (Text with EEA relevance).

F5 Substituted by Commission Regulation (EC) No 2007/2006 of 22 December 2006 implementing Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards the importation and transit of certain intermediate products derived from Category 3 material intended for technical uses in medical devices, in vitro diagnostics and laboratory reagents and amending that Regulation (Text with EEA relevance).

CHAPTER V

Requirements for serum of equidae

A. Raw material

1. Serum must:

(a) come from equidae which show no signs of the serious transmissible diseases referred to in Directive 90/426/EEC[(3)] or of any other serious transmissible disease to which equidae are susceptible; and

(b) have been obtained in bodies or centres not subject to health restrictions pursuant to that Directive.

B. Importation

2. Member States must authorise the import of serum of equidae if:

(a) **[**[F4]it comes from equidae born and raised in a third country that appears on the list of part XIII of Annex XI;**]**

(b) it was obtained, processed and dispatched in conformity with the following conditions:

(i) it comes from a country where the following diseases are compulsorily notifiable: African horse sickness, dourine, glanders, equine encephalomyelitis (all types including VEE), equine infectious anaemia, vesicular stomatitis, rabies, anthrax;

(ii) it was obtained, under the supervision of a veterinarian, from equidae which, at the time of collection, were free from clinical signs of infectious disease;

(iii) it was obtained from equidae that have remained since birth in the territory or, in case of official regionalisation according to Community legislation, in parts of the territory of a third country in which:

— Venezuelan equine encephalomyelitis had not occurred during the last two years,

— dourine had not occurred during the last six months, and

— glanders had not occurred during the last six months;

(iv) it was obtained from equidae that had never been present on a holding that had been subject to prohibition for animal health reasons or where:

— in the case of equine encephalomyelitis, the date on which all the equidae suffering from the disease were slaughtered was at least six months before the date of collection,

— in the case of infectious anaemia, all the infected animals had been slaughtered and the remaining animals showed a negative reaction to two Coggins tests carried out three months apart,

— in the case of vesicular stomatitis, the prohibition was lifted at least six months before the date of collection,

— in the case of rabies, the last recorded case was at least a month before the date of collection,

— in the case of anthrax, the last recorded case was at least 15 days before the date of collection, or

— all the animals of species susceptible to the disease located on the holding were slaughtered and the premises disinfected, at least 30 days before the date of collection (or, in the case of anthrax, at least 15 days before);

(v) it has undergone all precautions to avoid contamination with pathogenic agents during production, handling and packaging;

(vi) it was packed in sealed impermeable containers clearly labelled ‘serum from equidae’ and bearing the registration number of the establishment of collection;

(c) it comes from a plant approved by the competent authority of the third country meeting the specific conditions laid down in this Regulation; and

(d) **[**[F4]it is accompanied by a health certificate that conforms to the model set out in Chapter 4(A) of Annex X**]**

CHAPTER VI

Requirements for hides and skins of ungulates

A. Scope

1. The provisions of this Chapter do not apply:

(a) **[**[F1]to hides and skins of ungulates complying with the requirements of Regulation (EC) No 853/2004 of 29 April 2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin[(4)];**]**

(b) to hides and skins of ungulates having undergone the complete process of tanning;

(c) to 'wet blue';

(d) to 'pickled pelts'; and

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

2. Within the scope defined in paragraph 1, the provisions of this Chapter apply to fresh, chilled and treated hides and skins. For the purpose of this Chapter, 'treated hides and skins' means hides and skins that have been:

(a) dried;

(b) dry-salted or wet-salted for at least 14 days prior to dispatch;

(c) salted for seven days in sea salt with the addition of 2 % of sodium carbonate;

(d) dried for 42 days at a temperature of at least 20 ^{o}C; or

(e) preserved by a process other than tanning specified in accordance with the procedure referred to in Article 33(2).

B. Trade

[[F1]3. Trade in fresh or chilled hides and skins is subject to the same health conditions as those applicable to fresh meat pursuant to Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption[(5)].**]**

4. Trade in treated hides and skins is authorised on condition that the commercial document provided for in Annex II accompanies each consignment and attests that:

(a) the hides and skins have been treated in accordance with paragraph 2; and

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

C. Importation

5. Member States must authorise the import of fresh or chilled hides and skins if:

(a) they have been obtained from animals referred to in Article 6(1)(b) or (c);

(b) **[**[F4]**[**[F1]they come from a third country or, in the case of regionalisation in accordance with Community legislation, from a part of a third country, appearing on the list set out in Part XIV(A) of Annex XI and which, as appropriate to the species concerned:**]**

(i) for at least 12 months before dispatch, has been free from the following diseases:

— classical swine fever,

— African swine fever, and

— rinderpest, and

(ii) has been free for at least 12 months before dispatch from foot-and-mouth disease and where, for 12 months before dispatch, no vaccination has been carried out against foot-and-mouth disease;**]**

(c) they have been obtained from:

(i) animals that have remained in the territory of the country of origin for at least three months before being slaughtered or since birth in the case of animals less that three months old,

(ii) in the case of hides and skins from bi-ungulates, animals that come from holdings in which there has been no outbreak of foot-and-mouth disease in the previous 30 days, and around which within a radius of 10 km there has been no case of foot-and-mouth disease for 30 days,

(iii) in the case of hides and skins from swine, animals that come from holdings in which there has been no outbreak of swine vesicular disease in the previous 30 days, or of classical or African swine fever in the previous 40 days, and around which within a radius of 10 km there has been no case of these diseases for 30 days, or

(iv) animals that have passed the ante-mortem health inspection at the slaughterhouse during the 24 hours before slaughter and have shown no evidence of foot-and-mouth disease, rinderpest, classical swine fever, African swine fever or swine vesicular disease;

(d) they have undergone all precautions to avoid recontamination with pathogenic agents; and

(e) a certificate conforming to the model laid down in Chapter 5(A) of Annex X accompanies them.

6. Member States must authorise the import of treated hides and skins if:

(a) they have been obtained from animals referred to in Article 6(1)(b), (c) or (k);

(b) **[**[F1]they come either from:

(i) a third country or, in the case of regionalisation in accordance with Community legislation, from a part of a third country, appearing on the list set out in Part XIV(B) of Annex XI from which imports of fresh meat of the corresponding species are authorised and they have been treated in accordance with paragraph 2(a), (b) and (c) of A; or

(ii) a third country appearing on the list set out in Part XIV(B) of Annex XI and they have been treated in accordance with paragraph 2(c) or (d) of A; or

(iii) equidae or ruminant animals from a third country appearing on the list set out in Part XIV(C) of Annex XI, which have been treated in accordance with paragraph 2(a), (b) and (c) of A and after treatment have been kept separate for at least 21 days;

(c) in the case of salted hides and skins transported by ship, they have been treated in accordance with paragraphs 2(b) or (c) of A and have been kept separated after treatment during transportation for at least 14 days in the case of paragraph (b) or seven days in the case of paragraph (c) before importation and the health

certificate accompanying the consignment attests such treatment and the duration of the transportation; and

(d) a health certificate conforming to the model health certificate laid down in Chapter 5(B) of Annex X, or, in the case of hides and skins referred to in paragraph 6(b)(iii) of C of this Annex, an official declaration conforming to the model laid down in Chapter 5 (C) of Annex X, accompanies them.**]**

7. Fresh, chilled or treated hides and skins of ungulates must be imported in containers, road vehicles, railway wagons or bales sealed by the competent authority of the third country of dispatch.

CHAPTER VII

Requirements for game trophies

A. Raw material

1. Without prejudice to the measures adopted pursuant to Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein[6], game trophies:

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

(b) of species other than ungulates and birds,

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

2. Without prejudice to the measures adopted pursuant to Regulation (EC) No 338/97, game trophies of ungulates and birds not having undergone the treatment mentioned in paragraph 1(a) are subject to the following conditions. They must:

(a) 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

(b) comply with the conditions laid down in paragraphs 3 or 4 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.

3. In respect of game trophies consisting solely of bone, horns, hooves, claws, antlers or teeth, the trophies must:

(a) 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;

(b) have been disinfected with a product authorised by the competent authority, in particular with hydrogen peroxide where parts consisting of bone are concerned;

(c) 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; and

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

4. In respect of game trophies consisting solely of hides or skin, the trophies must:

(a) 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 that tanning approved in accordance with the procedure referred to in Article 33(2);

(b) 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; and

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

B. Importation

5. Member States must authorise the importation of treated game trophies from birds and ungulates, being solely bones, horns, hooves, claws, antlers, teeth, hides or skins, from third countries if:

(a) a certificate that conforms to the model laid down in Chapter 6(A) of Annex X accompanies them; and

(b) they comply with the requirements of paragraphs 3 and 4. However, in the case of dry-salted or wet-salted skins transported by ship, the skins need not be salted 14 days before dispatch, provided that they are salted for 14 days before importation**[**[F4]**;]**

(c) **[**[F6]they come from a third country appearing on the list set out in part XV (A) of Annex XI.**]**

Textual Amendments

F6 Inserted by Commission Regulation (EC) No 668/2004 of 10 March 2004 amending certain Annexes to Regulation (EC) No 1774/2002 of the European Parliament and of the Council, as regards the importation from third countries of animal by-products (Text with EEA relevance).

6. Member States must, in accordance with the requirements of paragraph 7, authorise the importation of game trophies from birds and ungulates consisting of entire anatomical parts, not having been treated in any way, from third countries:

(a) **[**[F4]that appear on the lists set out in part XV(B) and (C) of Annex XI as appropriate; and**]**

(b) from which the importation of all categories of fresh meat of the corresponding species is authorised.

7. Member States must authorise importation of the game trophies referred to in paragraph 6 if:

(a) they 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;

(b) they were 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; and

(c) a certificate conforming to the model laid down in Chapter 6(B) of Annex X accompanies them.

CHAPTER VIII

Requirements for wool, hair, pig bristles, feathers and parts of feathers

A. Raw material

[F2 1.

(a) Unprocessed wool, unprocessed hair, unprocessed pig bristles and unprocessed feathers and parts of feathers must have been obtained from animals referred to in Article 6(1)(c) or (k). They must be securely enclosed in packaging and dry. However, in the case of unprocessed feather and part of feathers sent directly from the slaughterhouse to the processing plant, the competent authority may allow derogation from the dry requirement, provided that:

(i) all necessary measures are taken to avoid any possible spread of disease;

(ii) the transport takes place in leak-proof containers and/or vehicles which must be cleansed and disinfected immediately after each use; and

(iii) the Member State notifies the Commission when such derogation is given.

(b) Movements of pig bristles from regions in which African swine fever is endemic are prohibited except for pig bristles that have:

(i) been boiled, dyed or bleached; or

(ii) 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 may not be regarded as a form of treatment for the purposes of this provision.**]**

2. The provisions of paragraph 1 do not apply to decorative feathers or feathers:

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

(b) in the form of consignments sent to private individuals for non-industrial purposes.

B. Importation

3. Member States must authorise the importation of pig bristles from third countries or, in case of regionalisation according to Community legislation, regions thereof, if:

(a) the pig bristles were obtained from animals originating, and slaughtered in a slaughterhouse, in the country of origin; and

(b) either:

(i) where no case of African swine fever has occurred during the previous 12 months, a certificate conforming to the model laid down in Chapter 7(A) of Annex X accompanies the consignment; or

(ii) where one or more cases of African swine fever have occurred during the previous 12 months, a certificate conforming to the model laid down in Chapter 7(B) of Annex X accompanies the consignment**[**F4**;]**

(c) **[**F6they come from a third country that appears on the list of part VIII of Annex XI as appropriate.**]**

4. **[**F1Member States must authorise the importation of unprocessed wool and hair, if they are:**]**

(a) securely enclosed in packaging and dry; and

(b) sent directly to the technical plant or to an intermediate plant in conditions such that any spread of pathogenic agents is avoided.

[F7**5.** The importation of unprocessed feathers and parts of feathers is prohibited.

Member States must authorise the importation of processed feathers and parts of feathers if:

(a) they are treated decorative feathers, treated feathers carried by travellers for their private use or consignments of treated feathers sent to private individuals for non-industrial purposes; or

(b) they are accompanied by a commercial document stating that the feathers or parts of feathers have been treated with a steam current or by another method ensuring the inactivation of pathogens and are securely enclosed in packaging and dry.**]**

Textual Amendments

F7 Inserted by Commission Regulation (EC) No 829/2007 of 28 June 2007 amending Annexes I, II, VII, VIII, X and XI to Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards the placing on the market of certain animal by-products (Text with EEA relevance).

[F4CHAPTER IX

Requirements for apiculture products

A. Raw material

[F1**1.** Apiculture by-products intended exclusively for use in apiculture must:**]**

(a) not come from an area which is subject of a prohibition order associated with an occurrence of:

(i) American foulbrood (*Paenibacillus larvae larvae*), except where the competent authority has assessed the risk to be negligible, issued a specific authorisation for use only in that Member State, and taken all other necessary measures to ensure no spread of that disease;

(ii) acariosis (*Acarapis woodi* (Rennie), except where the area of destination has obtained additional guarantees in accordance with Article 14(2) of Directive 92/65/EEC[7];

(iii) small hive beetle (*Aethina tumida*); or

(iv) Tropilaelaps spp. (*Tropilaelaps* spp); and

(b) meet the requirements provided for in Article 8(a) of Directive 92/65/EEC.

B. Importation

2. As the small hive beetle and *Tropilaelaps* spp. are not present in the Community, the following additional safeguards concerning importation of apiculture products have to be laid down.

[F1 3. Member States must authorise the importation of apiculture by-products, other than beeswax in the form of honeycomb, intended for use in apiculture if they:

(a) come from third countries that appear on the list in Part XII of Annex XI;

(b) either:

(i) have been subjected to a temperature of –12 °C or lower for at least 24 hours; or

(ii) in the case of wax, the material has been refined or rendered before importation; and

(c) are accompanied by a health certificate that conforms to the model set out in Chapter 13 of Annex X.**]**

[F7 4. Member States must authorise the importation of beeswax for technical purposes, other than beeswax in the form of honeycomb, if it:

(a) has been refined or rendered before importation; and

(b) is accompanied by a commercial document attesting that refinement or rendering.

5. The importation of beeswax in the form of honeycomb shall be prohibited.**]]**

CHAPTER X

Requirements for bones and bone products (excluding bone meal), horns and horn products (excluding horn meal) and hooves and hoof products (excluding hoof meal) intended for use other than as feed material, organic fertilizers or soil improvers

1. Member States must authorise the importation of bones and bone products (excluding bone meal), horns and horn products (excluding horn meal) and hooves and hoof products (excluding hoof meal) to produce technical products if:

(a) the products are dried before export and not chilled or frozen;

(b) 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;

(c) following the document checks provided for in Directive 97/78/EC, the products are conveyed directly to the technical plant**[**F4;**]**

(d) **[**F6they come from a third country appearing on the list set out in part XVII of Annex XI.**]**

2. Each consignment must be accompanied by:

(a) a commercial document stamped by the competent authority supervising the establishment of origin, including the following information:

(i) the country of origin,

(ii) the name of the establishment of production,

(iii) the nature of the product (dried bone/dried bone product/dried horns/dried horn products/dried hooves/dried hoof products), and

(iv) the fact that the product was:

— derived from healthy animals slaughtered in a slaughterhouse, or

— dried for 42 days at an average temperature of at least 20 °C, or

— heated for one hour to at least 80 °C to the core before drying, or

— **[**F4ashed for one hour to at least 800 °C to the core before drying, or**]**

— underwent an acidification process such that the pH was maintained at less than 6 to the core for at least one hour before drying, and

is not intended at any stage to be diverted for any use in food, feed material, organic fertilizers or soil improvers; and

(b) **[**F4a declaration of the importer that conforms to the model laid down in Chapter 16 of Annex X and that must be in at least one official language of the Member State through which the consignment first enters the Community and in at least one official language of the Member State of destination.**]**

3. On dispatch to the Community territory, the material must be enclosed in sealed containers or vehicles or carried in bulk in a ship. If transported in containers, the containers, and in all cases all the accompanying documents, must bear the name and the address of the technical plant.

[F4**4.** Following the border check provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the material must be transported direct to the technical plant.**]**

5. Records must be kept of the quantity and nature of the material, during manufacture, in such a way as to ensure that the material has actually been used for the intended purposes.

[F4CHAPTER XI

[F5Requirements for animal by-products for the manufacture of feed including petfood, and of technical products, excluding intermediate products as referred to in Article 1 of Commission Regulation (EC) No 2007/2006]

Member States must authorise the importation of animal by-products intended for the manufacture of feed including petfood, and for pharmaceutical products and other technical products if they:

1. come from third countries appearing on the lists set out in part VI and VII(A) and (B) of Annex XI as appropriate;

2. consist only of animal by-products referred to in Article 6(1)(a) to (j) and/or, when intended to be used for petfood, material derived from animals treated as referred to in the second paragraph of Article 28;

   [F1however, animal by-products for use in feed for farmed fur animals or for use in raw petfood must consist of animal by-products referred to in Article 6(1)(a) and (b) only;**]**

3. have been deep-frozen at the plant of origin or have been preserved in accordance with Community legislation in such a way to prevent spoiling between dispatch and delivery to the plant of destination;

4. have undergone all precautions to avoid contamination with pathogenic agents;

5. were packed in new packaging preventing any leakage;

6. **[**F1are accompanied by a certificate that conforms to one of the models set out in Chapter 3(D), 3(F) or 8 of Annex X;**]**

7. following the border checks provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, they are transported directly either:

   (a) to a petfood or technical plant, which has given the guarantee that the animal by-products shall be used only for the purpose of producing petfood or technical products as appropriate, as specified by the competent authority if necessary, and shall not leave the plant untreated other than for direct disposal; or

   (b) to an intermediate plant; or

   (c) to an authorised and registered user or collection centre, which has given the guarantee that the animal by-products shall be used only for permitted purposes, as specified by the Competent Authority if necessary;

   and

8.1. in the case of raw material for petfood production derived from animals which have been treated with certain substances prohibited in accordance with Directive 96/22/EC, as referred to in the second paragraph of Article 28 of this Regulation, it shall:

   (a) be marked in the third country before entry into the territory of the Community by a cross of liquefied charcoal or activated carbon, on each outer side of each frozen block, in such a way that the marking covers at

least 70 % of the diagonal length of the side of the frozen block and is at least 10 cm in width;

(b) in the case of material which is not frozen, be marked in the third country before entry into the territory of the Community by spraying it with liquefied charcoal or by applying charcoal powder in such a way that the charcoal is clearly visible on the material;

(c) be transported directly to:

(i) the petfood plant of destination in accordance with point 7(a) above;

or

(ii) an intermediate plant in accordance with point 7(b) above and from there directly to the petfood plant referred to under (i), provided that the intermediate plant:

— only handles material covered by this point 8.1, or

— only handles material destined for a petfood plant as referred to under (i);

and

(d) be manipulated to remove the marking provided for in (a) and (b) only in the petfood plant of destination and only immediately prior to use of the material for the manufacture of petfood;

8.2. where a consignment is made up of raw material, which has been treated as referred to in 8.1 above and other non-treated raw material, all the raw materials in the consignment must be marked as laid down in point 8.1(a) and (b) above.

8.3. the marking provided for in point 8.1(a) and (b) and 8.2 shall remain visible from the dispatch and until the delivery to the petfood plant of destination.**]**

[[F4]CHAPTER XII

Rendered fats from category 2 materials for oleochemical purposes

A. Processing standards

1. Rendered fats derived from category 2 material for oleochemical purposes must be produced using methods 1 to 5 as referred to in Annex V, Chapter III.

2. Rendered fats derived from ruminant animals must be purified in such a way that the maximum level of remaining total insoluble impurities does not exceed 0,15 % in weight;

B. Importation of rendered fats

3. Member States must authorise the importation of rendered fats derived from category 2 materials, intended to be processed using a method that at least meets the standards of one of the processes described in Annex VI, Chapter III, if it:

(a) comes from a third country that appears on a Community list set out in part IV of Annex XI;

(b) has been produced in accordance with this Regulation; and

(c) is accompanied by a health certificate that conforms to the model set out in Chapter 10(B) of Annex X.

4. The rendered fats must be conveyed by land and/or sea from the country of origin direct to a border inspection post in the Community.

5. Following the checks provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the rendered fats must be conveyed to a category 2 oleochemical plant where they are to be processed into fat derivatives.

6. The health certificate referred to in paragraph 3 must state that:

(i) the rendered fats will not be diverted for any use other than further processing by a method that at least meets the standards of one of the processes referred to in Chapter III of Annex VI; and

(ii) the resulting fat derivatives shall only be used in organic fertiliser or soil improvers or other technical uses, other than in cosmetics, pharmaceuticals and medical devices.

7. The health certificate provided for in paragraph 3 must be presented to the competent authority at the border inspection post at the first point of entry of the goods into the Community, and thereafter a copy must accompany the consignment until their arrival at the plant of destination.

8. Following the checks provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the rendered fats shall be transported directly to the plant of destination.**]**

[[F6]CHAPTER XIII

Fat derivatives

A. Processing standards

1. If rendered fat produced from category 2 material is used for the production of fat derivatives a method that at least meets the standards of one of the processes referred to in Chapter III of Annex VI shall be used.

B. Importation

2. Member States shall authorise the importation of fat derivatives only if a health certificate that conforms to the model set out in Chapters 14(A) or 14(B) of Annex X accompanies each consignment.

3. The health certificate referred to in paragraph 2 must state:

(a) whether or not the fat derivatives derive from category 2 or 3 materials;

(b) in the case of fat derivatives produced from category 2 material, that the products:

(i) have been produced using a method that at least meets the standards of one of the processes referred to in Chapter III of Annex VI; and

(ii) shall only be used in organic fertiliser or soil improvers or other technical uses, other than in cosmetics, pharmaceuticals and medical devices.

4. The health certificate provided for in paragraph 2 must be presented to the competent authority at the border inspection post at the first point of entry of the goods into the Community, and thereafter a copy must accompany the consignment until its arrival at the plant of destination.

5. Following the checks provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the fat derivatives shall be transported directly to the plants of destination.

CHAPTER XIV

Specific requirements for flavouring innards for the manufacture of pet food

The following conditions apply in addition to the requirements for approval laid down in Chapter I.

A. Raw Material

1. Only animal by-products referred to in Article 6(1)(a) to (j) may be used for the production of liquid/dehydrated processed products of animal origin used to enhance the palatability values of pet food.

B. Processing standards

2. Flavouring innards must have been submitted to a treatment method and parameters, which ensure that the product complies with the microbiological standards laid down in Annex VIII, paragraph 6 of Chapter II. After treatment, every precaution must be taken to ensure that the product is not exposed to contamination.

3. The end product must:

(a) be packed in new or sterilised packaging; or

(b) transported in bulk in containers or other means of transport that were thoroughly cleaned and disinfected with a disinfectant approved by the competent authority before use.

C. Importation

4. Member States must authorise the importation of flavouring innards if they:

(a) come from third countries that appear on the list set out in part VII(C) of Annex XI;

(b) come from petfood plants approved by the competent authority of the third country meeting the specific conditions laid down in Article 18;

(c) have been produced in accordance with this Regulation; and

(d) are accompanied by a health certificate that conforms to the model set out in Chapter 3(E) of Annex X.**]**

(**1**) 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 L 303, 31.10.1990, p. 6). Directive as last amended by Commission Decision 2000/505/EC (OJ L 201, 9.8.2000, p. 8).

(**2**) **[**[F4]This includes countries with sero-positive ruminant animals.**]**

(**3**) Council Directive 90/426/EEC of 26 June 1990 on animal health conditions governing the movement and import from third countries of equidae (OJ L 224, 18.8.1990, p. 42). Directive as last amended by Commission Decision 2001/298/EC (OJ L 102, 12.4.2001, p. 63).

(**4**) **[**[F1]OJ L 139, 30.4.2004, p. 55; corrected version (OJ L 226, 25.6.2004, p. 22).**]**

(**5**) **[**[F1]OJ L 18, 23.1.2003, p. 11.**]**

(**6**) OJ L 61, 3.3.1997, p. 1. Regulation as last amended by Commission Regulation No 1579/2001 (OJ L 209, 2.8.2001, p. 14).

(**7**) **[**[F4]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) to Directive 90/425/EEC (OJ L 268, 14.9.1992, p. 54).**]**

Textual Amendments

F1 Substituted by Commission Regulation (EC) No 829/2007 of 28 June 2007 amending Annexes I, II, VII, VIII, X and XI to Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards the placing on the market of certain animal by-products (Text with EEA relevance).

F4 Substituted by Commission Regulation (EC) No 668/2004 of 10 March 2004 amending certain Annexes to Regulation (EC) No 1774/2002 of the European Parliament and of the Council, as regards the importation from third countries of animal by-products (Text with EEA relevance).

Status:
Point in time view as at 24/07/2007.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EC) No 1774/2002 of the European Parliament and of the Council (repealed), ANNEX VIII.