Final Signed
July 20 1999

AGREEMENT
BETWEEN THE UNITED STATES OF AMERICA AND THE EUROPEAN COMMUNITY ON SANITARY MEASURES TO PROTECT PUBLIC AND ANIMAL HEALTH IN TRADE IN LIVE ANIMALS AND ANIMAL PRODUCTS

THE GOVERNMENT OF THE UNITED STATES OF AMERICA

of the one part, and

THE EUROPEAN COMMUNITY

of the other part,

DESIRING to safeguard public and animal health and to facilitate trade in animals and animal products between the United States of America (hereinafter referred to as "the U.S.") and the European Community (hereinafter referred to as "the Community");

RESOLVED to take the fullest account of the risk of spread of animal diseases and the measures put in place to control and eradicate such diseases, and in particular to avoid disruptions to trade;

REAFFIRMING their commitment to the rights and obligations established under the World Trade Organisation Agreement on the Application of Sanitary and Phytosanitary Measures (hereinafter referred to as the "SPS Agreement");

WHEREAS the Parties acknowledge that their systems of sanitary measures are intended to address similar objectives of providing comparable health assurances;

NOTING that the recognition by an importing country of the sanitary measures applied by an exporting country can permit greater efficiency in the utilization of inspection and verification resources;

HAVE DECIDED to conclude this Agreement and to this end have designated respect as their plenipotentiaries:

THE GOVERNMENT OF THE UNITED STATES OF AMERICA

Richard L. MORNINGSTAR
Ambassador,
Head of the Mission of the United States of America to the European Union

THE EUROPEAN COMMUNITY

Kalevi HEMILÄ
Minister for Agriculture and Forestry of the Republic of Finland
President-in-Office of the Council of the European Union

Franz FISCHLER
Member of the Commission of the European Communities

WHO HAVE AGREED AS FOLLOWS:

ARTICLE 1

OBJECTIVE

The objective of this agreement is to facilitate trade in live animals and animal products between the U.S. and the Community by establishing a mechanism for the recognition of equivalence of sanitary measures maintained by a Party consistent with the protection of public and animal health, and to improve communication and cooperation on sanitary measures.

ARTICLE 2

MULTILATERAL OBLIGATIONS

Nothing in this Agreement shall limit the rights or obligations of the Parties under the Agreement establishing the World Trade Organisation and its Annexes, in particular the SPS Agreement.

ARTICLE 3

SCOPE

1. This Agreement shall initially be limited to the sanitary measures applied by either Party to the live animals and animal products listed in Annex I, except as provided for in paragraph 2.

2. Unless otherwise specified under the provisions set out in the Annexes to this Agreement, this Agreement shall not apply to sanitary measures related to food additives, processing aids, flavours, colour additives, sanitary stamps, irradiation (ionisation), contaminants (including pesticides, chemical residues, mycotoxins, natural toxins, physical contaminants and animal drug residues), chemicals originating from the migration of substances from packaging materials; labelling of foodstuffs (including nutritional labelling); feed additives, animal feedingstuffs, medicated feeds and premixes.

3. The Parties may agree to modify this Agreement in the future to extend the scope to other sanitary or phytosanitary measures affecting trade between the Parties.

ARTICLE 4

REGULATORY AUTHORITIES

1. The U.S. – regulatory authority for imports and exports of live animals and animal products is as described in part A of Annex II.

2. The Community – control in veterinary affairs is as described in part B of Annex II.

ARTICLE 5

DEFINITIONS

For the purposes of this Agreement the following definitions shall apply:

(a) sanitary measures means sanitary measures as defined in Annex A, paragraph 1, of the SPS Agreement and falling within the scope of this Agreement. The reference to sanitary measures may cover individual sanitary measures or groups of sanitary measures for product areas, sectors, or parts of sectors, as appropriate;

(b) appropriate level of sanitary protection means the appropriate level of sanitary protection as defined in Annex A, paragraph 5, of the SPS Agreement;

(c) region means "zones" or "regions" as defined in the Animal Health Code of the *Office International des Epizooties (OIE)*, and for aquaculture as defined in the International Aquatic Animal Health Code of the OIE;

(d) Agreement means the entire text of this Agreement and all its Annexes.

ARTICLE 6

ANIMAL HEALTH STATUS

1. The importing Party shall recognise for trade the health status of regions, as determined by the exporting Party, with respect to the animal and aquaculture diseases specified in Annex III.

2. The importing Party shall recognise regionalisation decisions taken by the exporting Party in accordance with the criteria set out in Annex IV as the basis for trade from a Party where an area is affected by one or more of the diseases listed in Annex III.

3. Where a Party considers that it has a special status with respect to a specific disease other than those in Annex III, it may request recognition of this status. The importing Party may also request additional guarantees in respect of imports of live animals and animal products appropriate to the agreed status. The guarantees for specific diseases are specified in Annex V.

The exporting Party shall, if requested by the importing Party, provide full explanation and supporting data for the determinations and decisions covered by this Article. The importing Party may, where necessary for the protection of animal health, invoke the provisions of Article 12.

ARTICLE 7

EQUIVALENCE

1. In reaching a determination whether a sanitary measure maintained by an exporting Party achieves the importing Party's appropriate level of sanitary protection, the Parties shall follow a consultative process that includes the following steps:

(i) identification of the sanitary measure for which recognition of equivalence is sought;

(ii) explanation by the importing Party of the objective of its sanitary measure, including an assessment, as appropriate to the circumstances, of the risk or risks, that the sanitary measure is intended to address, and identification by the importing Party of its appropriate level of sanitary protection;

(iii) demonstration by the exporting Party that its sanitary measure achieves the importing Party's appropriate level of sanitary protection;

(iv) determination by the importing Party whether a sanitary measure achieves its appropriate level of sanitary protection after consideration of various factors, including where appropriate:

(a) risks identified by the importing Party and evidence provided by the exporting Party that its sanitary measures effectively address those risks;

(b) provisions of the exporting Party's legislation and regulations regarding standards, procedures, policies, infrastructure, enforcement and control;

(c) powers of the exporting Party's regulatory authorities and their structure, including their chain of command, *modus operandi*, and resources;

(d) evidence provided by the exporting Party of the efficacy of its enforcement and control programs.

The importing Party may carry out verification, as set out in Article 9, to assist this determination.

2. In carrying out the consultative process described in paragraph 1, and setting the trade conditions referred to in Article 8(2)(b), the Parties shall take account of experience and information already acquired.

3. Work under, or conclusion of, the consultative process for one product area, sector, or part of sector, shall not be dependent upon or delayed by work on any other product area, sector, or part of sector.

4. The final determination whether a sanitary measure maintained by an exporting Party achieves the importing Party's appropriate level of sanitary protection rests solely with the importing Party acting in accordance with its administrative and legislative framework.

ARTICLE 8

STATUS OF CONSULTATIONS

1. Annex V lists the live animals and animal product areas, sectors, or parts of sectors, and, for each area, sector or part thereof, sets forth the status of consultations regarding the recognition of equivalency of a Party's sanitary measures and the applicable trade conditions.

2. (a) With respect to sanitary measures recognised as equivalent for trade purposes at the date of entry into force of this Agreement, each Party, within its responsibilities, shall initiate the necessary legislative and administrative actions within 3 months to implement these recognitions. For sanitary measures that will be recognised as equivalent in the future, each Party shall take prompt and necessary steps to implement the recognitions.

(b) Where the trade conditions specified in Annex V include special conditions required by the importing Party to meet its appropriate level of protection, trade shall take place where the exporting Party meets the importing Party's conditions, without prejudice to the continuing consultative process.

3. The Parties shall carry out the respective actions set out in Annex V, taking into account the target deadlines for each product area, sector, or part of sector, with a view, where possible, to reaching recognition of equivalence, and to facilitate trade.

4. Annex V may be modified in accordance with Articles 14(2) and 16(2) to reflect changes made by each Party in recognitions or trade conditions.

ARTICLE 9

VERIFICATION PROVISIONS

1. The determination of the nature and frequency of checks to be applied to imports of live animals and animal products at external frontiers rests solely with the importing Party. Annex VII contains principles which shall guide such frontier checks.

2. In addition to carrying out checks on imports at the external frontier, the importing Party may verify compliance with the provisions of this Agreement through the application of procedures which may include, but are not limited to:

(a) an assessment of all or part of the exporting Party's total control programme, including, where appropriate, reviews of the exporting Party's inspection and audit programmes; and

(b) on-site checks and inspections.

3. The Community will carry out the verification procedures provided for in paragraph 2. The U.S. agencies identified in Annex II shall facilitate the performance of these verification procedures by the Community.

4. The U.S. agencies identified in Annex II will carry out the verification procedures provided for in paragraph 2. The Community shall facilitate the performance of these verification procedures by those agencies.

5. Upon the mutual consent of the Parties to this Agreement, either Party may:

(a) share the results and conclusions of its verification procedures with countries that are not parties to this Agreement, or

(b) use the results and conclusions of verification procedures carried out by countries that are not parties to this Agreement.

6. Each Party shall carry out the verification procedures in accordance with Annex VI. The Parties may agree to modify Annex VI, taking due account of relevant work carried out by International Organisations.

ARTICLE 10

INFORMATION EXCHANGE

1. The Parties shall exchange information on a uniform and systematic basis to improve communication, to engender mutual confidence, and to demonstrate the efficacy of the programs controlled. Where appropriate, this may be supported by exchanges of officials between the Parties.

2. The Parties shall notify each other of proposals to introduce new sanitary measures or to change existing sanitary measures, and shall provide the opportunity to comment on such proposals.

3. In addition to information on changes in sanitary measures, the Parties shall also exchange information on other relevant topics including:

- current developments affecting trade in live animals and animal products,

- the results of the checks and verification procedures provided for in Article 9.

4. Where a Party establishes, maintains or recognises a scientific committee, commission, expert group or other similar entity competent to study an issue relevant to this Agreement, the Party shall ensure timely consideration of, and response to, relevant scientific papers or studies submitted by the other Party.

5. The Parties agree to establish an appropriate means of exchanging information on rejected import consignments, relevant inspection-related information, and other problem areas concerning public or animal health.

6. The contact points for this information exchange are set out in Annex IX.

ARTICLE 11

NOTIFICATION

1. Each Party shall notify the other:

(a) immediately by oral communication followed within 24 hours in writing: of any serious or significant public or animal health risk, notably including any food control emergencies or situations where there is a clearly identified risk of serious health effects associated with the consumption of animal products;

(b) within 24 hours in writing: of the presence or evolution of any disease listed in Annex III; and

(c) without delay and in writing: of any significant changes in animal health status or of findings of epidemiological importance with respect to diseases other than those listed in Annex III; of changes in preventive policies, including vaccination policies; or, of any non-routine measures taken to protect public health or to control or eradicate animal disease.

2. Such notifications shall be made to the contact points set out in Annex IX.

3. Where either Party has serious concerns regarding a risk to public or animal health, consultations regarding the situation shall, on request, take place as soon as possible, and in any case within 14 days. Each Party shall endeavour in such situations to provide all the information necessary to avoid a disruption in trade, and to reach a mutually acceptable solution consistent with the protection of public or animal health.

ARTICLE 12

SAFEGUARDS

Either Party may take provisional measures necessary for the protection of public or animal health. These measures shall be notified within 24 hours to the other Party, and, on request, consultations regarding the situation shall be held within 14 days. The Parties shall take due account of any information provided through such consultations, and shall endeavour to avoid unnecessary disruption to trade, taking advantage where possible of the provisions of Article 11(3).

ARTICLE 13

OUTSTANDING ISSUES

The principles of this Agreement shall also be applied to address outstanding issues listed in Annex VIII. Modifications shall be made to this Annex and, as appropriate, other Annexes, to take account of progress made and new issues identified.

ARTICLE 14

JOINT MANAGEMENT COMMITTEE

1. A Joint Management Committee (hereinafter referred to as "the Committee"), consisting of representatives of the U.S. and the Community, is hereby established to guide the activities carried out under this Agreement. The Committee shall meet within one year of the entry into force of this Agreement and at least annually thereafter. The Committee may also address issues out of session by correspondence.

2. The Committee shall, at least once a year, review the Annexes to this Agreement. As appropriate, this review will take account of progress made on the continuing consultative process towards the recognition by the importing Party of the equivalence of sanitary measures maintained by the exporting Party and progress in completing the actions set out in Annex V. The Committee may recommend changes to the Annexes.

3. The Parties agree to establish Technical Working Groups, consisting of expert-level representatives of the U.S. and the Community, which shall identify and address technical and scientific issues arising from this Agreement.

When additional expertise is needed, the Parties may also establish ad hoc Technical Working Groups, notably scientific groups, whose membership need not be restricted to representatives of the Parties.

ARTICLE 15

TERRITORIAL APPLICATION

This Agreement shall apply, on the one hand, to the United States in respect of its entire territory, and on the other hand, to the territories in which the Treaty establishing the European Community is applied and under the conditions laid down in that Treaty.

ARTICLE 16

FINAL PROVISIONS

1. This Agreement shall be approved by the Parties in accordance with their respective procedures.

This Agreement shall enter into force on the first day of the month following the date on which the Parties notify each other that the procedures mentioned in the preceding sub-paragraph have been completed.

2. Each Party shall implement the commitments and obligations arising from this Agreement in accordance with its laws and procedures. Any changes to the Annexes to this Agreement that are agreed by the Parties shall be implemented accordingly.

3. Either Party may at any time propose modifications to this Agreement. Either Party may, upon 6 months' notice withdraw from the Agreement.

4. This Agreement shall be drawn up in two copies in the English language, each of these texts being equally authentic.

Done at Brussels on the twentieth day of July in the year one thousand nine hundred and ninety-nine.

For the Government of the
United States of America

Richard L. Morningstar

For the European Community

Karla Hamilton

F. Fischler

LIST OF ANNEXES

ANNEX I

PRODUCT COVERAGE

Tariff Line	General Description (1)
01	Live animals
02	Meat and edible meat offal
03	Fish and crustaceans, molluscs and other aquatic invertebrates
04	Dairy produce; birds' eggs; natural honey; edible products of animal origin not elsewhere specified or included
05	Products of animal origin, not elsewhere specified or included, <u>except</u> for products of human origin
15 01	Lard; other pig and poultry fat, rendered
15 02	Fats of bovine animals, sheep or goats
15 03	Lard stearin, lard oil, oleostearin, oleo-oil and tallow oil
15 04	Fats and oils and their fractions, of fish and marine mammals
15 05	Wool grease and fatty substances derived therefrom (including lanolin)
15 06	Other animal fats and oils and their fractions
15 16 10	Animal fats and oils and their fractions
15 17	Margarine; edible mixtures or preparations of animal or vegetable fats or oils, <u>except</u> for such products consisting solely of vegetable fats or oils or their fractions
15 18	Animal or vegetable fats and oils; inedible mixtures or preparations of animal or vegetable fats or oils or of fractions of different fats or oils of Chapter 15, not elsewhere specified or included, except for such products consisting solely of vegetable fats or oils or their fractions

(1) For definitive description refer to Tariff Code

15 22	Degras; residues resulting from the treatment of fatty substances or animal or vegetable waxes, except for such products consisting solely of material of non-animal origin
16	Preparations of meat, of fish or of crustaceans, molluscs or other aquatic invertebrates
17 02 10	Lactose and lactose syrup
19 01	Malt extract; food preparations of flour, meal, starch or malt extract; food preparations of goods of heading Nos 0401 to 0404, not elsewhere specified or included; except for such products consisting solely of material of non-animal origin
19 02	Pasta, whether or not cooked or stuffed (with meat or other substances) or otherwise prepared; couscous, whether or not prepared; except such products consisting solely of products of non-animal origin
21 04	Soups and broths and preparations therefor; homogenized composite food preparations; except such products consisting solely of products of non-animal origin
21 05	Ice cream and other edible ice, whether or not containing cocoa; except such products consisting solely of products of non-animal origin
21 06	Food preparations not elsewhere specified or included; except such products consisting solely of products of non-animal origin
23 01	Flours, meals and pellets, of meat or meat offal, of fish or of crustaceans, molluscs or other aquatic invertebrates, unfit for human consumption; greaves; except such products consisting solely of products of non-animal origin
23 09	Preparations of a kind used in animal feeding; except such products consisting solely of products of non-animal origin
30 01	Glands and other organs for organo-therapeutic uses; heparin and its salts; other animal substances prepared for therapeutic or prophylactic uses; except such products of human origin
30 02	Animal blood prepared for therapeutic, prophylactic or diagnostic uses; antisera and other blood fractions; vaccines, toxins, cultures of micro-organisms (excluding yeasts) and similar products

31 01	Animal or vegetable fertilisers, except such products consisting solely of products of non-animal origin
35 01	Casein, caseinates and other casein derivatives; casein glues
35 02	Albumins, albuminates and other albumin derivatives
35 03	Gelatin and gelatin derivatives; isinglass; other glues of animal origin, excluding casein glues of heading No 3501
35 04	Peptones and their derivatives; other protein substances and their derivatives, not elsewhere specified or included; hide powder, whether or not chromed
35 07	Enzymes; except such products consisting solely of products of non-animal origin
41 01	Raw hides and skins of bovine or equine animals
41 02	Raw skins of sheep or lambs
41 03	Other raw hides or skins
43 01	Raw furskins
51 01	Wool
51 02	Fine or coarse animal hair
51 03	Waste of wool or of fine or coarse animal hair
51 05	*Wool and fine or coarse animal hair*
97 05	Collections and collectors' pieces of zoological interest

ANNEX II

REGULATORY AUTHORITIES

A. U.S.

I. U.S. Control Authority

The federal agencies listed in this section are responsible for both domestically-produced and imported animals and animal products, unless otherwise noted.

In relation to imports into the U.S., these agencies are responsible for:

- conducting frontier checks provided for in the Agreement;
- carrying out the consultations provided for under Article 7 of the Agreement;
- carrying out the verification procedures provided for in Article 9 of the Agreement; and
- carrying out the information exchange provided for in Article 10, the notifications provided for in Article 11, and the safeguards provided for in Article 12 of the Agreement.

In relation to exports from the U.S., unless otherwise noted, these agencies are responsible for:

- controlling the circumstances of domestic production and processing;

- providing information concerning compliance with agreed upon regulatory requirements;

- providing agreed additional guarantees;

- carrying out the consultations provided for under Article 7 of this Agreement;

- carrying out the information exchange provided for in Article 10, the notifications provided for in Article 11, and the safeguards provided for in Article 12 of the Agreement.

A. CONTROL OF ANIMAL HEALTH

1. Animal Diseases/Pests

(a) Live animals (including apiculture bees), embryos, ova, semen and animal products – U.S. Department of Agriculture/Animal and Plant Health Inspection Service (USDA/APHIS)

(b) Imports of salmonid live fish, gametes and fertilized ova – Department of Interior/Fish and Wildlife Service (DOI/FWS)

(c) Imports of uneviscerated salmonid fish – DOI/FWS

(d) Animal Feed (including Pet Foods)

1. Transmission of disease from feed – USDA/APHIS

2. Adulteration, pesticides, chemical and microbial contamination, food additives, substances "generally recognised as safe" – Food and Drug Administration (FDA)

B. CONTROL OF PUBLIC HEALTH

1. Meat and poultry for human consumption

(a) Fresh meat and products from domesticated, farmed and wild cattle, sheep, swine, goats and equine – U.S. Department of Agriculture/Food Safety and Inspection Service (USDA/FSIS) ([2])

(b) Fresh meat and products from domestic and farmed chickens, turkeys, ducks, geese, and guinea fowl – USDA/FSIS ([3])

(c) Fresh meat and products from wild and farmed game, with the exception of those from IB1(a) and IB1(b) above – (FDA)

(d) Fresh meat and products from species other than above – FDA

([2]) With very limited exceptions, USDA/FSIS has sole jurisdiction for these foods until the time they leave the slaughterhouse. After the meat and products have left the slaughterhouse, USDA/FSIS and FDA share jurisdiction.
FDA is responsible for the approval of veterinary drugs and food additives in meat and poultry.

([3]) See preceding footnote.

(e) Enforcing adulteration provisions of the law and limits for residues of drugs, pesticides, heavy metals, mycotoxins, and other contaminants in food

1. Sampling of fresh meat and animal products and control of the fresh meat and products from domesticated, farmed and wild cattle, sheep, swine, goats, and equine, and for domesticated and farmed chickens (including liquid, frozen and dried egg products), turkeys, ducks, geese, and guinea fowl – USDA/FSIS

2. Sampling of fresh meat and animal products (including animal feed) and control of the fresh meat and products of other species – FDA

2. Eggs and Egg Products

(a) Shell eggs, hard-cooked eggs, ethnic egg delicacies, and imitation egg products – FDA

(b) Shell eggs (including cracks and dirties) for breaking for the production of liquid, frozen, and dried egg products (egg yolks, albumen, or any combination) - USDA/FSIS ([4])

3. Dairy

(a) All dairy products – FDA

([4]) FDA and FSIS share jurisdiction over these products after they have left the processing plant

4. Other Animal-Derived Foods (including Fish and Fishery Products)

(a) All other animal-derived foods – FDA

5. Animal Feed

(a) Adulteration, pesticides, chemical and microbial contamination, food additives, substances "generally recognised as safe" – FDA

II. Competent Authorities for Voluntary Programs

The federal agencies listed in this section are responsible for voluntary inspection and certification programs for domestically-produced animal products.

In relation to exports from the U.S., these agencies are responsible for:

- oversight of the circumstances of domestic production and processing for firms who participate in the voluntary program.

- providing information concerning compliance with agreed upon requirements for firms who participate in the voluntary program.

- providing agreed additional guarantees for firms who participate in the agreed program.

A. ANIMAL HEALTH

1. Non-salmonid fish and other non-mammalian aquatic animals, gametes and fertilised ova – USDA/APHIS, Department of Commerce/National Marine Fisheries Service (Commerce/NMFS)

2. Salmonid live fish, gametes, and fertilised ova – USDA/APHIS, Commerce/NMFS

3. Animal feed (including pet foods) containing fish and fishery products – USDA/APHIS, Commerce/NMFS

B. PUBLIC HEALTH

1. Fresh meat and meat products ([5]) from wild and farmed bison, ostrich, emu, rhea, rabbit, deer, partridge, and quail – USDA/FSIS

2. Snakes for human consumption – Commerce/NMFS

3. Shell eggs – USDA/AMS

4. Cooked omelets made from egg products, diced eggs made from egg products – USDA/FSIS

5. Dairy – USDA/AMS

6. Seafood (including live seafood) – Commerce/NMFS

([5]) These meat products must be made from fresh meat slaughtered under the USDA/FSIS voluntary program.

III. Federal Agencies that Issue Certification

This section lists the U.S. national agencies that issue export certificates agreed to by the U.S. and the EC ([6]). The agency issuing certificates may be the control authority or another national agency that is recognised by the control authority for that purpose. More than one agency may issue certificates for a product.

	DOC/ NMFS	DOI/ FWS	FDA	USDA/ AMS	USDA/ APHIS	USDA/ FSIS
A. ANIMAL HEALTH CERTIFICATIONS						
1. Live animals (including apiculture bees), embryos, ova, semen, and products of animal origin					X	
2. Non-salmonid fish and other non-mammalian aquatic animals, gametes and fertilised ova	X				X	
3. Salmonid live fish, gametes, and fertilised ova	X	X			X	
4. Wild waterfowl		X				
5. Animal feed	X				X	
B. PUBLIC HEALTH CERTIFICATIONS						
1. Meat and poultry for human consumption						
(a) Fresh meat and products from domesticated, farmed and wild cattle, sheep, swine, goats, and equine, and domesticated and farmed chickens, turkeys, ducks, geese, and guinea fowl						X
(b) Snakes	X		X			
(c) Fresh meat and products from species other than above			X			X

([6]) Note that the listing of a product in Section II does not mean that certificates will necessarily be required as part of agreements reached on equivalence. Such decisions will be made on a product-by-product basis.

Public health certifications cont'd	DOC/ NMFS	DOI/ FWS	FDA	USDA/ AMS	USDA/ APHIS	USDA/ FSIS
2. Eggs						
(a) Shell eggs, hard cooked eggs, ethnic egg delicacies, and imitation egg products			X	X		
(b) Liquid, frozen and dried egg products						X
3. Dairy						
(a) Butter, cheese, frozen desserts, and dried milk products			X	X		
(b) Fluid milk			X			
4. Seafood						
(a) Fish and fishery products including fish oil, reptiles (except snakes), snails and amphibians	X		X			
(b) Live fish (including shellfish and molluscs)	X		X			

B. EUROPEAN COMMUNITY

Control is shared between the national services in the individual Member States and the European Commission. In this respect the following applies:

- In terms of exports to the U.S., the Member States are responsible for control of the production circumstances and requirements, including statutory inspections, and issuing health certification attesting to the agreed standards and requirements.

- The European Commission is responsible for overall co-ordination, inspections/audits of inspection systems and the necessary legislative action to ensure uniform application of standards and requirements within the Single European Market.

ANNEX III

LIST OF DISEASES FOR WHICH REGIONAL FREEDOM IS RECOGNISED

Animal diseases

Foot and mouth disease
Swine vesicular disease
Peste de petits ruminants
Contagious caprine pleuropneumonia
Sheep and goat pox
African swine fever
Enterovirus encephalomyelitis
Newcastle Disease
Pseudorabies/Aujeszky's
Vesicular stomatitis
Rinderpest
Contagious bovine pleuropneumonia
Bluetongue
African horse sickness
Classical swine fever
Fowl plague (avian influenza)
Venezuelan Equine Encephalomeyelitis

Aquaculture diseases

The list of aquaculture diseases is to be discussed further by the Parties on the basis of the International Aquatic Animal Health Code of the OIE.

ANNEX IV

ZONING AND REGIONALISATION

The Parties have jointly determined that the following forms the basis for Regionalisation decisions for the diseases listed in accordance with Annex III. Each Party will recognise regionalisation decisions taken in accordance with the standard contained within this Annex.

Animal Diseases

In assessing risk from a given proposed importation of animals or animal products, three sets of factors may be considered:

1. Source risk factors.

2. Commodity risk factors.

3. Destination risk factors.

Source Risk Factors

The primary determinant of the risk of importing disease is the status of the country of origin in respect of the disease in question. However, declarations of disease freedom must be backed up by effective surveillance programmes.

The over-riding consideration in this context, therefore, is the quality of the veterinary infrastructure. No other factors can be assessed without full confidence in the veterinary administration. In particular, its ability to detect and control an outbreak of disease and to provide meaningful certification is crucial.

The ability to detect the presence of disease depends on the surveillance carried out. This surveillance can be active, passive, or both.

Active surveillance implies definitive action intended to identify the presence of disease, such as systematic clinical inspections, ante and post mortem examination, serology on farm or in abattoir, referral of pathological material for laboratory diagnosis, sentinel animals.

Passive surveillance means that the disease must be compulsorily notifiable and that there must be a sufficiently high level of supervision of the animals in order to ensure that the disease will be observed quickly and reported as a suspect. There must also be a mechanism for investigation and confirmation, and a high level of awareness of the disease and its symptoms by farmers and veterinarians.

Epidemio-surveillance may be augmented by voluntary and compulsory herd/flock health programmes, particularly those which ensure a regular veterinary presence on the farm.

Other factors to be considered include:

- disease history
- vaccination history
- controls on movements into the zone, out of the zone and within the zone
- animal identification and recording
- presence of disease in adjacent areas
- physical barriers between zones of differing status
- meteorological conditions
- use of buffer zones (with or without vaccination)
- presence of vectors and/or reservoirs
- active control and eradication programmes (where appropriate)
- ante and post mortem inspection.

On the basis of these factors, a zone may be defined.

The authority with the responsibility for implementing the zoning policy is in the best position to define and maintain the zone. When there is a high level of confidence in that authority, the decisions it makes can be the basis for trade.

The zones so defined may be assigned a risk category.

Possible categories are:

- low/negligible risk
- medium risk
- high risk
- unknown risk.

Calculation of estimates of risk for e.g. live animals may assist in this categorization. Import conditions may then be defined for each category, disease and commodity, individually or in groups.

Low/negligible risk implies that importation may take place based on a simple guarantee of origin.

Medium risk implies that some combination of certification and/or guarantees may be required before or after importation.

High risk implies that importation will only take place under conditions which significantly reduce the risk, e.g. by additional guarantees, testing or treatment.

Unknown risk implies that importation will only take place if the commodity itself is of very low risk, e.g. hides, wool, or under the conditions for "high risk" if the commodity factors warrant.

Commodity Risk Factors

These include:

- is the disease transmissible by the commodity?
- could the agent be present in the commodity if derived from a healthy and/or clinically affected animal?
- can the preceding factor be reduced, e.g. by vaccination?
- what is the likelihood that the commodity has been exposed to infection?
- has the commodity been obtained in such a way as to reduce the risk, e.g. deboning?
- has the commodity been subjected to a treatment which inactivates the agent?

Appropriate tests and quarantine will reduce the risk.

Destination Risk Factors

- presence of susceptible animals
- presence of vectors
- possible vector-free period
- preventative measures such as waste food feeding and animal waste rendering rules
- intended use of product e.g. petfood, human consumption only.

These factors are inherent in or are under the control of the importing country, and some may therefore be modified to facilitate trade. These may, for example, include restricted entry conditions e.g. animals to be confined to a certain vector free region until the incubation period has passed, or canalization systems.

However, destination risk factors will also be taken into account by the infected country with respect to the risk presented by movements from the infected part to the free part of its territory.

Aquaculture Diseases

Pending the development of any specific provisions to be included in this Annex, the basis for Regionalisation decisions for aquaculture diseases will be the International Aquatic Animal Health Code of the OIE.

RECOGNITION OF SANITARY MEASURES

The following glossary applies to the attached Annex V:

Yes (1)	The importing Party agrees that the exporting Party's measures achieve the importing Party's appropriate level of sanitary protection
Yes (2)	The importing Party agrees that the exporting Party's measures, with the special conditions set out, achieve the importing Party's appropriate level of sanitary protection
Yes (3)	Equivalence agreed in principle, subject to satisfactory completion of the actions. Pending completion, trade shall occur on the basis of the special conditions set out
NE	Not evaluated. Trade shall occur on the basis of compliance with the importing Party's requirements.
E	Still evaluating. Trade shall occur on the basis of compliance with the importing Party's requirements.

AI	Avian Influenza
ASF	African Swine Fever
BSE	Bovine Spongiform Encephalopathy
CEM	Contagious Equine Metritis
CFR	Code of Federal Regulations
CSF	Classical Swine Fever (Hog Cholera)
EBL	Enzootic Bovine Leucosis
EC	European Community
EPIA	Egg Products Inspection Act
FFDCA	Federal Food, Drug and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
FMD	Foot and Mouth Disease
IBR	Infectious Bovine Rhinotracheitis
ND	Newcastle Disease

OIE	Office International des Epizooties
PHSA	Public Health Service Act
PM	Post Mortem
ScVC	Scientific Veterinary Committee
SVD	Swine Vesicular Disease
TB	Bovine Tuberculosis
TME	Transmissible Mink Encephalopathy
TSE	Transmissible Spongiform Encephalopathy
U.S.	United States of America
WTO	World Trade Organisation

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
1. Live animals										
Animal health										
- Equidae	90/426 Annex B and C	9 CFR 92	E		EC to submit for each EC laboratory the testing procedures, antigens/ reagents used, audit/quality control program, external control/ laboratory approval programme. Inter-laboratory reference testing and exchange of samples between designated EC and U.S laboratories for CEM, glanders, dourine, piroplasmosis, equine infectious anaemia and equine viral arteritis to be carried out within 3 months of the entry into force of this Agreement. U.S. to consider, within 5 months of the entry into force of this Agreement, withdrawing requirement for post-import quarantine on the bases of results. U.S. to assess EC request on disease status for dourine and glanders within 3 months of EC submission. U.S. to review their CEM and piroplasmosis requirements within 3 months of the entry into force of this Agreement.	9 CFR 71, 75,91	90/426, 92/260, 93/195, 93/196, 93/197, 94/467	E		US to consider identifying horses by passport from 31.12.1997. EC to consider withdrawing requirement for isolation before departure for permanent imports within 6 months of the submission of the final report on VS outbreak.

• Commodity • Species • Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
1. Live animals (contd.) animal health										
• Bovine animals	64/432, 72/462, 90/425	9 CFR 92	E		U.S. to review BSE policy with respect to high and low incidence. U.S. to produce generic conditions for EC	9 CFR 71, 72, 73, 77, 78, 80, 91	72/462	E		EC to review U.S. dossier on bluetongue U.S. to provide details of RB51 brucellosis vaccine, for review by EC EC to produce conditions for U.S.
• Sheep/Goats	91/68	9 CFR 92	E		U.S. to produce generic conditions for EC	9 CFR 54, 71, 79, 77	91/68, 97/231	E		EC to review U.S. dossier on bluetongue U.S. to submit scrapie programme when final review is completed. EC to comment EC to produce conditions for U.S.
• Swine	64/432, 72/462, 90/425	9 CFR 92	E		U.S. to produce generic conditions for EC	9 CFR 71, 76, 77, 78, 85	72/462	E		EC to produce conditions for U.S.
• Dogs and cats	92/65	9 CFR 92	NE				92/65	NE		
• "Balai" animals	92/65	9 CFR 92	NE				92/65	NE		

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· Commodity · Species · Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
2. Live poultry and hatching eggs										
Animal health										
	90/539, 93/342	9 CFR 92	E		U.S. to produce generic conditions	9 CFR 71, 82, 145, 147	90/539, 93/432, 96/482, 96/483	E		
3. Semen										
Animal health										
· Bovine	88/407	9 CFR 98	E		U.S. to produce generic conditions for EC.	9 CFR 71, 77, 78	88/407, 94/577	E		EC to produce conditions to allow use of new elisa test kit for bluetongue EC to consider allowing movement between centres in two approved third countries
· Sheep/Goats	92/65	9 CFR 98	E		U.S. to produce generic conditions for EC.	9 CFR 71, 79	Directive 92/65	NE		
· Porcine	90/429	9 CFR 98	E		U.S. to produce generic conditions for EC.	9 CFR 71, 78, 85	90/429, 93/199	E		EC to examine U.S. request that CSF tests not be required on entry and exit from centres in countries free of the disease.
· Canine	92/65	9 CFR 98	NE				92/65	NE		
· Feline	92/65		NE				92/65	NE		

· Commodity · Species · Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
4. Equine semen, ova and embryos										
Animal health										
· Semen	92/65, 95/307	9 CFR 98	NE			9 CFR 71, 75	92/65, 96/539	NE		

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
4. Equine semen, ova and embryos – animal health – contd.										
- Ova	92/65, 95/294	9 CFR 98	NE			9 CFR 71, 75	92/65, 96/540	NE		
- Embryos	92/65, 95/294	9 CFR 98	NE			9 CFR 71, 75	92/65, 96/540	NE		
5. Embryos										
Animal health										
- Bovine	89/556	9 CFR 98	E		U.S to produce generic conditions for EC. U.S. to review suspension of imports from BSE affected countries.	9 CFR 71, 77, 78	89/556, 92/471	E		
- Ovine/ Caprine	92/65	9 CFR 98	NE				92/65	NE		

· Commodity · Species · Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
6. Fresh meat										
Animal health										
· Ruminants	64/432, 72/461, 72/462	9 CFR 94	Yes 2	Additional certification for bovines from BSE affected countries	U.S. to review rules on BSE with respect to high/low incidence regions	9 CFR 53 (in the case of an outbreak of exotic disease)	72/462, 82/426	Yes 2	3 month residence. Holding freedom from brucellosis for ovines and caprines	
· Equidae	64/432, 72/461, 72/462	9 CFR 94	Yes 1			9 CFR 53	72/462, 82/426	Yes 2	3 month residence	
· Porcine animals	64/432, 72/461, 72/462	9 CFR 94	Yes 1			9 CFR 53	72/462, 82/426	Yes 2	3 month residence. Holding freedom from brucellosis	

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
6. Fresh meat contd.										
Public health										
Ruminants [10] Equidae Porcine Ovine Caprine	64/433, 96/22, 96/23	9 CFR 301-381, 416, 417	Yes 3	Establishments listed in accordance with footnote (7), and fulfilling the relevant provisions of footnote (1).	Equivalency (Yes 2) shall be granted after the U.S. has completed verification of veterinary delivery systems. This process shall be completed within 12 months of the date of entry into force of this Agreement.	9 CFR 301-381, 416, 417	72/462, 93/158, 96/22, 96/23	Yes 3	Establishments listed in accordance with footnote (7), and fulfilling the relevant provisions of footnotes (2), (3) (4) and (5).	The EC shall evaluate the U.S. residue programme, and additional information to be submitted by the U.S., to determine whether it meets the EC level of protection. This evaluation shall be completed within 6 months of the entry into force of this Agreement. The EC shall evaluate the U.S. water standards to determine whether they meet the EC level of protection. This evaluation shall be completed within 6 months of the entry into force of this Agreement. The EC to evaluate a U.S. request, when submitted, on the need for continued trichinae testing of horsemeat.

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
6. Fresh meat - public health - contd.										
										Re footnote 5 (e), the results of the inspections after incision of pig hearts shall be jointly evaluated after 12 months, with a view to determining if modifications should be made to the provisions of footnote 5(e). Equivalency (Yes 2) shall be granted after the EC has completed verification of the application of the specified conditions. This process shall be completed within 12 months of the entry into force of this Agreement.
7. Poultry meat										
Animal health	91/494, 94/438	9 CFR 94	Yes 1			9 CFR 53	91/494, 93/342, 94/984	Yes 1		
Public health	71/118, 96/22, 96/23	9 CFR 381	Yes 3	Establishments listed in accordance with footnote (7), and fulfilling the relevant provisions of footnote (1). Post-mortem inspection to be carried out by official inspectors.	Equivalency (Yes 2) shall be granted after the U.S. has completed verification of veterinary delivery systems. This process shall be completed within 12 months of the date of entry into force of the agreement.	9 CFR 381.1 - 381.5	71/118, 96/22, 96/23, 96/712	Yes 3	Establishments listed in accordance with footnote (7), and fulfilling the relevant provisions of footnotes (2), (3), (4) and (6).	The EC shall evaluate the U.S. residue programme, and additional information to be submitted by the U.S. to determine whether it meets the EC level of protection. This evaluation shall be completed within 6 months of the entry into force of this Agreement

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
7. Poultry meat - public health - contd.										
										The EC shall evaluate the U.S. water standards to determine whether they meet the EC level of protection. This evaluation shall be completed within 6 months of the entry into force of this Agreement. The EC shall carry out a scientific review of the use of antimicrobial techniques, and in particular the use of TSP and/or organic acids, with full participation of U.S. scientists. The scientific review should be completed as soon as possible. Equivalency (Yes 2) shall be granted after the EC has completed verification of the application of the specified conditions. This process shall be completed within 12 months of the entry into force of this Agreement.

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
8. Meat Products										
Animal Health										
- Red Meat (ruminants/ equidae)	64/432, 72/461, 72/462, 80/215	9 CFR 94	Yes 2	Additional certification for bovines from BSE affected countries	U.S. to review rules on BSE with respect to high/low incidence regions	9 CFR 53	72/462, 97/221	Yes 2	Derived from meat meeting the conditions of point 6 (fresh meat).	
- Pigs	64/432, 72/461, 72/462, 80/216	9 CFR 94	Yes 1			9 CFR 53	72/462, 97/221	Yes 2	Derived from meat meeting the conditions of point 6 (fresh meat).	
- Poultry	92/118, 72/462, 80/215, 94/438	9 CFR 94	Yes 1			9 CFR 53	97/221	Yes 2	Derived from meat meeting the conditions of point 7 (poultrymeat).	
- Wild game and farmed game	92/495, 92/45	9 CFR 94	Yes 2	Additional certification for bovines from BSE affected countries	U.S. to review rules on BSE with respect to high/low incidence regions		92/495, 92/45, 97/221	NE		

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
8. Meat Products contd.										
Public health										
Ruminants [6] Equidae Pigs Poultry	77/99, 96/22, 96/23	CFR 301-335, 354, 381.1- 381.500	Yes 3	Establishments listed in accordance with footnote (7), and fulfilling the relevant provisions of footnote 1.	Equivalency (Yes 2) shall be granted after the U.S. has completed verification of veterinary delivery systems. This process shall be completed within 12 months of the date of entry into force of this Agreement.	9 CFR 301- 335, 354, 381.1-381.500	72/462, 77/99, 92/118, 96/22, 96/23	Yes 3	Derived from meat meeting the conditions of point 6 (fresh meat) and/or 7 (poultrymeat). Establishments listed in accordance with footnote (7), and fulfilling the relevant provisions of footnotes (2), (3) and (4).	The EC shall evaluate the U.S. residue programme, and additional information to be submitted by the U.S., to determine whether it meets the EC level of protection. This evaluation shall be completed within 6 months of the entry into force of this Agreement. The EC shall evaluate the U.S. water standards to determine whether they meet the EC level of protection. This evaluation shall be completed within 6 months of the entry into force of this Agreement. Equivalency shall be granted after the EC has completed verification of the application of the specified conditions. This process shall be completed within 12 months of the entry into force of this Agreement.

· Commodity · Species · Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
8. Meat Products - public health - contd.										
Wild game [6] Farmed game [6]	77/99, 96/22, 96/23	FFDCA, FIFRA, PHSA 21 CFR 70-82, 101, 109, 110.3-110.93, 113, 114, 170-189, 510-529, 556 40 CFR 180, 185	NE	Existing trade conditions		FFDCA, FIFRA, PHSA 21 CFR 70-82, 101, 109, 110.3-110.93, 113, 114, 170-189, 510-529, 556 40 CFR 180, 185	77/99, 92/118, 96/22, 96/23	NE		
9. Farmed game meat										
Animal health										
· Deer · Rabbit	72/461, 92/118, 91/495	9 CFR 94	Yes 2 Yes 1	Additional certification from BSE affected countries	U.S. to review rules on BSE with respect to high/low incidence regions		92/118, 91/495, 97/219	NE		
· Porcine	72/461, 92/118, 91/495	9 CFR 94	Yes 1				92/118	NE		
· Feathered	92/118, 72/462, 80/215, 94/438	9 CFR 94	Yes 1			9 CFR 94	92/118, 97/219	NE		

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
9. Farmed game meat contd.										
Public health										
See footnote (8) for ruminants	91/495, 96/22, 96/23, 97/219	FFDCA, FIFRA, PHSA 21 CFR 70-82, 101, 109, 110.3-110.93, 113, 170-189, 510-529, 556 40 CFR 180, 185 9 CFR 301-335, 352, 354	NE	Existing trade conditions		FFDCA, FIFRA, PHSA 21 CFR 70-82, 101, 109, 110.3-110.93, 113, 170-189, 510-529, 556 40 CFR 180, 185 9 CFR 301-335, 352, 354	91/495, 96/22, 96/23, 97/219	NE		
10. Wild game meat										
Animal health										
- Deer - Rabbit	92/45	9 CFR 94	E				92/45, 97/218	NE		
- Porcine	92/45	9 CFR 94	E				92/45, 97/220	NE		

· Commodity · Species · Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
10. Wild game meat - animal health - contd.										
· Feathered	92/45	9 CFR 94	E				92/45, 97/218	NE		
Public health										
See footnote (8) for ruminants	92/45, 96/22, 96/23, 97/218, 97/220	FFDCA, FIFRA, PHSA 21 CFR 70-82, 101, 109, 110.3-110.93, 170-189, 510-529, 556 9 CFR 301-335 40 CFR 180, 185	NE	Existing trade conditions		FFDCA, FIFRA, PHSA 21 CFR 70-82, 101, 109, 110.3-110.93, 170-189, 510-529, 556 9 CFR 301-335 40 CFR 180, 185	92/45, 96/22, 96/23, 97/218, 97/220	NE		

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
11. Fisheries products for human consumption										
Animal health										
- Fish/fisheries products	91/67	USDI Title 50	NE			USDI & Title 50	91/67	NE		EC to evaluate new U.S. standards if applicable.
- Bivalve molluscs/ crustaceans (excl. live)	91/67	USDI & Title 50	NE			USDI & Title 50	91/67	NE		
Public health										
- Fish/fisheries products	91/493, 96/22, 96/23	21 CFR 123, 1240 FFDCA, FIFRA, PHSA, 21 CFR 70-82, 180, 110.3-110.93, 113, 114, 123, 172-193, 1240	Yes 3	Low Acid Canned Food requirement	U.S. to provide a detailed indication of how the EC request for equivalence for Low Acid Canned Food can be considered. EC to provide (1) appropriate information and documentation on procedures for audit and control of implementation by Member States, and (2) information on application of HACCP systems in Member States.	21 CFR 123, 1240 FFDCA, FIFRA, PHSA, 21 CFR 70-82, 180, 110.3-110.93, 113, 114, 123, 172-193, 1240	91/493, 95/328, 96/22, 96/23	Yes 3	95/328	U.S. to inform the EC when the U.S. is ready to have the implementation of its seafood HACCP Regulation reviewed. EC to carry out review, involving as necessary examination of information and documentation to be provided by U.S. on procedures for audit and control of implementation. On-site verification of U.S. system to be carried out within 6 months of U.S. request.

· Commodity · Species · Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
11. Fisheries products for human consumption - Public Health - contd.										
· Fish/fisheries products contd.					U.S. to conduct on-site verification of EC system (including visit to EC central offices and observation of Commission audits of a number of Member States). U.S. to indicate any outstanding problems following above actions. The outcome of the on-site verification to be discussed with EC. If on-site verification satisfactory, the equivalence determination to be finalised, and any necessary procedures carried out.	NMFS Voluntary HACCP based Program 50 CFR 260		Yes 1		EC to indicate any outstanding problems following above actions within 45 days of on-site verification. The outcome of the on-site verification to be discussed with EC. If on-site verification satisfactory, the equivalence determination to be finalised, and any necessary procedures carried out. "Establishments" do not include "brokers or traders".

· Commodity · Species · Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
11. Fisheries products for human consumption - Public Health - contd.										
· Bivalve molluscs/ crustaceans (excl. live)	91/492	National Shellfish Sanitation Programme	Yes 3	Existing trade conditions	EC to supply the raw data used for the scientific assessment on flesh/water testing. U.S. shall respond to results of scientific assessment within 90 days of receipts of raw data. EC to provide (1) appropriate information and documentation on procedures for audit and control of implementation by Member States, and (2) information on application of HACCP systems in Member States. U.S. to conduct on-site verification of EC system (including visit to EC central offices and observation of Commission audits of a number of Member States). U.S. to indicate any outstanding problems following above actions.	National Shellfish Sanitation Programme	91/492	Yes 3	Existing trade conditions	Joint comparison of flesh/water testing for classification of production areas. U.S. to inform the EC when the U.S. is ready to have the implementation of its seafood HACCP Regulation reviewed. EC to carry out review, involving as necessary examination of information and documentation to be provided by U.S. on procedures for audit and control of implementation. On-site verification of U.S. system to be carried out within 6 months of U.S. request. EC to indicate any outstanding problems following above actions within 45 days of on-site verification.

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
11. Fisheries products for human consumption - Public Health - contd.										
- Bivalve molluscs/ crustaceans (excl. Live contd)					The outcome of the on-site verification to be discussed with EC. If on-site verification ~~satisfactory~~, the equivalence determination to be finalized, and any necessary procedures carried out.					The outcome of the on-site verification to be discussed with EC. If on-site verification satisfactory, the equivalence determination to be finalized, and any necessary procedures carried out. "Establishments" ~~do not include~~ "brokers or traders".
- Aquaculture ~~animals~~ and products	91/493, 96/22, 96/23	National Shellfish Sanitation Programme, FFDCA, FIFRA, PHSA, 21 CFR 110.3-110.93, 123, 1240, DVM	NE			National ~~Shellfish~~ Sanitation Programme, FFDCA, FIFRA, PHSA, 21 CFR 110.3-110.93, 123, 1240, DVM	91/493, ~~96/22, 96/23~~	NE		
12. Live fish/shellfish and gametes										
Animal health	91/67		NE				91/67	NE		

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
13. Milk and milk based products for human consumption										
Animal health										
- Cattle including buffalo - Sheep - Goats	64/432, 92/46	9 CFR 94	Yes 2	Certification to UHT for FMD affected regions For non-FMD affected countries/regions a certificate of origin is required.	U.S. to review whether double pasteurisation acceptable	9 CFR 77, 78	92/46, 95/343	Yes 2	TB and Brucella requirements for non-heat treated	EC to review U.S. TB and Brucella programmes

· Commodity · Species · Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
13. Milk and milk based products for human consumption contd.										
Public health										
- UHT-Milk/ sterilised Milk	92/46, 94/71, 95/340, 95/342, 96/22, 96/23, 97/115, 91/180, 92/608, 92/118, 96/90	FFDCA,FIFRA, PHSA 21 CFR 70-82, 108, 110.3-110.93, 113, 131, 172, 184, 510-520, 556, 1210, 1240 40 CFR 180, 185	Yes 3	Existing trade conditions.	U.S. to review Import Milk Act. U.S. to provide a detailed indication of how the EC request for equivalence for Low Acid Canned Food can be considered. Joint assessment of laboratories to be completed EC to provide appropriate information and documentation on procedures for audit and control of implementation by Member States. U.S. to review information provided, and to carry out on-site verification of EC system.	FFDCA,FIFRA, PHSA 21 CFR 70-82, 108, 110.3-110.93, 113, 131, 172, 184, 510-520, 556, 1210, 1240 40 CFR 180, 185	92/46, 94/71, 95/340, 95/342, 95/343, 96/22, 96/23, 97/115, 91/180, 92/608, 92/118, 96/90	Yes 3	EC requirements for somatic cell and plate counts Certification as per 95/343	U.S. to consider including HACCP system in dairy products Joint assessment of laboratories to be completed Discussions on somatic cells and plate counts to continue U.S. to provide appropriate information and documentation on procedures for audit and control of implementation. EC to review information provided, and to carry out on-site verification of U.S. system. The outcome of the on-site verification to be discussed with U.S. If on-site verification satisfactory, the equivalence determination to be finalised, and any necessary procedures carried out

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
13. Milk and milk based products for human consumption - public health - contd.										
- UHT-Milk/ sterilised Milk contd		Pasteurised Milk Ordinance for Grade A Products and related documents			The outcome of the on-site verification to be discussed with EC. If on-site verification satisfactory, the equivalence determination to be finalised, and any necessary procedures carried out. The U.S. to provide a detailed indication of how the EC request for equivalence to "Grade A" can be considered, and thus to allow the possibility of export of such products to the U.S.	Pasteurised Milk Ordinance for Grade A Products and related documents				
- Pasteurised products	92/46, 94/71, 95/340, 95/342, 96/22, 96/23, 97/115, 91/180, 92/608, 92/118, 96/90	FFDCA, FIFRA, PHSA 21 CFR 70-82, 108, 110.3-110.93, 113, 131, 133, 135, 172, 184, 510-520, 556, 1210, 1240 40 CFR 180, 185	Yes 3	Existing trade conditions E coli requirement (for cheeses)	U.S. to review Import Milk Act. Discussions on differences in finished product criteria for E coli to continue. Joint assessment of laboratories to be completed.	FFDCA, FIFRA, PHSA 21 CFR 70-82, 108, 110.3-110.93, 113, 131, 133, 135, 172, 184, 510-520, 556, 1210, 1240 40 CFR 180, 185	92/46, 94/71, 95/340, 95/342, 95/343, 96/22, 96/23, 97/115, 91/180, 92/608, 92/118, 96/90	Yes 3	EC requirements for somatic cell and plate counts Certification as per 95/343	U.S. to consider including HACCP system in dairy products Joint assessment of laboratories to be completed Discussions on somatic cells and plate counts to continue U.S. to provide appropriate information and documentation on procedures for audit and control of implementation

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
13. Milk and milk based products for human consumption - public health - contd.										
- Pasteurised products contd		Pasteurised Milk Ordinance for Grade A Products and related documents			EC to provide appropriate information and documentation on procedures for audit and control of implementation by Member States U.S. to review information provided, and to carry out on-site verification of EC system. The outcome of the on-site verification to be discussed with EC. If on-site verification satisfactory, the equivalence determination to be finalised, and any necessary procedures carried out The U.S. to provide a detailed indication of how the EC request for equivalence to "Grade A" can be considered, and thus to allow the possibility of export of such products to the U.S.	Pasteurised Milk Ordinance for Grade A Products and related documents				EC to review information provided, and to carry out on-site verification of U.S. system. The outcome of the on-site verification to be discussed with U.S. If on-site verification satisfactory, the equivalence determination to be finalised, and any necessary procedures carried out.

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
13. Milk and milk based products for human consumption - public health - contd.										
- Not pasteurised (raw or thermised)	92/46, 94/71, 95/340, 95/342, 97/115, 91/180, 92/608, 92/118, 96/22, 96/23, 96/90	FFDCA, FIFRA, PHSA 21 CFR 70-82, 108, 110, 113, 133, 172, 184, 185, 510-520, 556, 1240 40 CFR 180	Yes 3	Compliance with E coli requirement (for cheeses) Prohibition on products not matured for more than 60 days at temperature above 35°F (+2°C).	Discussions on differences in finished product criteria for E coli to continue. Joint assessment of laboratories to be completed EC to provide appropriate information and documentation on procedures for audit and control of implementation by Member States. U.S. to review information provided, and to carry out on-site verification of EC system. The outcome of the on-site verification to be discussed with EC. If on-site verification satisfactory, the equivalence determination to be finalised, and any necessary procedures carried out. The U.S. to consider a dossier, to be submitted by the EC, for cheese not matured for more than 60 days, and thus to allow the possibility of export of such products to the U.S.	FFDCA, FIFRA, PHSA 21 CFR 70-82, 108, 110, 113, 133, 172, 184, 185, 510-520, 556, 1240 40 CFR 180	92/46, 94/71, 95/340, 95/342, 95/343, 97/115, 91/180, 92/608, 92/118, 96/22, 96/23, 96/90	Yes 3	Compliance with EC requirements for somatic cell and plate counts Certification as per 95/343	U.S. to consider including HACCP system in dairy products. Joint assessment of laboratories to be completed. Discussions on somatic cells and plate counts to continue. U.S. to provide appropriate information and documentation on procedures for audit and control of implementation. EC to review information provided, and to carry out on-site verification of U.S. system. The outcome of the on-site verification to be discussed with U.S. If on-site verification satisfactory, the equivalence determination to be finalised, and any necessary procedures carried out.

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
14. Milk and milk based products not for human consumption										
Animal health										
- Cattle including buffalo - Sheep - Goats All pasteurised or UHT or Sterilised	92/118, 64/432	9 CFR 94.16	Yes 2	For non-FMD affected regions, a certificate of origin is required. For FMD affected regions, certification to UHT	U.S. to review if double pasteurisation of products from FMD affected regions is acceptable.	9 CFR 77,78	92/118, 95/341	NE		
-Unpasteurised colostrum for pharmaceutical use [11a]	92/118	9 CFR 94.16	NE			9 CFR 77,78	92/118	NE		

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
15. Minced meat										
Animal health										
- Ruminants	64/432, 72/461, 72/462	9 CFR 94	Yes 2	Additional certification for bovines from BSE affected countries.	U.S. to review rules on BSE with respect to high/low incidence regions.		72/462	NE		
- Pigs	64/432, 72/461, 72/462	9 CFR 94	Yes 1				72/462	NE		
Public health										
Ruminants [6] Pigs	94/65	9 CFR 301-381	Yes 3	Establishments listed in accordance with footnote (7), and fulfilling the relevant provisions of footnote (1).	Equivalency shall be granted after the U.S. has completed verification of veterinary delivery systems. This process shall be completed within 12 months of the date of entry into force of this Agreement.	9 CFR 301-381	94/65, 97/29	Yes 3	Derived from meat meeting the conditions of point 6 (fresh meat). Establishments listed in accordance with footnote (7), and fulfilling the relevant provisions of footnotes (2), (3) and (4).	The EC shall evaluate the U.S. residue programme, and additional information to be submitted by the U.S., to determine whether it meets the EC level of protection. This evaluation shall be completed within 6 months of the entry into force of this Agreement. The EC shall evaluate the U.S. water standards to determine whether they meet the EC level of protection. This evaluation shall be completed within 6 months of the entry into force of this Agreement.

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
15. Minced meat - public health - contd.										
										Equivalency (Yes 2) shall be granted after the EC has completed verification of the application of the specified conditions. This process shall be completed within 12 months of the entry into force of this Agreement. EC to consider reviewing scope of definition of minced meat.
16. Meat preparations										
Animal health										
- Ruminants - Equidae	64/432, 72/461, 72/462	9 CFR 94	Yes 2	Additional certification for bovines from BSE affected countries.	U.S. to review rules on BSE with respect to high/low incidence regions.		72/462	NE		
- Pigs	64/432, 72/461, 72/462	9 CFR 94	Yes 1				72/462	NE		
- Poultry/Wild game/Farmed game	92/118, 72/462, 80/215, 94/438	9 CFR 94	Yes 1				91/494, 93/342, 94/984	NE		

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
16. Meat preparations contd.										
Public health										
Ruminants (8) Equidae Pigs Poultry	94/65	9 CFR 301-381	Yes 2/3	Establishments listed in accordance with footnote (7), and fulfilling the relevant provisions of footnote (1).	Equivalency shall be granted after the U.S. has completed verification of veterinary delivery systems. This process shall be completed within 12 months of the date of entry into force of this Agreement.	9 CFR 301-381	94/65, 97/29	Yes 3	Derived from meat meeting the conditions of point 6 (fresh meat) and/or 7 (poultrymeat). Establishments listed in accordance with footnote (7), and fulfilling the relevant provisions of footnotes (2), (3) and (4).	The EC shall evaluate the U.S. residue programme, and additional information to be submitted by the U.S., to determine whether it meets the EC level of protection. This evaluation shall be completed within 6 months of the entry into force of this Agreement. The EC shall evaluate the U.S. water standards to determine whether they meet the EC level of protection. This evaluation shall be completed within 6 months of the entry into force of this Agreement. Equivalency shall be granted after the EC has completed verification of the application of the specified conditions. This process shall be completed within 12 months of the entry into force of this Agreement.

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
16. Meat preparations - public health - contd.										
Wild game (4) Farmed game (4)	94/65	FIFRA, FFDCA, PHSA 21 CFR 70-82, 101, 109, 110.3-110.93, 113, 170-189, 510-529, 556 40 CFR 180, 185	NE	Existing trade conditions		FIFRA, FFDCA, PHSA 21 CFR 70-82, 101, 109, 110.3-110.93, 113, 170-189, 510-529, 556 40 CFR 180, 185	94/65	NE		
17. Animal casings for human consumption										
Animal health										
- Cattle	92/118, 64/432, 72/461, 72/462	9 CFR 96	Yes 2	Non-commingle ment (see footnote 9). No trade allowed for countries affected by BSE.	U.S. to review rules on BSE with respect to high/low incidence regions. U.S. to review 94.8(a)(i)(v) of CFR for non-commingle ment.		92/118 94/187	NE		
- Pigs	92/118, 64/432, 72/461, 72/462	9 CFR 96	Yes 2	Non-commingle ment (see footnote 9). Certification attesting to process and origin for casings originating in ASF free countries/regions but processed in ASF affected country/region.	U.S. to review 94.8(a)(i)(v) of CFR for non-commingle ment.		92/118 94/187	NE		

· Commodity · Species · Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
17. Animal casings for human consumption - animal health contd.										
- Sheep - Goats	92/118, 64/432, 72/461, 72/462	9 CFR 96	Yes 2	Non-commingiement (see footnote 9). No trade allowed for countries affected by BSE Certification attesting to process and country of origin for casings originating in BSE free countries but processed in BSE affected country.	U.S. to review 94.8(a)(i)(v) of CFR for non-commingiement.		92/118 94/187	NE		
Public health	77/99	FFDCA, FIFRA, PHSA 21 CFR 70-82, 101, 109, 110.3-110.93, 113, 114, 170-189, 510-529, 556 40 CFR 180, 185	NE			FFDCA, FIFRA, PHSA 21 CFR 70-82, 101, 109, 110.3-110.93, 113, 114, 170-189, 510-529, 556 40 CFR 180, 185	77/99, 92/118 Draft Decision notified to WTO	NE		

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
18. Animal casings not for human consumption										
Animal health										
- Cattle	92/118, 64/432 72/461, 72/462	9 CFR 96	Yes 2	Non-commingiement (see footnote 9). No trade allowed for countries affected by BSE	U.S. to review rules on BSE with respect to high/low incidence regions. U.S. to review 94.8(a)(i)(v) of CFR for non-commingiement		92/118 94/187	NE		
- Pigs	92/118, 64/432 72/461, 72/462	9 CFR 96	Yes 2	Non-commingiement (see footnote 9). Certification attesting to process and origin for casings originating in ASF free countries/regions but processed in ASF affected country/region.	U.S. to review 94.8(a)(i)(v) of CFR for non-commingiement		92/118 94/187	NE		
- Sheep - Goats	92/118, 64/432 72/461, 72/462	9 CFR 96	Yes 2	Non-commingiement (see footnote 9). No trade allowed for countries affected by BSE. Certification attesting to process and country of origin for casings originating in BSE free countries but processed in BSE affected country.	U.S. to review 94.8(a)(i)(v) of CFR for non-commingiement		92/118 94/187	NE		

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
19. Hides and skins										
Animal health										
- Cattle - Sheep - Goats - Pigs	92/118, 72/461, 72/462	9 CFR 95.5, 95.6	Yes 1				92/118 97/168	E		EC to identify basis for salting requirement
20. Canned petfood containing high/low risk material										
- Containing mammalian material	92/118 90/667 92/562	9 CFR 94, 95 FFDCA, FIFRA 21 CFR 110.3-110.93, 507-509, 570, 573-589	Yes 2	Special rules for BSE countries. Shelf stable for remainder.	U.S. to review rules on BSE with respect to high/low incidence regions.	FFDCA, FIFRA 21 CFR 110.3-110.93, 507-509, 570, 573-589	92/118 94/309 96/449 97/199	E		EC to examine U.S. claim to be BSE free. EC to consider alternative guarantees for mammalian material, including U.S. proposal to remove all risk material of known U.S. TSE species from petfood.
- Containing only non-mammalian material	92/118 90/667 92/562	99 CFR 94, 95 FFDCA, FIFRA 21 CFR 110.3-110.93, 507-509, 570, 573-589	Yes 2	Shelf stable for remainder.		FFDCA, FIFRA 21 CFR 110.3-110.93, 507-509, 570, 573-589	92/118 94/309 96/449 97/199	E	Establishments shall have been validated by the U.S. for alternative heat treatment including 30 day freedom from clostridia	

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
21. Canned petfood containing only low risk material										
- Containing mammalian material	92/118, 90/667	9 CFR 94, 95 FFDCA, FIFRA 21 CFR 110.3-110.93, 507-509, 570, 573-589	Yes 2	Special rules for BSE countries. Shelf stable for remainder.	U.S. to review rules on BSE with respect to high/low incidence regions	FFDCA, FIFRA 21 CFR 110.3-110.93, 507-509, 570, 573-589	92/118, 94/309, 96/449, 97/199	E		
- Containing only non-mammalian material	92/118, 90/667	9 CFR 94, 95 FFDCA, FIFRA 21 CFR 110.3-110.93, 507-509, 570, 573-589	Yes 2	Shelf stable.		FFDCA, FIFRA 21 CFR 110.3-110.93, 507-509, 570, 573-589	92/118, 94/309, 96/449, 97/199	E	Establishments shall have been validated by the U.S. for alternative heat treatment including 30 day freedom from clostridia	
22. Dry and semi moist petfood containing only low risk material										
	92/118 94/309	9 CFR 94, 95 FFDCA, FIFRA 21 CFR 110.3-110.93, 507-509, 570, 573-589	Yes 2	Restrictions for BSE countries	U.S. to examine EC 90° core temperature requirement as providing sufficient guarantees against FMD, CSF, SVD, ASF and ND. U.S. to review rules on BSE	FFDCA, FIFRA 21 CFR 110.3-110.93, 507-509, 570, 573-589	92/118, 94/309, 96/449, 97/199	E	Establishments shall have been validated by the U.S. for alternative heat treatment including 30 day freedom from clostridia	

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
23. Dry and semi moist petfood containing high/low risk material										
- Containing mammalian material	92/118, 94/309	9 CFR 94, 95 FFDCA, FIFRA 21 CFR 110.3-110.93, 507-509, 570, 573-589	Yes 2	Restrictions for BSE countries	U.S. to examine EC 90°C core temperature requirement as providing sufficient guarantees against FMD, CSF, SVD, ASF and ND. U.S. to review rules on BSE with respect to high/low incidence regions.	FFDCA, FIFRA 21 CFR 110.3-110.93, 507-509, 570, 573-589	92/118, 94/344, 96/449, 97/199	E		EC to examine U.S. claim to be BSE free. EC to consider alternative guarantees for mammalian material, including U.S. proposal to remove all risk material of known U.S. TSE species from petfood.
- Containing only non-mammalian material	92/118, 94/309	9 CFR 94, 95 FFDCA, FIFRA 21 CFR 110.3-110.93, 507-509, 570, 573-589	Yes 1		U.S. to examine EC 90°C core temperature requirement as providing sufficient guarantees against ND.	FFDCA, FIFRA 21 CFR 110.3-110.93, 507-509, 570, 573-589	92/118, 94/344, 97/199	E	Establishments shall have been validated by the U.S. for alternative heat treatment including 30 day freedom from clostridia	

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
24. Bones and bone products for human consumption ("other products" as defined in 77/99/EEC)										
Animal health										
Fresh meat (ruminants, horses, pigs)	64/432 72/461 80/215 72/462	9 CFR 95	Yes 2	Restrictions for BSE countries.	U.S. to review rules on BSE with respect to high/low incidence regions.		72/462 97/221	NE		
Farmed game - Pigs, deer	91/495	9 CFR 95	Yes 2	Restrictions for BSE countries.	U.S. to review rules on BSE with respect to high/low incidence regions.		91/495	NE		
Fresh meat - Poultry	92/118, 80/215, 72/462, 94/438	9 CFR 95	Yes 1				92/118	NE		
Feathered, farmed and wild game	92/45 91/495	9 CFR 95	Yes 1				92/45 91/495	NE		
Wild game - Pigs, deer	92/45	9 CFR 95	Yes 2	Restrictions for BSE countries.	U.S. to review rules on BSE with respect to high/low incidence regions		92/45	NE		
Public health										
All species (*)	77/99, 92/118	9 CFR 95	NE				77/99, 92/118	NE		EC to consider establishing conditions.
Feathered, farmed and wild game (*)	64/433, 77/99, 92/118	FIFRA, FFDCA, 21 CFR 70-82, 108, 109, 110.3-110.93, 113, 170-189, 510-529, 556	NE			FIFRA, FFDCA, 21 CFR 70-82, 108, 109, 110.3-110.93, 113, 170-189, 510-529, 556	77/99, 92/118 Draft Decision notified to WTO	NE		

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
25. Bones, horns and hooves and their products not for human consumption										
Animal health	96/239	9 CFR 95	Yes 1			9 CFR 53	94/446	NE		
26. Processed animal protein for human consumption										
Animal health										
Fresh meat (ruminants, equidae, pigs)	64/432, 72/461, 80/215, 72/462	9 CFR 95	Yes 2	Not accepted from BSE countries.	U.S. to review rules on BSE with respect to high/low incidence regions.		72/462, 97/221	NE		EC to examine U.S. claim to be BSE free. EC to consider alternative guarantees for mammalian material, including U.S. proposal to remove all risk material of known U.S. TSE species from petfood.
Farmed game - Pigs, deer	91/495	9 CFR 95	Yes 2	Not accepted from BSE countries.	U.S. to review rules on BSE with respect to high/low incidence regions.		91/495	NE		
Fresh meat - Poultry	92/118, 80/215, 72/462, 94/438	9 CFR 95	Yes 1				92/118	NE		
Feathered, farmed and wild game	92/45, 91/495	9 CFR 95	Yes 1				92/45 91/495	NE		
Wild game - Pigs, deer	92/45	9 CFR 95	Yes 2	Not accepted from BSE countries.	U.S. to review rules on BSE with respect to high/low incidence regions.		92/45	NE		

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
26. Processed animal protein for human consumption contd.										
Public health										
All species (*)	77/99, 92/118		Yes 1				77/99, 92/118	NE		
Feathered, farmed and wild game (*)	77/99	FIFRA, PHSA, FFDCA, 21 CFR 70-82, 108, 109, 110.3-110.93, 113, 170-189, 510-529, 556	NE			FIFRA, PHSA, FFDCA, 21 CFR 70-82, 108, 109, 110.3-110.93, 113, 170-189, 510-529, 556	77/99, 92/118 Draft Decision notified to WTO	NE		
27. Processed animal protein not for human consumption										
Containing material of mammalian origin										
Ruminants	92/118 90/667	9 CFR 95 FIFRA, FFDCA, 21 CFR 110.3-110.93, 507-509, 570, 573-589	Yes 2	Not accepted from BSE countries.	U.S. to review rules on BSE with respect to high/low incidence regions.	FIFRA, FFDCA, 21 CFR 110.3-110.93, 507-509, 570, 573-589	90/667, 92/118 92/562, 94/344 96/449, 97/198	NE		EC to examine U.S. claim to be BSE free. EC to consider alternative guarantees for mammalian material, including U.S. proposal to remove all risk material of known U.S. TSE species from petfood.
Non-ruminants	92/118 90/667	9 CFR 95 FIFRA, FFDCA, 21 CFR 110.3-110.93, 507-509, 570, 573-589	Yes 3			FIFRA, FFDCA, 21 CFR 110.3-110.93, 507-509, 570, 573-589	92/118, 90/667, 96/449	NE	Establishments shall have been validated by the U.S. for alternative heat treatment including 30 day freedom from clostridia	

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
27. Processed animal protein not for human consumption contd.										
Containing only material of non-mammalian origin										
Poultry and fish	92/118, 90/667	9 CFR 95	Yes 1				90/667, 92/118, 92/562, 94/344, 97/198	NE	Establishments shall have been validated by the U.S. for alternative heat treatment including 30 day freedom from clostridia.	
Non-ruminants	92/118, 90/667	9 CFR 95	Yes 1				92/118, 90/667	NE		
28. Serum of equidae										
Animal health	92/118, 94/143	9 CFR 95, 122	NE				92/118, 94/143	NE		
29. Blood and blood products intended for human consumption										
Animal health										
Fresh meat (ruminants, equidae, pigs)	64/432, 72/461 80/215, 72/462	9 CFR 95, 122	E	BSE rules for ruminants	U.S. to review rules on BSE with respect to high/low incidence regions. U.S. to produce generic conditions for EC	9 CFR 53	72/462 97/221	NE		
Farmed game - Pigs, deer	91/495	9 CFR 95, 122	Yes 2	BSE rules for ruminants	U.S. to review rules on BSE with respect to high/low incidence regions.		91/495	NE		
Fresh meat - Poultry	92/118, 80/215 72/462, 94/438	9 CFR 95, 122	Yes 1				92/118	NE		

· Commodity · Species · Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
29. Blood and blood products intended for human consumption - Animal health - contd.										
Feathered, farmed and wild game	92/45, 91/495	9 CFR 95, 122	Yes 1				92/45, 91/495	NE		
Wild game - Pigs, deer	92/45	9 CFR 95, 122	Yes 1				92/45	NE		
Public health	77/99	9 CFR 301-381, 416, 417 FFDCA, FIFRA, 21 CFR 110.3-110.93, 507-509, 570, 573-589	NE			9 CFR 301-381, 416, 417 FFDCA, FIFRA, 21 CFR 110.3-110.93, 507-509, 570, 573-589	77/99, 92/118 Draft Decision notified to WTO	NE		EC to consider establishing conditions.
30. Blood and blood products not intended for human consumption										
Animal health	92/183, 92/118	9 CFR 95.4, 122	Yes 2	BSE rules for ruminants. Permit required.	U.S. to review rules on BSE with respect to high/low incidence regions.	9 CFR 53	92/183, 92/118	Yes 2	Bluetongue treatment requirements.	EC to consider use of tests for bluetongue in place of treatment.

· Commodity · Species · Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
31. Lard and rendered fats intended for human consumption										
Animal health										
Fresh meat (ruminants, horses, pigs)	64/432, 72/461, 80/215	9 CFR 95	Yes 2	BSE rules for ruminants	U.S. to review rules on BSE with respect to high/low incidence regions.		72/462, 97/221	NE		
Farmed game - Pigs, deer	91/495	9 CFR 95	Yes 2	BSE rules for ruminants	U.S. to review rules on BSE with respect to high/low incidence regions.		91/495	NE		
Fresh meat - Poultry	92/118 80/215 94/438	9 CFR 95	Yes 1				92/118	NE		
Feathered, farmed and wild game	92/45 91/495	9 CFR 95	Yes 1				92/45 91/495	NE		
Wild game - Pigs, deer	92/45	9 CFR 95	Yes 2	BSE rules for ruminants	U.S. to review rules on BSE with respect to high/low incidence regions.		92/45	NE		
Public health										
All species (*)	77/99, 92/118		NE				77/99, 92/118	NE		
Feathered, farmed and wild game (*)	77/99	9 CFR 301-381, 416, 417 FIFRA, PHSA, FFDCA, 21 CFR 70-82, 108, 109, 110.3-110.93, 113, 170-189, 510-529, 556	NE			9 CFR 301-381, 416, 417 FIFRA, PHSA, FFDCA, 21 CFR 70-82, 108, 109, 110.3-110.93, 113, 170-189, 510-529, 556	77/99, 92/118 Draft Decision notified to WTO	NE		

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
32. Lard and rendered fats not intended for human consumption										
	92/118 90/667 72/461	9 CFR 95	Yes 2	BSE rules for ruminants	U.S. to review rules on BSE with respect to high/low incidence regions.		92/118 Draft Decision notified to WTO	NE		EC to review requirements to consider inclusion of alternative heat treatment systems. EC to review U.S. bacteriological testing regime for protein fraction.
33. Raw material for feeding stuffs, pharmaceutical or technical use										
Animal health	92/118	9 CFR 95, 122	Yes 1			9 CFR 53	92/118	E		EC to consider laying down certification requirements for imports.
34. Apiculture products for apiculture										
Animal health	92/118		E				92/118, 94/860	NE		
35. Game trophies										
Animal health	92/118	9 CFR 95	Yes 1			9 CFR 53	92/118 96/590	E		

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
36. Manure										
Animal health	92/118	9 CFR 95	E		U.S. to provide temperature requirements for manure from regions affected by serious transmissible disease	9 CFR 53	92/118	E		
37. Wool, feathers and hair										
Animal health										
- Wool	92/118	9 CFR 95	Yes 1			9 CFR 53	92/118	NE		
- Pigbristles	92/118	9 CFR 95	Yes 1			9 CFR 53	92/118 94/435	NE		
Public health		FFDCA, PHSA 21 CFR 1240.70	NE			FFDCA, PHSA 21 CFR 1240.70		NE		
38. Honey										
Animal health			NE					NE		
Public health	92/118	FFDCA, FIFRA, PHSA 21 CFR 70-82, 109, 110.3-110.93, 520.182, 520.1660d	NE			FFDCA, FIFRA, PHSA 21 CFR 70-82, 109, 110.3-110.93, 520.182, 520.1660d	92/118	NE		

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
39. Frogs' legs										
Animal health										
Public health	92/118, 96/340	FFDCA, FIFRA, PHSA 21 CFR 70-82, 108, 110.3-110.93, 113, 114, 123, 1240	NE			FFDCA, FIFRA, PHSA 21 CFR 70-82, 108, 110.3-110.93, 113, 114, 123, 1240	92/118, 96/340	NE		EC to review U.S. HACCP rules when submitted.
40. Snails for human consumption										
Animal health										
Public health	92/118, 96/340	FFDCA, FIFRA, PHSA 21 CFR 70-82, 108, 110.3-110.93, 113, 114, 123, 1240	NE			FFDCA, FIFRA, PHSA 21 CFR 70-82, 108, 110.3-110.93, 113, 114, 123, 1240	92/118, 96/340	NE		

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
41. Egg products for human consumption										
Animal health	90/539	9 CFR 94	Yes 2	Permit required from areas affected by Newcastle disease	U.S. to review permit requirement.		90/539, 93/342	Yes 1		
Public health	89/437, 91/684, 92/118, 96/23	7 CFR 59 EPIA Public Law 91-597	E		U.S. to supply information on the legal basis for recognition of equivalence. U.S. to complete assessment of EC public health legislation.	7 CFR 59 EPIA Public Law 91-597	89/437, 91/684, 92/118, 96/23, 97/38	E	Establishments listed in accordance with footnote (7), and fulfilling the relevant provisions of footnote (2). The following tests are to be conducted, as specified in Annex VI to Directive 89/437, on U.S. egg products for dispatch to Europe: Chemical tests - 3 OH butyric acid - lactic acid - succinic acid - egg shell remains, egg membrane, other particles Bacteriological tests - mesophile counts - enterobacteriaceae - salmonella - staphylococcus Methods Internationally recognised methods such as: ISO, NMKL, AOAC	EC to complete assessment of U.S. public health legislation.

- Commodity - Species - Animal/Public health	European Community Exports to the United States					United States Exports to the European Community				
	Trade Conditions		Equiv (Cat)	Special Conditions	Actions	Trade Conditions		Equiv (Cat)	Special Conditions	Actions
	EC Standards	U.S. Standards				U.S. Standards	EC Standards			
42. Shell eggs										
Animal health	90/539	9 CFR 94	Yes 2	Permit required from areas affected by Newcastle disease.	U.S. to review permit requirement.	9 CFR 94	90/539, 93/342	Yes 1		
Public health	89/437, 91/684, 94/371, 96/23	FFDCA, FIFRA, PHSA, EPIA 21 CFR 5.10(a)(4) and (a) (13), 70-82, 100.135, 110.3-110.93, 172.140, 172.882, 182.884, 178, 520, 524, 556, 558, 1240 40 CFR 180 7 CFR 56	E		U.S. to review legal basis for recognition of equivalence. U.S. to complete assessment of EC public health legislation.	FFDCA, FIFRA, PHSA, EPIA 21 CFR 5.10(a)(4) and (a) (13), 70-82, 100.135, 110.3-110.93, 172.140, 172.882, 182.884, 178, 520, 524, 556, 558, 1240 40 CFR 180 7 CFR 56	89/437, 91/684 94/371, 96/23	E	Footnote (4)	EC to complete assessment of U.S. public health legislation.
43. Gelatin for human consumption and technical use										
Animal health		9 CFR 94	NE					NE		
Public health	92/118	FFDCA, FIFRA, PHSA 21 CFR 70-82, 109, 110.3-110.93, 570, 573-589	NE			FFDCA, FIFRA, PHSA 21 CFR 70-82, 109, 110.3-110.93, 570, 573-589	92/118	NE		

FOOTNOTE 1

The Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems; Final Rule was published at 61 Federal Register 38806-38989 and amends various provisions of CFR Parts 304, 310, 320, 327, 381, 416 and 417.

Provisions on SSOPs and E coli testing applicable.

The U.S. and the EC shall discuss, well in advance of their date of implementation, the staged elements in the above rule to determine whether any further special conditions are needed.

FOOTNOTE 2

Horizontal issues, fresh meat, meat products, game meat, poultry meat, minced meat, meat preparations, egg products

(a) Packaging material

Packaging material shall be kept in separate rooms that are used exclusively for this purpose and free of dust and vermin.

Packaging material shall not be stored on the floor.

Waxed assembled boxes shall not be nested, unless a liner will be added.

ANNEX VI

GUIDELINES FOR CONDUCTING AN AUDIT

Where standards, guidelines, or recommendations pertaining to the conduct of audits are adopted by one of the relevant international standard-setting organisations, the Parties will review the contents of this Annex, and make any appropriate modifications.

GENERAL PROVISIONS

1. Definitions

The following definitions shall apply to terms used in this annex:

1.1. audit – assessment of performance.

1.2. auditee – the exporting Party whose enforcement and control programme is the subject of the audit.

1.3. auditor – the importing Party that conducts the audit.

1.4. establishment – processing plant for animals or animal products.

1.5. facility – site other than processing plants where animals or animal products might be handled, excluding retail premises.

2. General Principles

2.1. The auditor and the auditee should cooperate in carrying out audits in accordance with the provisions set out in this Annex. The audit team should include representatives of both the auditor and the auditee, and the auditee should designate personnel responsible for facilitating the audit. Specialised professional skills may be necessary to carry out audits of specialised systems and programmes.

2.2. Audits should be designed to check the effectiveness of the auditee's enforcement and control programme rather than to reject individual animals, consignments of food or establishments.

2.3. The auditee must operate a documented programme to demonstrate to the auditor that standards are being met on a consistent basis.

2.4. The frequency of audits should be based on the performance of the exporting Party in carrying out its enforcement and control programme. A low level of performance should result in an increased frequency of audit, for example to ensure that unsatisfactory performance has been corrected.

2.5. Audits, and the decisions based on them, should be made in a transparent and consistent manner.

PROCEDURES

3. Preparation of the Audit Plan

In consultation with the auditee, the auditor should prepare an audit plan that covers the following points:

3.1. the subject, depth and scope of the audit;

3.2. the date and place of the audit, and the types of any establishments or facilities to be visited so that appropriate audit team members may be chosen;

3.3. a timetable up to and including the presentation of the final report;

3.4. the language or languages in which the audit will be conducted and the report written;

3.5. the identity of the members of the audit team, including the leader;

3.6. a schedule of meetings with officials and visits to establishments or facilities, including unannounced visits, as appropriate; and

3.7. provisions for respect of commercial confidentiality and avoidance of conflicts of interest.

4. Opening Meeting

An opening meeting should be held between representatives of both Parties. At this meeting the auditor will review the audit plan and confirm that adequate resources and documentation are available and all necessary arrangements have been made for conducting the audit.

5. Document Review

5.1. The document review may include, for example, the following:

* records concerning compliance programmes;
* inspection and internal audit reports;
* documentation concerning corrective actions and sanctions;
* records of compliance actions taken;
* sampling plans and their results;
* documents associated with verification; and
* regulatory procedures followed by the auditee.

5.2. In the case of an audit that is subsequent to a determination of equivalence, the document review may also consist of a review of relevant changes to the inspection and certification systems since the determination of equivalence or since the previous audit.

5.3. The auditee will cooperate fully with the auditor in the document review process and help to ensure that the auditor has access to requested documents and records.

6. On-site Verification

6.1. The decision to conduct on-site verification should take into account factors such as the risks associated with the animals or animal products concerned, the history of conformity with requirements by the industry sector or exporting country, the volume of product produced and imported or exported, changes in infrastructure and the nature of the inspection and certification systems.

6.2. On-site verification may involve visits to production and manufacturing establishments, facilities, food handling or storage areas and control laboratories to check the accuracy of the information contained in the documentary material referred to in 5.1.

6.3. When checks of establishments or facilities are carried out, the auditee will carry out the check of the establishment or facility, following the auditee's usual procedures, and the auditor will generally participate as an observer, though is free to check other aspects of performance if deemed necessary.

6.4. The auditee will cooperate fully with the auditor in the on-site verification process and facilitate the auditor's entry into the establishments and facilities that are the subject of the on-site verification.

7. Follow-up Audit

A follow-up audit may be conducted to verify the correction of deficiencies identified in a prior audit.

8. Working Documents

Working documents may include checklists of elements to evaluate, such as the following:

* legislation;
* structure and operations of inspection and certification services;
* establishment and facility structure, layout, operations and working procedures;
* health statistics, sampling plans and results;
* compliance action and procedures;
* reporting and complaint procedures; and
* training programmes.

9. Closing Meeting

A closing meeting shall be held between representatives of both Parties, including officials responsible for the inspection and certification programmes of the auditee. At this meeting the auditor will present the findings of the audit. The information should be presented in a clear, concise manner so that the conclusions of the audit are clearly understood.

10. Audit Report

The auditor shall provide the auditee with a draft report of the audit generally within 60 days of the conclusion of the audit. To the extent possible, the report shall be presented in a standardised format to be agreed upon by the Parties in order to make the approach to audit more uniform, transparent and efficient. The report will assess the adequacy of the auditee's enforcement and control programme and identify any deficiencies noted during the conduct of the audit. Thereafter, the auditee may within 60 days comment on the draft report and shall describe any specific corrective actions that will be taken, preferably with target dates for completion. Any comments made by the auditee shall be included in the final report.

FRONTIER CHECKS

The Parties recognise the distinction between documentary, identity and physical checks carried out at external frontiers on imports of live animals and animal products.

The Parties further recognise the need to take a systematic approach to carrying out frontier checks.

Both Parties agree that charges may be made for these checks, in conformity with the relevant provisions of Annex C to the SPS Agreement.

Live Animals

The Parties may apply physical checks to all consignments of live animals.

Animal Products

In setting their physical checking frequencies for imports of animal products, the Parties shall take due account of the checks applied by the exporting Party prior to export and the historic performance of products imported from the exporting Party.

The Parties may modulate their physical checking frequencies for imports of animal products, notably in the light of progress made toward the recognition of equivalence under the consultative process provided for in Article 7.

ANNEX VIII

OUTSTANDING ISSUES

The Parties agree to work to further develop agreed arrangements concerning frontier checks, including the frequency of physical checks.

The Parties agree to work together on their respective arrangements concerning feed additives, animal feedingstuffs, medicated feeds and premixes.

ANNEX IX

CONTACT POINTS

The U.S. will send the information provided for in Article 10, and carry out the notifications provided for in Article 11, to:

Agricultural Counsellor
European Union
Delegation of the European Commission to the United States
2300 M Street NW
Washington DC 20037

phone: 1 202 862 9560
fax: 1 202 429 1766

The Community will send the information provided for in Article 10, and carry out the notifications provided for in Article 11, to:

Agricultural Attaché
Office of Agricultural Affairs
U.S. Mission of the European Union
40 Blvd du Regent
1000 Brussels, Belgium

phone: 32 2 508 2760
fax: 32 2 511 0918

Assembled boxes with liners shall not be nested.

Boxes shall not be handled by personnel who are handling exposed product.

Boxes shall be assembled in a sanitary manner, either in a separate room or, if on the cutting room floor, never within 3 metres of exposed product.

(b) Facility requirements for light coloured walls and cove molding

Walls shall be smooth, durable, impermeable, and of a colour which permits detection of insanitary conditions.

Walls shall have washable surfaces.

Walls and floor junctures shall be constructed and maintained so as to assure that surfaces are clean and free of contamination. Establishments that do not use cove molding to provide a smooth transition from floor to wall to facilitate cleaning must provide an equivalent alternative means, such as sealing of cracks between walls and floors, to maintain sanitary conditions.

(c) Medical certification by a medical doctor

Prior to employment, new employees shall be examined by a medical doctor or by another medically qualified person who is sufficiently trained to identify communicable diseases and working under the supervision of a medical doctor.

Establishments shall have in place an appropriate program to continuously monitor employee health.

Pre-employment examinations and ongoing health monitoring shall be carried out either by a medical doctor or by a person with appropriate medical training (e.g. a physician's assistant or a registered nurse).

All cases of suspected disease shall be referred to a medical doctor for diagnosis.

Establishments shall keep records of medical examinations and shall make those records available to auditors upon request.

(d) Wooden pallets in exposed product areas

The use of wooden pallets in areas where there is exposed product shall be phased out. In the interim:

- no wooden pallets shall be used within 3 metres of exposed product;

- pallets shall be clean, structurally sound, and covered with a sanitary plastic sheet.

Those establishments which are already using plastic pallets shall continue to do so.

When wooden pallets are used in coolers or freezers, all product present shall be hygienically packaged to prevent contact of product with wood.

(e) Separation of lavatories and work areas

Toilet rooms shall be properly ventilated and shall be separated from exposed product rooms by either a vestibule or a dressing room.

(f) Dry Storage of Non-Food Material

Detergents, disinfectants and similar substances shall be stored separately from food and from wrapping and packaging material.

(g) Water Testing

Water testing shall continue to be carried out in accordance with EC requirements.

FOOTNOTE 3

Fresh meat, game meat, meat products, minced meat and meat preparations of red meat species and poultry.

(a) Waste water

All establishments shall have an efficient drainage and plumbing system, and all drains and gutters shall be properly installed with traps and vents approved by FSIS, in accordance with 9 CFR 381.49 (a), (c).

(b) Separate storage of edible and inedible products

Condemned and other inedible meat and offal shall be removed in a hygienic manner, and as quickly as possible, from rooms containing edible material.

(c) Separate storage of packaged and unpackaged products

Unpackaged meat may not be stored in chilling or freezer rooms containing packaged meat.

(d) Structural wood

Wooden structures shall be in good condition, impermeable, smooth, durable rot-proof and sealed with a waterproof coating.

(e) Use of suspended showers, sprays and hoses

Meat shall not be contaminated by splashing.

They shall not be used as a substitute for handwashing facilities.

(f) Sterilization of equipment

Establishments shall provide sterilization equipment (batch or local sterilizers) to clean utensils as often as necessary. Implements such as knives or hooks which come into contact with meat shall be cleaned and sterilized frequently, and in any case whenever they have been in contact with contaminated material or surfaces such as the external surfaces of hides. Sterilization shall be done with hot (>82°C) water.

FOOTNOTE 4

Additional Guarantees for Finland and Sweden

For trade from the U.S. to Sweden and Finland, the U.S. will certify in accordance with Council Decision 95/409/EC (Fresh: Veal, beef and pigmeat), Council Decision 95/410/EC (Live poultry for slaughter), Council Decision 95/411/EC (Fresh poultrymeat), Commission Decision 95/160/EC (Breeding poultry and day old chicks), Commission Decision 95/161/EC (Laying hens) and Commission Decision 95/168/EC (Table eggs for human consumption).

No attestation is required for fresh meat as defined in Council Directive 72/462/EEC intended for an establishment for the purposes of pasteurisation, sterilisation or for treatment having an equivalent effect.

FOOTNOTE 5

Fresh meat, game meat, meat products, minced meat, meat preparations

(a) Accommodation for sick and suspect animals

Wood shall not be used for pens for sick and suspect animals.

Sick and suspect animals shall not be allowed to come into contact with animals intended for slaughter for export to the Community.

Pens for sick and suspect animals shall be sited and constructed to preclude contact with animals intended for slaughter for export to the Community and effluent from such pens shall not flow into adjoining pens or passageways.

(b) Veterinary supervision of ante-mortem inspection

All cattle intended for slaughter for export to the EC shall be inspected by an official FSIS veterinarian, except:

- feedlot animals inspected at the feedlot by a USDA accredited veterinarian; and

- other fattening animals under the age of 30 months inspected at the holding by a USDA accredited veterinarian;

which shall be inspected by an official FSIS inspector with appropriate training, knowledge, skills and abilities to carry out this function.

All pigs intended for slaughter for export to the EC shall be inspected by an official FSIS veterinarian, except for market hogs (animals up to 1 year of age), which shall be inspected by an official FSIS inspector with appropriate training, knowledge, skills and abilities to carry out this function.

All animals demonstrating abnormal signs shall be diagnosed and disposed of by an official FSIS veterinarian.

(c) Trichina testing

Establishments shall test horsemeat for trichinae.

Pigmeat shall be tested or subjected to cold treatment in accordance with 9 CFR 318.10.

(d) Opening of stomachs and intestines

There must be a separate room for emptying and cleaning stomachs and intestines, unless the processing is done by closed-circuit mechanical equipment which avoids contamination and eliminates odours.

(e) Pig Hearts Incision

For market hogs (animals up to 1 year old) which are destined or from which some part is destined for the EC a statistically representative sample, both in numbers or percentage and geographical origin, of hearts shall be incised and their interior surfaces inspected by FSIS personnel, with the results being recorded.

The U.S. shall inform the EC of the sampling methodology, level of confidence, and programme they intend to use for the sampling referred to above.

Hearts of all sows and boars (animals over 1 year of age) which are destined or from which some part is destined for the EC shall be incised and their interior surfaces inspected by FSIS personnel, with the results being recorded.

(f) Batch condemnation

If carcasses, offals and blood are not correlated at the final post-mortem inspection point, a batch system shall be operated in such a way that FSIS can demonstrate that if a carcass is condemned its offal and blood shall also be condemned.

(g) Partial Approval

The veterinary authorities of the U.S. and the EC may on a bilateral basis grant request for partial approval of red meat establishments for certain products, in accordance with the general and specific provisions of this Agreement in respect of hygienic production and ante and post mortem inspection of slaughter animals, under the following conditions:

1. The establishment shall develop a Quality Assurance (QA) program which addresses the mode of operation, the identification of product, and the segregation of the product from receiving to shipping. Establishments which want to apply for partial approval must meet the facility requirements to ensure physical and/or time separation of approved and non-approved products.

2. The QA shall include an establishment monitoring schedule and a log to document both monitoring actions and corrective actions.

3. The QA program shall be acceptable to the regulatory inspector in charge of the establishment and the controlling veterinary authority of the importing party on request.

4. The regulatory inspector in charge of the establishment shall monitor the establishment's application of the QA program and document such monitoring and ensure correction of deficiencies.

5. The importing Party may verify the practical implementation of the QA program. In this case, the establishment needs to be in a position to demonstrate the program on the spot during an inspection. For this purpose, all relevant documentation shall be presented.

6. Should an inspection on the spot and/or the document-check in an establishment reveal serious deficiencies, the possibility of partial approval may either be refused or revoked.

FOOTNOTE 6

Poultrymeat

(a) Counterflow Chilling

Where counterflow chilling systems are used, alternative chilling systems to the EC standards may be used providing equivalent guarantees as regards avoidance of cross contamination, and carcass temperatures at the point of exit from the chilling systems as set out under point (b) below, which have been validated and assessed by FSIS before the establishment is proposed for listing for export to the EC. This validation and assessment shall be carried out without the use of antimicrobial treatment (decontamination), throughout a full day's production, and with microbiological analyses for aerobic plate counts, enterobacteriacae and E coli before and after chilling. This assessment shall be carried out each time any changes are made to a plant's chilling system. Records shall be kept of the validations and assessments, and FSIS shall make these available to the EC.

(b) Poultry product temperature requirements

Poultry shall be chilled to an internal temperature of 40 degrees F (4.4 degrees C) in the shortest time possible after slaughter.

- In the case of small birds (up to 6 pounds), the internal temperature of 40 degrees shall be achieved by the end of the immersion chilling process.

- Where crushed ice is used to chill large birds (over 6 pounds) after immersion chilling, such use must not result in cross contamination of the product.

When further processing (cutting) occurs after poultry has been chilled to 40 degrees F, the internal temperature may exceed 40 degrees F for a maximum of one hour, but may not exceed 50 degrees F (10 degrees C).

(Transportation temperature shall be in accordance with 9 CFR 381.66.)

(c) Crushed Ice

The use of crushed ice must not result in cross contamination of the product. When crushed ice is used for further transport or storage, stacking of boxes with leakholes or other practices which could result in cross contamination shall be prohibited.

FOOTNOTE 7

Establishment Listing (applicable to all products where listing provisions apply)

1. The exporting Party is responsible for ensuring that establishments/plants authorised to export, and products certified for export, meet the relevant requirements.

The exporting Party shall screen establishments to ensure that they meet the relevant requirements before proposing establishments for listing for export. The list, or lists, of approved establishments, and additions and deletions to such lists, shall be supplied to the importing Party by the exporting Party. The importing Party shall make modifications to the lists of approved establishments efficiently, on the basis of the information supplied by the exporting Party. Dissemination of such lists shall be carried out without delay (*).

2. The importing Party may carry out verification procedures, including inspection of the establishments, to ensure that the relevant requirements are being met.

3. The Parties will work towards increasing the responsibility for the management of lists of establishments by the exporting Party in the light of experience obtained under the operation of the provisions of paragraphs 1 and 2.

4. The Parties will review the functioning of the abovementioned provisions regarding lists of establishments in the light of experience at each meeting of the Committee provided for under Article 14, and for the first time no later than 31 December 1997.

FOOTNOTE 8

Bison and Water Buffalo

For exports to the U.S., bison and water buffalo are considered as game meat.

For exports to the EC, bison and water buffalo are considered as fresh meat.

(*) The EC will carry out this commitment in accordance with the procedure laid down in Article 5 of Council Decision 95/408/EC. The U.S. will carry out this commitment in accordance with a similar timetable

FOOTNOTE 9

Non-commingling – meat, meat products, game meat, poultry meat, minced meat, meat preparations

Establishments which slaughter both animals whose meat is eligible for export and animals whose meat is not eligible for export to one of the Parties, or handle such meat, shall comply with the following conditions:

1. Animals from which the meat is intended for export shall be kept separate from those which are not of the same status while at the slaughter establishment.

2. Following slaughter of animals which are not eligible for export and before slaughter of animals eligible for export purposes, all areas, utensils and equipment liable to contact the live animals and meat, including stunning, bleeding, flaying, deboning, cutting and packing areas shall be cleaned and disinfected. Staff shall change into clean protective clothing and wash their hands and boots thoroughly.

3. Meat intended for export shall not be handled, cut or otherwise processed in the same room at the same time as meat not eligible for export.

4. Meat intended for export shall be packed in clean new packaging which is clearly distinguishable from that containing meat not eligible for export. It shall be stored in such a way as to ensure that no cross contamination occurs.

5. Records of the origin of the animals from which the meat is produced shall be retained for a period of 6 months after export. They shall be available for inspection by the Regulatory Authority.

6. Compliance with the above conditions shall be certified by an official veterinarian.

FOOTNOTE 10

Milk and Milk Products not for human consumption

Excludes products regulated as animal drugs in the U.S.

FOOTNOTE 11

Residue Testing

Residue testing shall continue to be carried out by the U.S. in accordance with applicable EC requirements.