AGREEMENT IN THE FORM OF AN EXCHANGE OF LETTERS

Concerning amendments to the annexes to the Agreement between the European Community and the United States of America on sanitary measures to protect public and animal health in trade in live animals and animal products

A. *Letter from the European Community*

Brussels, 7 October 2004

Your Excellency,

With reference to the Agreement between the European Community and the United States of America on sanitary measures to protect public and animal health in trade in live animals and animal products, I have the honour to propose to you to amend the Annexes of the Agreement as follows:

As recommended by the Joint Management Committee established under Article 14(1) of the Agreement, replace the texts of point 6 of Annex V and of footnote (1) to the Agreement with the text in Appendix A to the present letter, and replace the text of Annex VI to the Agreement, with the text in Appendix B to the present letter.

I would be obliged if you would confirm the agreement of the United States of America to such amendments to point 6 of Annex V, to footnote (1), and to Annex VI to the Agreement.

Please accept, Sir, the assurance of my highest consideration.

For the European Community
Jaana HUSU-KALLIO

Enclosure: Appendix A to replace Annex V, point 6 and footnote (1) to the Agreement and Appendix B to replace Annex VI to the Agreement

B. *Letter from the United states of America*

Brussels, 6 April 2005

Dear Madam,

I refer to your letter of 7 October 2004 containing details of the proposed Appendix A to replace Annex V, point 6 and footnote (1) and Appendix B to replace Annex VI of the Agreement of July 20 1999 between the United States of America and the European Community on the sanitary measures to protect public and animal health in trade in live animals and animal products.

In this regard, I have the honor to confirm the acceptability to the United States of America of the proposed amendments as recommended by the Joint Management Committee established under Article 14(1) of the Agreement, a copy of which is attached hereto. It is my understanding that these amendments shall take effect on the date on which the EC notifies the US that it has completed the necessary procedures for implementing these amendments.

Please accept the assurances of my high consideration.

For the Ambassador
Norval E. FRANCIS

Enclosure: Appendix A to replace Annex V, point 6 and footnote (1) to the Agreement and Appendix B to replace Annex VI to the Agreement

APPENDIX A

'ANNEX V

— Commodity — Species — Animal/public health	EC exports to the United States					United States exports to the EC				
	Trade conditions		Equivalence	Special conditions	Action	Trade conditions		Equivalence	Special conditions	Action
	EC standards	US standards				US 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	US 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	Three 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	Three month residence	
— Porcine animals	64/432 72/461 72/462	9 CFR 94	Yes 1			9 CFR 53	72/462 82/426	Yes 2	Three month residence Holding freedom from brucellosis	
Public health										
Ruminants ([8]) 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) Testing for *Enterobacteriaceae* and total viable count carried out as per Decision 2001/471/EC of 8 June 2001, except that:	Equivalency (Yes 2) shall be granted after the US 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 US residue programme, and additional information to be submitted by the US, to determine whether it meets the EC level of protection. This evaluation shall be completed within six months of the entry into force of this Agreement

— Commodity — Species — Animal/public health	EC exports to the United States					United States exports to the EC				
	Trade conditions		Equivalence	Special conditions	Action	Trade conditions		Equivalence	Special conditions	Action
	EC standards	US standards				US standards	EC standards			
Ruminants ([8]) Equidae Porcine Ovine Caprine *(cont'd)*				— random sampling must be carried out throughout the slaughter period — the four sample collection sites for cattle, swine, sheep, goats and horses cannot be changed from those specified in Decision 2001/471/EC of 8 June 2001						The EC shall evaluate the US water standards to determine whether they meet the EC level of protection. This evaluation shall be completed within six months of the entry into force of this Agreement. The EC to evaluate a US request, when submitted, on the need for continued *trichinae* testing of horsemeat. Regarding 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'

FOOTNOTE 1

'([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 applicable.

The USA 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.'

APPENDIX B

'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;

1.6. animal health investigation — a site visit undertaken to gather or verify information related to the status or conditions of a particular region with regard to one or more of the animal diseases identified in Annex III.

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.

Information is collected through interviews, review of documents and records, and site visits. Changes to controls since the adoption of the Agreement or since the previous audit are included. Information may be verified through inquiries and checks on other sources; these may include physical observation, measurements, samples and records. Information obtained during the course of the audit should be documented.

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. The auditee's enforcement and control programme covered by the Agreement should be adequately assessed.

2.2.1. The basis for the assessment of all audits conducted in accordance with the Agreement is provided by the standards of either the exporting party, or a combination of the standards of the exporting party and importing party, and any special conditions as appropriate for the particular audit. Such standards and appropriate special conditions are outlined in Annex V, and provided for in Article 6.

2.2.2. It is recognised that on-site audits undertaken in the process of determining initial equivalence will normally be conducted using only the standards of the exporting country, whereas subsequent on-site audits undertaken for the purpose of verifying delivery of a previously established condition of equivalence will be conducted using the standards of the exporting party, those relevant standards of the importing party that have not been determined to be equivalent and for which compliance is required, and any agreed special conditions outlined in Annex V.

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.

2.4.1. Information to be used in establishing the frequency of audits may include, *inter alia*:

— epidemiological analysis,

— the results of previous audits,

— results from veterinary checks at the border (including results from collection and analysis of samples from import consignments),

— period since last audit,

— volume of trade,

— public health surveillance results,

— animal disease list freedom,

— and environmental and geographical factors.

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

The auditor should:

2.5.1. Ensure that audit conclusions are based on objective evidence or data and observations, which can be verified as accurate and reliable;

2.5.2. Remain free of any conflicting interest or improper influence;

2.5.3. Ensure that the audit procedure is conducted with the objectives of

— verifying that previously recognised conditions of equivalence are being delivered by the exporting party, and

— identifying to the auditee areas where improvements can be introduced to enhance the performance of the auditee's documented control programme so that it can deliver initially, or continue to deliver, a condition of equivalence necessary to meet the importing party's appropriate level of protection;

2.5.4. Ensure that all documents and records received during the audit are retained and safeguarded as agreed by both parties and according to each party's applicable laws and regulations;

2.5.5. Ensure that commercial confidentiality is respected according to each party's applicable laws and regulations.

The auditee should:

2.5.6. Provide information within the scope of the audit, which is requested by the auditor, in a timely manner during the audit or within 20 working days thereafter to ensure that the audit objectives can be met;

2.5.7. Cooperate with and assist the auditor in the performance of his/her duties so that the audit objectives are achieved. This includes:

— informing personnel involved in the audit about its objectives;

— appointing suitably qualified members of staff to accompany the audit team,

— providing the necessary facilities needed for the audit team in order to ensure an effective and efficient audit process,

— providing access to the sites and to documents necessary to carry out the audit, as requested by the auditor.

2.6. Animal health investigations

Animal health investigations are conducted in order to gather appropriate epidemiological and other information concerning the disease status of a particular region (whether a Member State/State, part of a Member State/State or parts of more than one Member State/State). An animal health investigation may be carried out by one party (referred to here as the importing party) to support the initial determination made by the other party (referred to here as the exporting party) of the disease status of a region (i.e. first-time recognition of freedom from a specified disease), or following a disease outbreak.

OPERATIONAL GUIDELINES

Preparing for audits

3. *Advance preparation*

3.1. Programming of audits

In order to ensure that audits can be adequately prepared and carried out in the most efficient manner, the Parties should:

— establish a tentative audit programme covering, where practicable, a 12-month period, taking due account of, *inter alia*, the analysis described under 2.4 of Annex VI to the Agreement, and the actions set out in Annex V of the Agreement; this indicative programme should be reviewed on a six-monthly basis in order to establish a rolling audit programme,

— confirm, at the earliest stage possible, preferably 60 days prior, the intention to carry out the audits foreseen in the indicative programme,

— notify, at the earliest stage possible, the auditee of any anticipated changes to the indicative programme,

— exchange information on programmes of audits foreseen to be carried out outside the scope of the Agreement as might be necessary and appropriate to facilitate the provisions of paragraph 6.3.

3.2. Audit initiation

The following will normally provide a basis for the initiation of audits:

— audits identified in the indicative programme,

— audits upon invitation by the auditee,

— audits at the justified request of either contracting party to the Agreement, such as audits undertaken in the event of serious concerns by either Party regarding emerging or newly identified risks to public or animal health.

In all cases, the auditor should provide the auditee with sufficient notice of the intended audit, in order to enable it to make the arrangements necessary for a satisfactory completion of the audit. The advance time of this notice should reflect the urgency related to public and animal health associated with its performance.

Communication by the auditor to the auditee

3.3. Pre-audit activities

3.3.1. Preparation of the audit plan

In consultation with the auditee, the auditor should prepare an audit plan. The audit plan should be submitted by the auditor to the auditee sufficiently in advance of the audit to allow time for information to be supplied by the auditee, preferably 60 days prior to the intended commencement date of the audit. The audit should be designed to be flexible in order to permit changes in emphasis based on information gathered prior to, or during the audit.

The plan should include:

— the subject, depth and scope of the audit,

— the objectives of the audit,

— identification of the relevant standards set out in Annex V against which the audit will be carried out. Specifically, these are the standards of the exporting party when the audit is conducted as the initial on-site evaluation of performance of the auditee's control programme as part of the determination as to whether a condition of equivalence exists, or a combination of the exporting party's standards and the importing party's standards, as amended by the appropriate special conditions set out in Annex V, when a subsequent audit is conducted to verify a previously determined condition of equivalence,

— 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,

— a timetable up to and including the presentation of the final report,

— the language or languages in which the audit will be conducted and the report written,

— the identity of the members of the audit team, including the leader,

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

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

3.3.2. Agreement with the auditee of the plan and dates

If the auditee objects to any provisions detailed in the audit plan, such objections are to be made known immediately to the auditor, usually within 10 working days after receipt of the audit plan. Objections should be resolved between the auditor and the auditee. Proposed amendment(s) to the audit plan, as a consequence of information obtained either prior to or during the audit, should be communicated by the proposing party to the other party as soon as practicable.

3.3.3. Obtaining the necessary documentation from the auditee

Prior to the audit, the auditor may request documentation from the auditee that is relevant to its preparation and execution. Such documentation may include, for example:

— legislation and relevant technical standards and specifications,

— management structure of the auditee,

— regulatory functions and powers of the auditee, and results of any enforcement actions,

— approval procedures operated by auditee,

— details concerning control programmes, including copies of working documents, manuals and similar operational guides.

The auditor may request clarification from the auditee concerning any documentation that has been submitted.

Conducting the audit

4. *Opening meeting*

The auditee and auditor should have an opening meeting at a site agreed to in advance by both sides. Where necessary and appropriate to clarify issues pertaining to the audit, the opening meeting may be held in Washington, D.C. for audits conducted by European Commission teams, or in either Brussels, Belgium or Grange, Ireland for audits conducted by US teams. In other cases, opening meetings may be held at appropriate sites, such as EU Member State capitals or US cities, as may be practical and convenient for the particular audit. Wherever the opening meeting takes place, it should be chaired by an appropriate representative of the auditee's competent authority(ies). The purpose of an opening meeting is to:

— introduce the audit team to the auditee,

— confirm the subject, depth, scope, audit standards and objectives of the audit,

— outline the working methods and procedures to be used during the audit,

— confirm the official communication links between the audit team and the auditee during the course of the audit, including establishing which representatives of the official services will accompany the audit team at each visit,

— confirm the government and non-government sites to be visited,

— confirm the appropriate number and roles of audit team members to participate in or observe site visits to production establishments or facilities,

— confirm the time, date and location of the closing meeting and any interim meetings with the auditee,

— confirm travel and accommodation arrangements,

— confirm that the resources and facilities needed by the audit team will be made available,

— confirm the reporting methods to be used,

— request any additional documentation identified during the pre-audit stage as necessary for the conduct of the audit,

— answer any questions the auditee has concerning the audit process.

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,

— 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 by the auditor as to the nature and extent of on-site verifications should take into account factors such as the area concerned, the history of conformity with requirements by the sector or exporting country as determined by prior audits and/or veterinary checks at the border (including results of sampling and analysis of import consignments), the volume of product produced and imported or exported, changes to the infrastructure and the nature and operation of the national 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 the auditor is free to check other aspects of performance, if deemed necessary. Due to time constraints, the auditor may elect not to observe a full, comprehensive inspection by the auditee, but may, instead, verify particular inspection practices through off-site interviews with the auditee's inspection staff.

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.

6.5. Where on-the-spot checks reveal a serious potential or actual risk to human or animal health, the auditor should immediately inform the auditee of such an assessment, who should take appropriate action to correct an identified and confirmed risk.

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,

— training programmes.

8.1. Support documents

Documents supporting audit findings, conclusions and recommendations should be standardised as much as possible in order to make the performance of the audit and the presentation of its findings uniform, transparent and reliable. The support documents may include any aides memoire or other background information of elements to evaluate.

9. *Closing meeting*

As with the opening meeting, the closing meeting may be held at a site that is mutually convenient to both the auditee and the auditor. The closing meeting should also be chaired by an appropriate representative of the auditee's competent authority(ies).

The purpose of the closing meeting is to:

— re-confirm the subject, depth, scope, audit standards and objectives of the audit,

— remind the auditee that the audit is based on a sampling of the system controls and does not purport to reflect all of the system deficiencies,

— provide the auditee with the auditor's preliminary findings and/or a general overview of the auditor's findings,

— present details of the substantive deficiencies identified along with the objective evidence for such deficiencies,

— offer any additional explanation necessary to ensure that the auditee understands the nature of the substantive deficiencies,

— confirm that full details of the audit will be provided in the form of an audit report and that the auditee will have an opportunity to comment on the report,

— allow the auditee to comment on the audit findings or to raise any points of clarification.

Post-audit activities

10. *Audit report*

The audit report should provide a balanced picture of the audit findings, and include conclusions and recommendations that accurately reflect these findings. It should normally cover the following:

— the subject, depth, scope, audit standards and objectives of the audit,

— details of the audit plan,

— identification of the reference documents against which the audit was conducted,

— auditor evaluation of findings against the standards subject of the audit,

— area(s) of disagreement between the auditor and auditee,

— the auditor's recommendations as to which substantive deficiencies should be corrected,

— the response to the presentation of the findings including any undertakings given to address identified deficiencies.

10.1. Commercial confidentiality must be respected in the preparation and subsequent distribution of the audit report. Prior to the audit, each party will inform the other of its laws and procedures for protecting confidential commercial information and other information that may be deemed sensitive by one or both parties. Each party will respect fully its own requirements for protecting confidential information. Where significant differences exist between the parties in the nature of information that must be protected, the parties will identify these differences prior to the audit and agree on the appropriate procedures to be followed.

10.2. Draft reports are to be sent to the auditee within the time limits specified in the Agreement. The auditee may comment within 60 days, and should describe any specific corrective actions that will be or have been taken in order to deliver equivalence initially, or to continue to deliver equivalence, including target dates for completion.

10.3. Amendments to the text of the final report in response to comments from the competent authority should be limited to the correction of factual inaccuracies. However, other comments made by the auditee may be indicated separately in the report if they serve to clarify the report's contents. The auditee's comments should, in any case, be attached to the final report.

11. *Corrective action follow up*

Verification of corrective action necessary to deliver equivalence will vary according to the nature of the original deficiency. Verification of corrective action by the auditee may include the following:

— review of assurances provided by the auditee,

— review of documentation provided by the auditee,

— follow up audits,

— review of stated corrective action in a subsequent audit.

The follow up audit process is similar to the normal audit, but it would focus on confirming that the action taken by the auditee satisfactorily addresses and resolves the identified deficiencies. A follow up report concerning the corrective action should be prepared and distributed in a manner similar to the original audit report.

Animal health investigations

12. *Animal health investigations*

12.1. General principles

All parties involved in an animal health investigation should cooperate in carrying out the investigation in an open and transparent manner, with a view to completing all necessary procedures as quickly as possible.

12.2. Procedures

12.2.1. Programming of animal health investigation and animal health investigation initiation

In most cases, this investigation will be undertaken at the request of the exporting party. The results of an animal health investigation should provide essential information regarding disease risk associated with exports of specified commodities from that region. The importing party shall acknowledge such a request in a timely manner, and shall identify a contact person to work closely with representatives of the exporting party. Necessary site visits will be scheduled expeditiously with the input of all parties.

In the event of an outbreak of one of the diseases identified in Annex III and in case that safeguard or regionalisation measures have been adopted, the importing party may require that an animal health investigation take place before trade in affected products can be resumed. In order to minimise the disruption of trade and facilitate the recognition of disease freedom or identification or appropriate risk mitigation measures, the appropriate representatives of both the importing and exporting parties will work to schedule the investigation as quickly as possible. While the timing of the visit will depend on progress in bringing the outbreak under control, the two parties should enter into discussions at the earliest practical stage.

12.2.2. Pre-visit activities

The importing party will identify the regions to be visited as part of the site visit, as well as the types of entities to be included, in direct communication with the exporting party. The two parties should work in close consultation to prepare an investigation plan that covers the following points:

— the proposed dates of the site visit,

— the area(s) to be visited and the types of information that will need to be gathered,

— the names of the investigation team members, including the leader of the investigation team,

— a schedule of meetings with officials and visits to farms or other locations,

— specific documentation that will be requested as part of the investigation, such as applicable disease eradication and control legislation, surveillance and monitoring data, reports on trace-backs and traceforwards, vaccination records if carried out, epidemiological data related to the outbreak in question or recent outbreaks, laboratory reports etc.,

— the names of the appropriate contact persons of the exporting party (this would include representatives from the appropriate services of all Member States/States involved), as well as the responsible regulatory authorities of both parties.

The investigation plan should be completed prior to the departure of the investigation team and transmitted to all parties involved in the animal health investigation.

12.2.3. Conducting the investigation

12.2.3.1. Opening meeting

An opening meeting should be held between representatives of all parties. At this meeting, the investigating party will review the investigation plan and confirm that the necessary arrangements have been made for conducting the investigation.

The location of the opening meeting will be determined as part of the investigation plan, and may, if appropriate, be hosted by representatives of the appropriate regulatory authorities.

The purpose of this opening meeting is to:

— introduce the investigation team to the representatives of the exporting party,

— outline the principal areas of investigation and procedures to be followed,

— confirm the official communication links between the investigation team and the representatives of the exporting party,

— confirm the schedule and sites to be visited,

— confirm the date, time and location of the closing meeting,

— confirm travel and accommodation arrangements,

— confirm that resources and documentation needed by the investigation team will be made available,

— answer any questions regarding the investigation on the part of the exporting party representatives.

12.2.3.2. Documenting the investigation

The officials conducting the investigation will keep a written record of their findings, together with documentation supplied by the host party representatives. The record will include the locations visited, including farms, and the names and titles of officials interviewed as part of the investigation.

12.2.3.3. Closing meeting

A closing meeting shall be held between representatives of both parties. The location of the meeting will be determined as part of the investigation plan, and may, if appropriate, be hosted by officials of the appropriate regulatory authorities.

The purpose of the meeting is to:

— review the principal areas of investigation and the procedures followed,

— provide an opportunity for the exporting party representatives to clarify any issues related to the investigation or the documentation provided,

— identify any additional information required to complete the evaluation,

— answer any questions regarding the evaluation and the subsequent actions,

— establish an indicative time table for providing the animal health investigation assessment and/or the report to the exporting party.

12.2.4. Evaluation

The evaluation should be science based, transparent, and consistent with relevant international standards and with similar evaluations conducted by the importing party.

Depending on the procedures of the importing party, the assessment and/or the report may be made public. Comments on the assessment and/or the report by the exporting party will be governed by existing regulatory requirements of the importing party.'