

Official Journal

of the European Communities

ISSN 0378 - 6978

L 68

Volume 36

19 March 1993

English edition

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II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DECISION

of 26 October 1992

concerning the conclusion of an Agreement in the form of an exchange of letters between the European Economic Community and the United States of America concerning the application of the Community third country Directive, Council Directive 72/462/EEC, and the corresponding United States of America regulatory requirements with respect to trade in fresh bovine and porcine meat

(93/158/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 113 thereof,

Having regard to Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine animals and swine and ovine and caprine animals and fresh meat or meat products from third countries ⁽¹⁾, hereafter referred to as 'the Community third country Directive',

Having regard to Commission Decision 87/257/EEC of 28 April 1987 on the list of establishments in the United States of America approved for the purpose of importing fresh meat into the Community ⁽²⁾,

Having regard to the recommendation from the Commission,

Whereas, under an exchange of letters signed on 7 May 1991, as referred to in Article 2 (2) of Decision 91/552/EEC, the Commission and the Government of the United States of America commenced a comparative examination of the Community third country Directive and corresponding United States of America regulatory

requirements with respect to trade in fresh bovine and porcine meat, with the objective of determining whether Community and United States of America requirements are equivalent;

Whereas, this comparative examination has been completed and has shown that the regulatory requirements of the Community and the United States of America basically provide equivalent safeguards against public health risks;

Whereas, to ensure recognition of equivalency, it is desirable to establish an agreed process for the application of the regulatory requirements of both the Community and the United States of America in order to safeguard and facilitate future trade in fresh bovine and porcine meat; whereas an Agreement has been reached to that end;

Whereas, in the context of the establishment of such a process, the Commission will submit appropriate proposals to the Council on the Community third country Directive;

Whereas, in the intervening period between conclusion of the Agreement and full implementation of the measures contained therein, interim measures are required to allow for the approval of additional establishments in the United States of America for the purpose of importing fresh bovine and porcine meat into the Community;

Whereas the Agreement should be approved,

⁽¹⁾ OJ No L 302, 31. 12. 1972, p. 28. Directive as last amended by Regulation EEC No 1601/92 (OJ No L 173, 27. 6. 1992, p. 13).

⁽²⁾ OJ No L 121, 9. 5. 1987, p. 46. Decision as last amended by Council Decision 91/522/EEC (OJ No L 283, 11. 10. 1991, p. 14).

HAS DECIDED AS FOLLOWS:

Article 1

The Agreement between the European Economic Community and the United States of America in the form of an exchange of letters concerning the application of the Community third country Directive, Council Directive 72/462/EEC and the corresponding United States of America regulatory requirements with respect to trade in fresh bovine and porcine meat is hereby approved on behalf of the European Economic Community.

The text of the Agreement is attached to this Decision.

Article 2

The President of the Council is hereby authorized to designate the person empowered to sign the Agreement in order to bind the Community.

This Decision shall be published in the *Official Journal of the European Communities*.

Done at Luxembourg, 26 October 1992.

For the Council
The President
J. GUMMER

AGREEMENT

in the form of an exchange of letters between the European Economic Community and the United States of America concerning the application of the Community third country Directive, Council Directive 72/462/EEC, and the corresponding United States of America regulatory requirements with respect to trade in fresh bovine and porcine meat

Letter No 1

Sir,

I refer to the exchange of letters of 7 May 1991 between the Commission and the United States of America and the subsequent negotiations concerning the application of the Community third country Directive, Council Directive 72/462/EEC, and the corresponding United States of America regulatory requirements, with respect to trade in fresh bovine and porcine meat.

During the abovementioned negotiations, both Parties agreed to the following:

1. By the exchange of letters of 7 May 1991 the Community and United States agreed to undertake a comparison of the Community third country Directive and the corresponding United States regulatory requirements with the objective of determining whether Community and United States requirements are equivalent. This process has been completed and has shown that both regulatory systems basically provide equivalent safeguards against public health risks.
2. The process of comparison identified some differences in legal and/or administrative requirements which, unless modified, preclude recognition of equivalence. Both Parties undertake to make the initiatives for the necessary modifications as soon as possible.

On issues which involve interpretation or implementation of legal and/or administrative requirements, both Parties undertake to apply actions on relevant issues in accordance with Annex I. With regard to these issues, both parties agree to complete implementation within six months of signing this Agreement.

3. With particular reference to issue No 26 in Annex I, concerning an alternative system for cold treatment of trichinae in pigmeat, the Community undertakes to have evaluated this issue not later than 31 January 1993.
4. Both Parties accept the desirability of following a mutually agreed approach.

In the context of the completion of the Single European Market, the United States recognize the need to apply uniform principles to the Member States of the Community.

5. Both Parties agree on the desirability of further cooperation with a view to harmonizing administrative actions. This would include frequency and timing of review visits in respect of the operation of their respective foreign veterinary inspection services responsible for reviewing third countries' health systems and establishments wishing to export meat.
6. Both Parties accept the principle of regionalization for control of animal diseases. In this respect, both Parties accept the desirability of a mutually agreed approach to the application of such policies.

The United States undertake to continue the recognition of freedom of individual Member States from specified animal diseases, without the application of additional safeguards, after implementation of the single market strategy.

The United States will undertake to amend its import policy regulations and legislation concerning FMD, rinderpest and other relevant diseases in the light of the concept of regionalization.

7. Within the context of a new working relationship between the United States and Community veterinary inspection services, both Parties agree to take the steps necessary to establish an improved on-the-spot dialogue between the veterinarians at plant level both with the objective of finding solutions on-the-spot and of improving their professional dialogue.
8. Both Parties agree to the enhancement of FSIS role (Annex III). The United States undertake to implement the provisions of Annex III in the shortest possible time.
9. Both Parties undertake to initiate and develop cooperative actions in accordance with Annex IV.
10. In the intervening period, between signing this Agreement and full implementation of the measures contained herein, the interim measures provided in Annex II shall apply.
11. The two Parties undertake to endeavour to complete all the necessary procedures to implement fully this Agreement by 31 December 1993. Within one year of its signature, both Parties agree to jointly review the operation of this Agreement, including the interim measures.
12. The Parties agree that the application of this Agreement will bind reviewers of both Parties and will constitute a satisfactory resolution of the current dispute involving the third country Directive.
13. Based on experience gained from operation of this Agreement, the Community will consider on the basis of mutual agreement, the possibility of approving plants certified by FSIS as being in compliance with Community requirements prior to visits by reviewers. The United States already operate such a system.
14. The two Parties agree to initiate discussions as soon as possible on other problems in the veterinary field in relation to trade in animals and products of animal origin. This includes, amongst others, monitoring of residues, poultrymeat, meat products and live animals.

I have the honour to propose that, if the foregoing is acceptable to your Government, this letter and your confirmatory reply shall together constitute and evidence an Agreement between the European Economic Community and the United States of America on the matter.

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

*On behalf of
the Council of the European Communities*

Letter No 2

Sir,

I have the honour to acknowledge receipt of your letter of today's date which reads as follows:

I refer to the exchange of letters of 7 May 1991 between the Commission and the United States of America and the subsequent negotiations concerning the application of the Community third country Directive, Council Directive 72/462/EEC, and the corresponding United States of America regulatory requirements, with respect to trade in fresh bovine and porcine meat.

During the abovementioned negotiations, both Parties agreed to the following:

1. By the exchange of letters of 7 May 1991 the Community and United States agreed to undertake a comparison of the Community third country Directive and the corresponding United States regulatory requirements with the objective of determining whether Community and United States requirements are equivalent. This process has been completed and has shown that both regulatory systems basically provide equivalent safeguards against public health risks.
2. The process of comparison identified some differences in legal and/or administrative requirements which, unless modified, preclude recognition of equivalence. Both Parties undertake to make the initiatives for the necessary modifications as soon as possible.

On issues which involve interpretation or implementation of legal and/or administrative requirements, both Parties undertake to apply actions on relevant issues in accordance with Annex I. With regard to these issues, both parties agree to complete implementation within six months of signing this Agreement.

3. With particular reference to issue No 26 in Annex I, concerning an alternative system for cold treatment of trichinae in pigmeat, the Community undertakes to have evaluated this issue not later than 31 January 1993.
4. Both Parties accept the desirability of following a mutually agreed approach.

In the context of the completion of the Single European Market, the United States recognize the need to apply uniform principles to the Member States of the Community.

5. Both Parties agree on the desirability of further cooperation with a view to harmonizing administrative actions. This would include frequency and timing of review visits in respect of the operation of their respective foreign veterinary inspection services responsible for reviewing third countries' health systems and establishments wishing to export meat.
6. Both Parties accept the principle of regionalization for control of animal diseases. In this respect, both Parties accept the desirability of a mutually agreed approach to the application of such policies.

The United States undertake to continue the recognition of freedom of individual Member States from specified animal diseases, without the application of additional safeguards, after implementation of the single market strategy.

The United States will undertake to amend its import policy regulations and legislation concerning FMD, rinderpest and other relevant diseases in the light of the concept of regionalization.

7. Within the context of a new working relationship between the United States and Community veterinary inspection services, both Parties agree to take the steps necessary to establish an improved on-the-spot dialogue between the veterinarians at plant level both with the objective of finding solutions on-the-spot and of improving their professional dialogue.

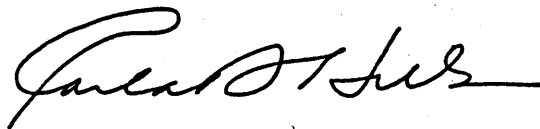
8. Both Parties agree to the enhancement of FSIS role (Annex III). The United States undertake to implement the provisions of Annex III in the shortest possible time.
9. Both Parties undertake to initiate and develop cooperative actions in accordance with Annex IV.
10. In the intervening period, between signing this Agreement and full implementation of the measures contained herein, the interim measures provided in Annex II shall apply.
11. The two Parties undertake to endeavour to complete all the necessary procedures to implement fully this Agreement by 31 December 1993. Within one year of its signature, both Parties agree to jointly review the operation of this Agreement, including the interim measures.
12. The Parties agree that the application of this Agreement will bind reviewers of both Parties and will constitute a satisfactory resolution of the current dispute involving the third country Directive.
13. Based on experience gained from operation of this Agreement, the Community will consider on the basis of mutual agreement, the possibility of approving plants certified by FSIS as being in compliance with Community requirements prior to visits by reviewers. The United States already operate such a system.
14. The two Parties agree to initiate discussions as soon as possible on other problems in the veterinary field in relation to trade in animals and products of animal origin. This includes, amongst others, monitoring of residues, poultrymeat, meat products and live animals.

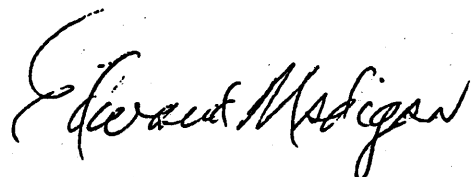
I have the honour to propose that, if the foregoing is acceptable to your Government, this letter and your confirmatory reply shall together constitute and evidence an Agreement between the European Economic Community and the United States of America on the matter.'

I have the honour to confirm that my Government is in agreement with the contents of your letter.

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

*On behalf of
the Government of the United States of America*


11-13-92



ANNEX I

RECOMMENDED ACTIONS

Explanatory note

Annex I contains the recommendations of the joint United States-Community technical group on slaughterhouse and meat inspection requirements. This group was convened in November 1991 to complete the comparison of United States and Community requirements called for in the 14 May 1991 exchange of letters. Working from the attached list of 60 points of contention identified by both sides, the technical group identified the legal requirements which apply to each of these issues. In some cases, the requirements were found to be different, but in those instances where the requirements were similar, the group carried its investigation further to determine the source of the problem.

The results of the group's deliberations were summarized and formed the basis for the conclusions presented in the left-hand column of Annex I. Following further consideration, the group developed the joint recommendations for further action which appear in the right-hand column.

1. Knocking (stunning) area
2. Ante-mortem (facilities)
3. Ante-mortem (facilities)
4. Ante-mortem (inspection)
5. Ante-mortem (inspection)
6. Sticking (sterilization of sticking knife between cuts)
7. Sticking (sterilization of sticking knife between carcasses)
8. Sticking (provision of apron washing cabinets for 'sticker')
9. Use of 'drop hoses'
10. Livestock trucks (control of washing facilities)
11. Post-mortem inspection (identification and correlation of parts; batch condemnation)
12. Post-mortem inspection (procedures)
13. Personnel requirements (veterinary oversight)
14. Personnel requirements (health marks)
15. Personnel requirements (medical certificates)
16. Personnel requirements (welfare facilities)
17. Personnel requirements (clothing use restrictions)
18. Facilities (dry storage — packaging materials)
19. Facilities (storage of non-food substances)
20. Facilities (prohibition against wood structures)
21. Facilities (prohibition against wood equipment)
22. Facilities (potable water — frequency of testing)
23. Facilities (potable water — testing methods)
24. Temperature requirements (products)
25. Temperature requirements (recording devices)
26. Temperature requirements (destruction of trichinae)
27. Testing for trichinae in horsemeat
28. Sanitary dressing (line speeds)
29. Sanitary dressing (congestion)
30. Sanitary dressing (inspection personnel)
31. Sanitary dressing (hand washing/tool sanitizing)
32. Sanitary dressing (product flow requirements)
33. Offal handling (green offal)
34. Offal handling (red offal)
35. Offal handling (tonsil removal)
36. Separation of operations

37. Drainage in suspect animal lairage
38. Separation of healthy and suspect animals
39. Sanitizing sticking knife between each carcase
40. Eviscerator's boot and apron wash
41. Livestock truck washing facilities
42. Veterinary supervision
43. Prior approval of blueprints, equipment and material
44. Non-uniform, on-the-spot actions by United States inspectors (line speed)
45. Non-uniform, on-the-spot actions by United States inspectors (bovine masseters and paratoid lymph node incisions)
46. Non-uniform, on-the-spot actions by United States inspectors (inspection of bovine peri-ocular region)
47. Post-mortem inspection (procedures)
48. Administrative actions (time for rectification of deficiencies)
49. Administrative actions (on-the-spot de-listing)
50. Administrative actions (lack of transparency of reporting system)
51. Administrative actions (import controls following suspected irregularities)
52. Administrative actions (submission of written monthly reports)
53. Administrative actions (control of transit product)
54. Demands made of Community veterinary services for certification on quality matters
55. Residues
56. Administrative actions (requirements for exporting firm to set up a financial trust)
57. Transparency of means for recognizing that a country is free from disease
58. Recognition of regional health status
59. The acceptance of Community sanitary measures applied via common Community disease management decisions
60. Apparent discrimination and lack of uniformity of United States authorities as regards recognition of different Member States' disease status

RECOMMENDATIONS ON ISSUES

ISSUE	CONCLUSION OF DISCUSSION	RECOMMENDED ACTIONS
1.	<i>Requirement to stun on poll</i> The United States agree not to use poll stunning for slaughtering of animals destined for the Community	Adaptation of FSIS instructions. No changes in Community requirements.
2.	<i>Use of wood in lairages</i> Both sides agree that wood must not be used in pens for sick and suspect animals and, in other cases, wood should not be recommended.	Adaptation of FSIS instructions. Amendment of Community instructions — (VM p. 13). In the phrase, 'However, where wood has been accepted temporarily, it must be gradually replaced with other materials . . .', 'must' should be replaced by 'should'.
3. and 37.	<i>Separate drainage for suspect animal pens</i> 'Separate drainage' is understood by both sides to mean that the drainage system should exclude any possibility that healthy animals can come into contact with effluent from pens containing suspect animals. This can be achieved by use of gratings or other effective means.	Adaptation of FSIS instructions. The Community will consider the need for clarification of the Community instructions — (VM).

ISSUE	CONCLUSION OF DISCUSSION	RECOMMENDED ACTIONS
4. and 38.	<i>Prevention of contact of suspect animals</i> This recommendation is based on regulatory requirements and established procedures in United States facilities leading to prompt disposal of condemned animals. The aim is to prevent further contact with healthy animals at the soonest possible time following their recognition as unacceptable for slaughter.	FSIS instruction will ensure that animals not acceptable for slaughter should immediately be removed. Clarification of Community instructions — (VM p. 16): '... Facilities for sick and suspect animals must be constructed ...' should be replaced by: '... Facilities for sick and suspect animals, taking into account diseases present in the region, should be constructed ...'.
5.	<i>Veterinary to perform ante-mortem inspection</i> The problem concerns ante-mortem veterinary inspection of animals at the slaughterhouse. The United States has proposed a solution which includes the following components: — that Community requirements permit that inspection be carried out on the farms (feed lot), — that the United States supply assurance that inspection is carried out at the feed lot by an accredited veterinary surgeon recognized by FSIS, — that the existing United States systems as indicated in the United States documentation (Annex V, subannex III in paragraph III, subparagraphs 1 and 2 but not 3), will continue to be applied on arrival at the slaughterhouse.	Both sides should consider further actions necessary.
6., 7. and 39.	<i>Sterilization of sticking knife between cuts and between carcasses</i> The inspector in charge of facilities approved for export to the Community shall take special care of the Community's concern for insuring that implements which have come in contact with the external surface of hides are cleaned before being used again on fresh meat.	Should be reflected in FSIS instructions. Community instructions (VM) should reflect that any implements which have been in contact with the external surface of hide shall be cleaned before they are used again.
8.	<i>Apron washing cabinets for 'sticker'</i> Withdrawn on the understanding that the preference for aprons to be washed in cabinets does not exclude use of flexible showers in accordance with point 9.	See point 9.
9.	<i>Use of 'drop-hoses'</i> Both sides agree that 'suspended, flexible showers, sprays and hoses' should only be used provided that: 1. contamination of fresh meat by splashing is prevented; 2. they are not used as a substitute for suitable handwashing facilities; and 3. they may generally only be used for carcase-wash following post-mortem inspection.	Should be reflected in FSIS instructions. Should be reflected in Community instructions — (VM).
10.	<i>Requirements for authorizing truck-wash facilities:</i> The United States require that means of transport for meat are cleaned acceptably and sanitized and checked by the responsible inspector before being used for that purpose. Establishments are authorized to use wash facilities of their choice on or off the premises of the plant. The location of the site of these premises is available from the plant management.	This situation should be reflected by relevant FSIS instructions and Community instructions — (VM).

ISSUE

CONCLUSION OF DISCUSSION

RECOMMENDED ACTIONS

To avoid contamination of the site, trucks used for transporting livestock are not normally washed on the site of the establishment. Responsibility for insuring that livestock-transporting vehicles are maintained in a sanitary condition rests with APHIS. In the case where disease-control measures are necessary trucks are cleaned and sanitized under the official control of APHIS at identified sites.

Both sides agree that cleaning and sanitizing of trucks can take place *on* or *off* the premises of the plant, provided that the location of the sites for meat vehicles are available to veterinary inspectors from the plant management. In the case of livestock transport, officially identified sites will be under the official controls of APHIS where disease control is necessary.

11. *Correlation of parts for post-mortem inspection (batch condemnation)*

Both sides agree on the need to correlate all offals with the carcase for the purpose of post-mortem inspection. They also agree that if the blood or offal of several animals is collected in the same container before the completion of the post-mortem inspection, the entire contents must be declared unfit for human consumption if the carcase of one of the animals concerned has been declared unfit for human consumption. (See Annex V schematic presentation).

FSIS instruction should reflect the need for the inspector in charge to demonstrate the effective operation of batch condemnation and correlation.

The Community agrees to consider the United States batching procedure as indicated in annexed schematic presentation as an acceptable batching procedure.

12. and *Post-mortem inspection procedures*

47. Both sides indicated details of differences in specific post-mortem inspection procedures for the different animal species. Exchange of documentation did not enable agreement to be reached. Both sides agree, however, that a joint review could lead to resolution of the matter.

Both sides agree on a joint evaluation of post-mortem inspection operations.

13. and *Veterinary control of cold stores, cutting, health marks and health labelling devices.*

The issues were examined on the basis of written documentation presented by the United States concerning the organization and responsibilities of the United States inspection system.

These issues were addressed in relation to an enhanced role of the FSIS as regards export to the Community.

Adaptation of FSIS instructions in accordance with Annex III.

The Community will consider further actions necessary including any necessary changes in its requirements.

15. *Requirement for medical certificates of first employment*

It is noted that the Community legislation gives the possibility of specific guarantees, which may be required regarding the medical supervision of staff working on, and handling, fresh meat.

The United States legislation requires that no operator of an official establishment shall employ in any department where any product is handled or prepared any person showing evidence of a communicable disease in a transmissible stage (does not include a specific requirement for medical certificates).

The United States will ensure that plant managements can demonstrate and document the way in which the United States requirements are applied in practice. This information will be made available to the official inspector on request.

The follow up system of medical supervision and official enforcement will be in accordance with the documentation presented by the FSIS. The Community will examine whether the United States follow-up system gives adequate guarantees for Community requirements (on a case-by-case basis).

16. *Welfare facilities*

Both sides agree that Community and United States requirements are basically the same.

Practical problems should be handled on a case-by-case basis in the ongoing review process between the United States and the Community at plant level.

ISSUE	CONCLUSION OF DISCUSSION	RECOMMENDED ACTIONS
17. <i>Employee clothing</i>	Both sides agree: — that Community and United States requirements are basically the same — that clothing of specified colour (e.g. white) is not a mandatory requirement, and — that clean working clothes shall be worn at the start of each working day and shall be changed during the day when required.	FSIS instruction will require that the industry and the FSIS be able to describe and demonstrate when necessary the system in place for enforcing United States requirements at plant level.
18. <i>Requirements for separate store for packaging materials</i>	Both sides agree that measures must be taken to insure that meat and meat products are not contaminated by wrapping and packaging materials.	FSIS guidelines to the industry should indicate Community requirements, that wrapping and packaging material, which will be taken into rooms where exposed fresh meat or offals are handled must be stored in separate rooms and in a way to avoid any contamination. The Community instructions — (VM) should include indications whereby the objectives of 'no air connection' in Community legislation could be satisfied in order to avoid contamination of packaging and wrapping materials.
19. <i>Facilities for dry storage of non-food items</i>	Both sides agree that detergents, disinfectants and similar substances should be stored in a secure place, in order to avoid contamination of meat or packaging material. A secure place could be a cupboard, trunk or similar storage facility. Handling of any such material must avoid any possibility of contamination of fresh meat or wrapping or packaging material.	Adaptation in FSIS instructions. No changes in Community requirements.
20. <i>Structural wood</i>	Both sides agree that the absolute Community prohibition of wood covers instruments and working equipment which might come into contact with fresh meat or offals. As regards the structural use of wood both sides agree that such structures must be in good condition, impermeable, smooth durable, rot-proof and scaled with a coating that is waterproof. The United States proposed that the structural and overhead wooden beams (including beams in chillers and coolers) that have been impregnated with an approved compound (e.g. hot linseed oil) fulfill this requirement.	The United States has presented a paper to support its proposal. The Community will consider whether this can be considered an acceptable structural use of wood. The United States will incorporate provisions in FSIS instructions to ensure effective control and hygienic maintenance of structural surfaces.
21. <i>Wooden equipment</i>	Withdrawn on grounds that it is not a major issue. The United States agree that the use of wood in this area shall be phased out.	Any specific problems that arise should be addressed during plant review, it being understood that emergency maintenance equipment, such as ladders, may be used provided that there is no risk of contamination of fresh meat or offals.
22. and 23. <i>Potable water (testing frequency and biological parameters).</i>	It is noted that in accordance with Article 4 (c) of Council Directive 72/462/EEC specific guarantees may be required concerning the quality of the potable water used by establishments.	FSIS should present specific guarantees concerning the quality of potable water used by each establishment. The Community undertakes to consider promptly all submissions.

ISSUE	CONCLUSION OF DISCUSSION	RECOMMENDED ACTIONS
24.	<i>Meat temperature requirements</i> Discussions indicate that the United States system appears to obtain meat temperatures required by Community legislation.	The Community will consider whether the temperatures achieved operationally by the United States system are acceptable. The United States will incorporate provisions in FSIS instructions to ensure that the veterinarian in charge effectively enforces Community meat temperature requirements.
25.	<i>Temperature recording devices</i> The United States side requests that handwritten recording of room temperatures be considered acceptable in low volume plants.	The Community will consider whether handwritten recording of room temperatures can be acceptable in low volume plants.
26.	<i>Temperature for 'trichinae' destruction</i> The United States has presented an alternative cold temperature treatment system to the Community for the destruction of trichinae in pigmeat (see Annex V).	The Community agrees to examine the United States' documentation in order to determine whether it provides an acceptable alternative health guarantee.
27.	<i>Necessity to examine horse meat for trichinae</i> The United States has presented documentation questioning the necessity to examine horsemeat for trichinae.	The Community agrees to study scientifically the documentation presented by the United States.
28., 29., 30., 31. and 32.	<i>Sanitary dressing</i> Both systems rely on the judgement of the official veterinarian to determine whether sanitary dressing is carried out in such a way that an acceptable level of hygiene is maintained. Problems arise from an apparent difference in the unwritten standards applied by each system.	Both sides recommend that there should be improved on-the-spot dialogue between the veterinarians at plant level both with the objective of finding solutions on the spot and of improving their professional dialogue. The above recommendation should be supported by a clearer understanding of the interpretation of the Community requirements by FSIS. Should be done against the background of an enhanced role for FSIS in the Community plant approval process, including inspection and hygienic control. Should be supported by ongoing bilateral contacts within an established structure. This dialogue should involve all appropriate levels of the inspection services including veterinary inspection staff charged with plant inspection on both sides (see Annex IV).
33.	<i>Necessity for separate room to clean stomachs and intestines</i> It is agreed by both sides that Community legislation (Directive 64/433/EEC) does not require a separate room provided that the conditions enumerated in Chapter 11, 14c of that Directive are fulfilled.	A clarification of the Community requirements on this point should be considered with a view to indicating that in relation to green offal from pigs, partitioning should be required, on a case-by-case basis, where it is necessary to prevent contamination of fresh meat or offals.
34.	<i>Handling of red offal</i> Withdrawn. The problem arose from a misunderstanding of Community requirements and should not arise in the future.	
35.	<i>Offal handling (pig tonsil removal)</i> It is agreed by both sides that the removal of pig tonsils should be made in a way to prevent contamination of the head and tongue. The issue should be solved during plant review.	A clarification of the Community instructions — (VM) on this point should be considered.

ISSUE	CONCLUSION OF DISCUSSION	RECOMMENDED ACTIONS
36.	<i>Separation of operations</i> Withdrawn on the understanding that no condiments or spices will be handled or used in the same place where fresh meat is handled, cut or chopped.	
40.	<i>Eviscerators boots and apron wash</i> The United States side confirms that it applies the same requirements to imported and domestically produced products. That is to say that the United States only requires washing when contamination occurs. As a result of the discussions that have taken place in the context of these negotiations any misunderstanding of United States requirements should have been eliminated.	Future questions arising from the application of these requirements should be addressed during plant review (see Annex IV).
41.	<i>Truck wash facilities</i> Withdrawn. The problem arose from the application of implementing measures. There is a difference in legal requirements. As there is no United States requirement the problem should not arise in the future (see point 10).	
42.	<i>Veterinary supervision of plants</i> The United States confirms that veterinary supervision requirements applicable to Community plants for export to the United States does not exceed United States domestic requirements.	
43.	<i>Prior approval of blueprints of equipment and materials</i> It was clarified during the course of the discussion that the United States does not impose an absolute requirement that plants in foreign countries submit blueprints to their national authorities for prior approval.	The United States will continue to apply equivalence for this requirement.
44., 45., 46., 47., 48., 49., 50., 51.	<i>Administrative actions</i> <i>Idem</i> 28 to 32	See Annex III. See Annex IV.
52.	<i>Administrative actions (submissions of monthly reports)</i> In the overall context of equivalency there should be periodic visits by a veterinarian at supervisory level of the exporting country to approved establishments, in principle on a monthly basis. Written reports of the above visits should be made available to the visiting inspection officials representing importing countries. Such visits or reports should not be required during periods when establishments are not operating or are not engaged in producing products for exportation to the host country.	Further details for this issue should be established within the framework of Annex IV including the matter of confidentiality. See Annexes III and IV.
53.	<i>Administrative actions (control of transit products)</i> The problem appears to arise from the requirements of countries of destination (insisting upon having sealed containers opened at the transit point) and not the United States.	See Annex IV.

ISSUE	CONCLUSION OF DISCUSSION	RECOMMENDED ACTIONS
54.	<i>Demands made of Community veterinary services for certification on quality matters</i> Not addressed at technical level in accordance with the agreement to exclude these issues from these talks.	
55.	<i>Demands made of Community veterinary services for residues</i> Not addressed at technical level in accordance with the agreement to exclude these issues from these talks.	
56.	<i>Financial trust fund</i> Prior to granting export approval, the United States requires Community plant operators to set up a financial trust fund to be used to pay for inspections for additional animal health safeguards which are required by the USDA. The Community questions the justification for this mandatory requirement. Changes of USDA regulation may be possible.	The USDA will review its requirement for a financial trust fund from Community exporting plants.
57.	<i>Transparency of means used for recognizing that a country is free from disease</i> Both sides use a system that relies on requests for information and on-site visits to gather information about the conditions in foreign countries. In both systems, a committee evaluates the data in relation to, and gives an opinion on, disease status prior to the final decision. In the United States this process, in some cases, has taken more than one year because of administrative procedures. The onus is on the exporting country to apply for recognition of its status in both systems. The status depends, amongst other things, on the import policy in the exporting country. As of 1 July 1992, veterinary checks at internal borders in the Community will be replaced by a system which includes reinforced checks at the origin. Both sides agree that this system should provide sufficient health guarantees to allow the existing health status of Community Member States to be maintained.	The USDA will undertake to continue the recognition of the freedom of the Member States from animal diseases as follows: FMD and rinderpest United Kingdom, Ireland, Denmark Code 94.1 VVND United Kingdom, Ireland, Denmark Code 94.6 Hog cholera United Kingdom, Ireland, Denmark Code 94.9 SVD United Kingdom, Ireland, Denmark, Luxembourg Code 94.12 ASF all except Italy, Portugal, Spain Code 94.8 AHS all except Portugal and Spain Code 92.301 without the application of additional safeguards after 1 July 1992 when internal veterinary border controls are removed in the Community. However, in view of changing patterns of trade, the USDA is considering the application of non-comminglement requirements to Irish meat plants (these are already applied in the United Kingdom and Denmark). Non-comminglement in this context means that the plant concerned does not handle at the same time, animals, meat or products from countries which are not recognized as free from relevant diseases and that there is no mixing of the meat or products destined for the United States with meat or products from such countries. The USDA will undertake to rapidly process applications from Member States which are not now recognized as free from certain diseases by USDA. For the purpose of recognition of disease free status, USDA will undertake to accept Community legislation which is legally binding on all Member States, where it exists, and is the legal basis for animal disease control measures and animal health policy in relation to imports of live animals, meat and products.

ISSUE	CONCLUSION OF DISCUSSION	RECOMMENDED ACTIONS
58.	<i>Recognition of regional health status</i> The Community has submitted a document to APHIS, entitled 'The Community Single Market — a new strategy in the field of animal and plant health'. This details the management structure for dealing with epizootic animal disease in the Community. Both sides recognize the potential benefits of the regionalization concept when dealing with outbreaks of exotic epizootic diseases, and that the criteria for definition of the region and the method of management of the region are critical. APHIS has established a working group to study the application of the regionalization concept to animal disease control measures.	The Community Commission will undertake to provide the necessary data to expedite the listing of Member States as free from animal diseases as appropriate. On the basis of the Community strategy paper the USDA recognizes that Community policy for disease control on a regional basis may give acceptable guarantees to prevent the spread of animal disease via products of animal origin. The United States will reconsider its import policy in the light of the regionalization concept, and if appropriate, will undertake to amend its regulations and legislation concerning FMD, rinderpest and other relevant diseases.
59.	<i>The acceptance of Community sanitary measures applied to countries or regions with different disease incidence</i> Both sides recognize that certain diseases may be present at different levels of incidence in countries or regions and that a different level of risk is attached to imports from countries or regions with different disease incidence.	The USDA recognizes that BSE is of low incidence in Ireland and France and presents a different epidemiological situation to that in the United Kingdom. The USDA accepts that a different incidence of a specific disease may exist between different countries and that the risk of importation from countries with a low incidence is less than from those with a high incidence, and will evaluate BSE and scrapie research available, study OIE recommendations, and implement risk assessment studies with a view to modify import procedures.
60.	<i>Apparent discrimination and lack of uniformity of United States authorities as regards recognition of different Member States disease status</i> Both sides agree that the recognition of disease-free status depends on the disease situation, control system, etc. and that countries should be treated without discrimination. Imports of certain types of product are accepted by the USDA from some countries although the countries are not free from SVD, but these products are not accepted from other countries which are considered free by the Community. Studies indicate that SVD virus survival may exceed 500 days in certain cured ham products. Therefore, the USDA is carrying out an evaluation of the SVD status of the exporting country concerned.	The USDA will undertake to apply risk reduction measures uniformly to all Member States of similar status. The USDA will undertake not to unduly delay acceptance of imports after the results of scientific studies are available and agrees that any such studies should be relevant to the disease situation in the Member State concerned.

ANNEX II

17 July 1992

INTERIM MEASURES

With the objective of meeting the requirements of the Community third country Directive and without prejudice to Annex I to this Agreement, both Parties agree that the Community will accept, subject to the usual Community listing procedures, products from United States porcine and bovine animal slaughterhouses which comply with Community and United States requirements with the following temporary, specific modifications.

1. Application of the recommendation on issues Nos 1 to 4, 6 to 11, 13 to 19, 22 to 24 and 35 (Annex I).
2. FSIS will operate an enhanced role in accordance with Annex III.
3. Both parties will initiate the development of cooperative actions in accordance with Annex IV.
4. Concerning the post-mortem inspection of pig hearts, the incision will be made by plant personnel prior to the heart inspection by FSIS personnel.
5. Wooden beams used in chillers are accepted provided that they are in good condition, smooth and treated with hot linseed oil or other acceptable compounds to render them impermeable, sealed and rot-proof and that FSIS ensures effective control of hygienic maintenance. When perished, wooden beams will be replaced by alternative materials.
6. Cleaning and preparation of pigs stomachs (issue 33)

in relation to green offal from pigs, cleaning and preparation shall not take place in the slaughter room during preparation of product for Community markets,

or

in relation to green offal from pigs partitioning of the closed-circuit mechanical equipment shall be required on a case-by-case basis, where it is necessary to prevent contamination of fresh meat or offal.

In addition, during this intervening period, veterinary ante-mortem inspection of all animals for slaughter at the slaughterhouse will continue to apply.

ANNEX III

Non-paper

ENHANCEMENT OF FSIS ROLE IN RELATION TO INSPECTION AND ASSURANCES
CONCERNING PLANT LISTING

1. The United States has explained the FSIS organization and responsibilities in detail, as indicated below in a letter from Dr Dubbert, Deputy Administrator International Programmes of 27 April 1992.

STRUCTURE AND CONTROL OF THE EXPORT OPERATIONS OF THE FOOD SAFETY AND
INSPECTION SERVICE*1. Organizational structure*

The Food Safety and Inspection Service (FSIS) is composed of five major programme areas, each of which is headed by a Deputy Administrator who answers directly to the Administrator (see Figure 1-1). The two programme areas that play the largest role in ensuring that fresh meat for export to foreign countries is safe, wholesome, and accurately labelled are international programmes and inspection operations. As is the case with all five programme areas, international programmes and inspection operations are organizationally linked through the office of the administrator. However, in practice these two programme areas coordinate their activities at the appropriate working levels.

A. International programmes

Within international programmes, responsibility for developing and coordinating export policy rests with the export coordination division. The Director of the export coordination division is a veterinarian and there are five veterinarians on the staff of the division. Based on an ongoing review of the import requirements of roughly 80 foreign countries, including every Community Member State, the export coordination division has developed a database that contains instructions on how to satisfy the requirements for every product exported to each country. FSIS policy on exports to any given country is translated into regulatory practice through the instructions contained in this database. (See attached instructions for exports to the United Kingdom.) The database can be accessed directly by exporting establishments, and paper copies of the instructions, including updates and other amendments, are provided by the export coordination division to the regional offices of inspection operations for dissemination to exporting establishments.

In addition to updating and disseminating these instructions, the export coordination division also is responsible for maintaining lists of establishments that are approved for export to specific foreign countries. Visits by foreign reviewers to these establishments are managed by the export coordination division from Washington. To coordinate the development and implementation of export policy, international programmes endeavour to include appropriate inspection operations personnel, as well as a member of the export coordination staff, in all foreign reviews. The observations made by the foreign reviewers on deficiencies in the establishment at the time of the exit meetings with the inspector-in-charge and plant management are fed into the international programmes database and often result in changes in the instructions for specific foreign countries.

B. Inspection operations

An important part of the regulatory function performed by inspection operations is the implementation of the export policy developed by international programmes. The inspection activities of FSIS are carried out by a network of five regional offices, 26 area offices, and 188 inspection circuits. Each regional office is managed by a regional director who is a veterinarian. In the 23 areas that contain slaughter establishments the area offices are run by area supervisors who are veterinarians, and the circuit supervisors who manage the slaughter inspection circuits in these areas are also veterinarians. This pyramidal structure has at its base the inspector-in-charge (IIC) in the slaughter establishments. Thus, the chain of command in inspection operations runs from the Deputy Administrator to the Regional Directors through the area supervisors to the circuit supervisors and finally to the IICs.

Built into the inspection operations organizational structure is a system of checks that begins with the oversight function of the regional and area offices. However, the key link in the chain of command between the regional/area level and the establishments themselves is the circuit supervisor. This means that he also is the principal conduit of information between the establishments and the export coordination division of international programmes. The circuit supervisor is responsible for visiting all of the slaughter establishments in his circuit regularly and is required to carry out an in-depth review of each facility, including a check for compliance with foreign countries' import requirements. This review yields a written report which, when necessary, forms the basis for a plant improvement programme to address specific deficiencies noted by the circuit supervisor. In many cases, the area supervisor and slaughter and processing experts from the regional office join the circuit supervisor when he makes the quarterly reviews.

II. *Control and responsibility at plant level*

A. Slaughter establishments

The inspector-in-charge in each slaughter establishment is responsible for inspection and control of slaughter operations. In all but the smallest facilities, the IIC is a veterinarian, and he is assisted by a staff composed of other veterinarians and meat inspectors. The IIC's specific responsibilities include certifying that foreign countries' requirements, as they are recorded in the instructions from Washington, are being met. Although the IIC normally delegates certain parts of his overall responsibility (post-mortem inspection, for example) to his staff, his signature must appear on the export certificate. By signing the export certificate for a consignment of products destined for the Community, for example, the IIC certifies that the products in that consignment qualify for export to the Community.

The IIC does not control (physically) United States or Community labelling materials. (The IIC does control the USDA brand that is applied on the kill floor.) Although the IIC is responsible for ensuring that all product leaving the slaughterhouse is properly identified, plant management actually purchases, stores, and applies (under FSIS supervisor) all United States and Community labels. While the IIC is not directly responsible for the labelling material, he does have complete control over export certificates. All export certificates are issued directly to the IIC from the regional offices. The IIC is responsible for maintaining an inventory of certificates in his possession and keeping them in a secure place. As an additional control, all cartons in a given shipment are stamped with the number on the export certificate that is prepared for that shipment and the stamp used for making the cartons is controlled by the IIC.

B. Cutting plants and cold stores

Consistent with FSIS regulations, a trained veterinarian normally is not present in most cutting plants and cold stores in the United States. However, both types of facility are under the supervision of the circuit supervisor, who is in most cases a veterinarian. Normally it is possible to satisfy the Community's requirements for veterinary supervision by ensuring the presence of a veterinarian when cutting is being done for the Community market or product in cold stores is being prepared for export to the Community. In the majority of cases, FSIS is able to accommodate facilities interested in exporting to the Community because the cutting premises are part of an integrated plant headed by an IIC or cold stores are located near a Community-approved slaughterhouse.

2. The United States side has expressed its willingness to explore ways to change its policy in relation to inspection and assurances concerning plant listing to enhance the role of the FSIS

3. The United States has in addition indicated:

'Concerning FSIS participation in the Community approval process for United States plants . . . FSIS will only ask the Community to inspect those plants we fully believe to meet the Community's requirements.

When necessary, the FSIS will certify the correction of deficiencies.'

4. As regards implementation of the above:

FSIS/export coordination division (ECD) will work with United States-MEF to identify plants interested in exporting to the Community.

These plants will then be visited by FSIS/ECD staff who will offer technical assistance, professional advice and explanation of Community requirements.

The information regarding Community requirements in the export coordination division database will be used by the veterinary chain of command responsible for the review of facilities wishing to be approved for export to the Community.

Based on these plant visits FSIS/ECD will nominate plants for Community review.

Administratively the EEC will be asked by FSIS/ECD only to visit plants they fully believe meet the Community requirements after these in depth reviews of the facility concerned.

Following the request of the FSIS, the EEC will undertake to make inspection visits without undue delay.

FSIS/ECD personnel will accompany Community review teams.

Following visits by EEC reviewers, FSIS/ECD will address correction of deficiencies in order to obviate visits by EEC officials, and will certify the correction of deficiencies.

The inspector in charge of each establishment shall use the database information regarding Community requirements in order to fulfil specific responsibilities including certifying that Community requirements are met.

The same database information regarding Community requirements in the export coordination division database will be made available to the EEC. The contents and any changes envisaged by either side will be agreed by ongoing cooperation procedures.

The written reports of periodic routine oversight visits by the veterinary chain of command will be available on request to visiting foreign reviewers.

FSIS will immediately notify Community authorities when it determines that operations in a plant are incompatible with Community requirements, and after changes such as cessation of operation or significant structural or operational alterations.

Slaughter premises will have constant veterinary presence, cutting premises will be visited at least once a day by an official veterinarian and stores will be visited periodically by an official veterinarian when they are not under the supervision of the veterinary inspector in charge of combined plants. The responsible veterinarian shall have control of United States stamps and brands which are kept in locked premises. Community labels and marks will also be under the control of the veterinarian (and kept in locked facilities). The responsible veterinarian shall sign all EEC health certificates (issue items 13 and 14).

Ante-mortem inspection will be carried out by a veterinarian (issue item 5).

5. Based on the experience gained from the operation of the above system, the United States requests that plants certified by the FSIS as being in compliance with Community requirements be approved by the Community prior to visit by Community inspectors.
6. The EEC will consider in the context of a mutually agreed approach, the possibilities of approving plants certified by the competent authorities of Third Countries prior to visits by Community reviewers.

ANNEX IV

PROPOSAL FOR UNITED STATES-COMMUNITY COOPERATION PROCEDURE

Issues where improved communication and cooperation is necessary

A number of issues appear to arise from decisions taken at different levels of responsibility where the legislation is not specific. The assessments indicate that these fall into at least three levels where recommendations for improved cooperation could be made.

(a) *Recommendations concerning administrative problems at general level*

Both sides agree that a closer system of formalized contacts should be established at the appropriate level to address future problems and misunderstandings in the area. Since problems may arise on a daily basis between services it is not sufficient to have bilateral contacts only once or twice a year. Each side will identify contact persons who will be available on a daily basis to coordinate bilateral communications. Veterinary attaches can play a useful role in this context (issue items 17 and 40).

(b) *Recommendations concerning problems arising from application of implementing measures*

Both sides agree that a system should be established for reviewing recommendations and instructions developed by each side before they are formally adopted. This will lead to a more common approach to the development of these guidelines. In addition an improved system for the exchange of relevant information should be developed.

(c) *Recommendation concerning issues arising from acceptance of professional, individual judgement of official veterinarians*

Both systems rely on professional veterinary judgement for a number of decisions.

In order to get to a common approach during actual inspection, it could be suggested that joint seminars and training programmes be arranged.

Both sides agree that it may also be necessary to establish an administrative route of appeal and a system for resolution of disputes between veterinarians at the plant level (issue items 28 to 32).

(d) *Recommendation concerning issues which might be resolved by improved cooperation at scientific level*

A number of issues would appear to need more detailed scientific study in order to be resolved. It might be recommended that cooperation in scientific work between nominated instances be instituted and financed by both administrations.

ANNEX V

Annex I.C

ORGANIZATION, STRUCTURE AND RESPONSIBILITIES OF FSIS

United States Department of Agriculture

Food Safety and Inspection Service

Washington, D.C.
20250

27 April 1992

Mr. Thad Lively
Agricultural Officer
U.S. Mission to the European Communities
PSC B2 Box 002
APO AL 09742

Dear Thad:

Following is the structure and control of the export operations of the Food Safety and Inspection Service.

I. Organizational Structure

The Food Safety and Inspection Service (FSIS) is composed of five major program areas, each of which is headed by a Deputy Administrator who answers directly to the Administrator (see Figure 1-1). The two program areas that play the largest role in ensuring that fresh meat for export to foreign countries is safe, wholesome, and accurately labeled are International Programs and Inspection Operations. As is the case with all five program areas, International Programs and Inspection Operations are organizationally linked through the Office of the Administrator. However, in practice these two program areas coordinate their activities at the appropriate working levels.

A. International Programs

Within International Programs, responsibility for developing and coordinating export policy rests with the Export Coordination Division. The Director of the Export Coordination Division is a veterinarian and there are five veterinarians on the staff of the division. Based on an ongoing review of the import requirements of roughly 80 foreign countries, including every EC member state, the Export Coordination Division has developed a database that contains instructions on how to satisfy the requirements for every product exported to each country. FSIS policy on exports to any given country is translated into regulatory practice through the instructions contained in this database. (See attached instructions for exports to the United Kingdom.) The database can be accessed directly by exporting establishments, and paper copies of the instructions, including updates and other amendments, are provided by the Export Coordination Division to the Regional Offices of Inspection Operations for dissemination to exporting establishments.

In addition to updating and disseminating these instructions, the Export Coordination Division also is responsible for maintaining lists of establishments that are approved for export to specific foreign countries. Visits by foreign reviewers to these establishments are managed by the Export Coordination Division from Washington. To coordinate the development and implementation of export policy, International Programs endeavors to include appropriate Inspection Operations personnel, as well as a member of the Export Coordination Staff, in all foreign reviews. The observations made by the foreign reviewers on deficiencies in the establishment at the time of the exit meetings with the inspector-in-charge and plant management are fed into the International Programs database and often result in changes in the instructions for specific foreign countries.

B. *Inspection Operations*

An important part of the regulatory function performed by Inspection Operations is the implementation of the export policy developed by International Programs. The inspection activities of FSIS are carried out by a network of five regional offices, 26 area offices, and 188 inspection circuits. Each regional office is managed by a regional director who is a veterinarian. In the 23 areas that contain slaughter establishments the area offices are run by area supervisors who are veterinarians, and the circuit supervisors who manage the slaughter inspection circuits in these areas are also veterinarians. This pyramidal structure has at its base the inspector-in-charge (IIC) in the slaughter establishments. Thus, the chain of command in Inspection Operations runs from the Deputy Administrator to the Regional Directors through the area supervisors to the circuit supervisors and finally to the IICs.

Built into the Inspection Operations organizational structure is a system of checks that begins with the oversight function of the regional and area offices. However, the key link in the chain of command between the regional/area level and the establishments themselves is the circuit supervisor. This means that he also is the principal conduit of information between the establishments and the Export Coordination Division of International Programs. The circuit supervisor is responsible for visiting all of the slaughter establishments in his circuit regularly and is required to carry out an in-depth review of each facility, including a check for compliance with foreign countries' import requirements. This review yields a written report which, when necessary, forms the basis for a plant improvement program to address specific deficiencies noted by the circuit supervisor. In many cases, the area supervisor and slaughter and processing experts from the regional office join the circuit supervisor when he makes the quarterly reviews.

II. Control and Responsibility at Plant Level

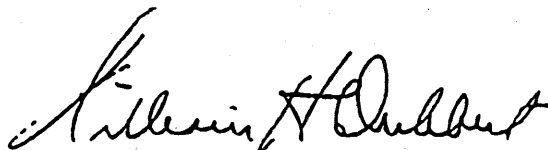
A. *Slaughter Establishments*

The inspector-in-charge in each slaughter establishment is responsible for inspection and control of slaughter operations. In all but the smallest facilities, the IIC is a veterinarian, and he is assisted by a staff composed of other veterinarians and meat inspectors. The IIC's specific responsibilities include certifying that foreign countries' requirements, as they are recorded in the instructions from Washington, are being met. Although the IIC normally delegates certain parts of his overall responsibility (post-mortem inspection, for example) to his staff, his signature must appear on the export certificate. By signing the export certificate for a consignment of products destined for the EC, for example, the IIC certifies that the products in that consignment qualify for export to the Community.

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B. *Cutting Plants and Cold Stores*

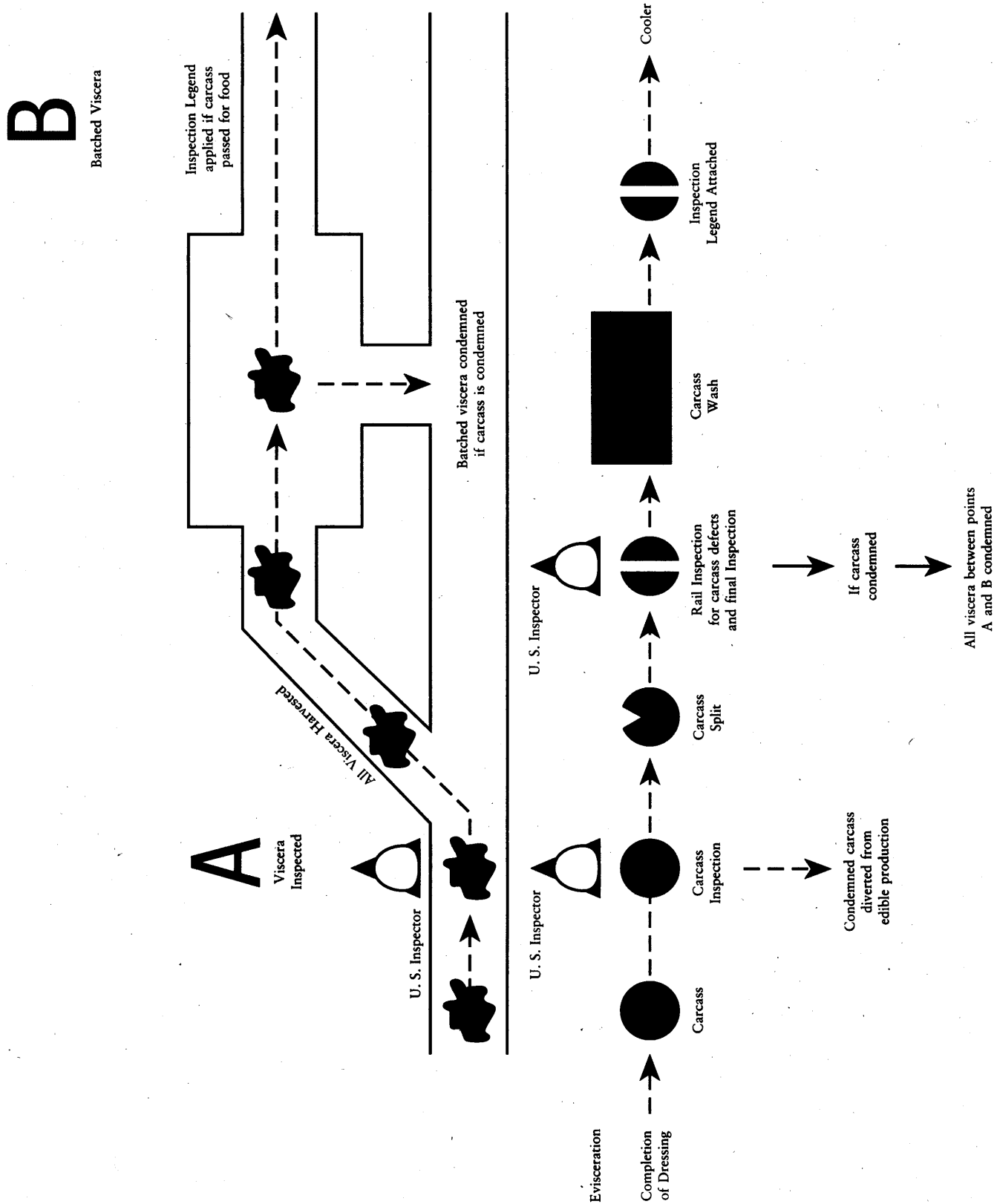
Consistent with FSIS regulations, a trained veterinarian normally is not present in most cutting plants and cold stores in the United States. However, both types of facility are under the supervision of the circuit supervisor, who is in most cases a veterinarian. Normally it is possible to satisfy the EC's requirements for veterinary supervision by ensuring the presence of a veterinarian when cutting is being done for the EC market or product in cold stores is being prepared for export to the Community. In the majority of cases, FSIS is able to accommodate facilities interested in exporting to the EC because the cutting premises are part of an integrated plant headed by an IIC or cold stores are located near an EC-approved slaughterhouse.



William H. Dubbert
Deputy Administrator
International Programs

Annex II

POST-MORTEM CORRELATION AND BATCHING



*Annex III***VETERINARY ANTE-MORTEM INSPECTION****FINAL DRAFT****5. Ante-mortem Inspection by an Official Veterinarian**

Issue: Should ante-mortem inspections be performed by official veterinarians?

US 9 CFR 311.1 — Disposal of disease or otherwise adulterated carcasses and parts: general — The veterinary medical officer shall exercise his judgement regarding the disposition of all carcasses or parts of carcasses under this part in a manner which will ensure that only wholesome, unadulterated product is passed for human food (legal requirement that dispositions of all carcasses be based on judgement of veterinary).

US — Meat and Poultry Manual permits up to 90 % of sorting prior to observation of the animals by FSIS inspectors to be carried out by non-veterinarians and non-inspectors.

US — 9 CFR 309.1(a): 'All livestock offered for slaughter in an official establishment shall be examined and inspected . . . before slaughter.' (No legal requirement that ante-mortem inspection be performed by a veterinarian.)

Basis for Requirements

- A. In so far as the European Community and the US cattle brought to slaughter are similar in age and health status the two systems are parallel to one another. Under both EC and US systems, each animal that has served more than one purpose during its lifetime before going to slaughter is thoroughly examined by a veterinarian upon ante-mortem inspection. The differences between the EC and US systems lie in the handling of animals that are unique to the cattle industry and for which there is no counterpart in the EC system.

I. US Cattle Industry

The US cattle industry is composed of utility and feedlot animals.

Utility cattle are culled at the end of their productive life. Cull animals represent 15 % of the animals presented for slaughter and deemed fit for human consumption. These animals have served more than one purpose during their lifetimes. For example, they may have been used in dairy production or as breeders in the cow/calf herds. Characteristically, they are older and subject to a variety of health problems. When they are presented for slaughter, they require close scrutiny by a veterinarian.

Fed (feedlot) cattle represent 85 % of all animals sent to slaughter. These animals are unique by EC standards because they are generally younger (18 to 24 months old) when sent to slaughter; in the prime of their lives; in excellent health and vitality; have had excellent medical care and inoculations; have been given a scientifically designed nutritional program; have been raised in large holdings in semi-isolation to reduce their exposure to contagion and other risks; and, very importantly, have been raised solely for the purpose of providing meat.

II. EC System

It is our understanding of the EC system that animals presented for slaughter have led multi-purpose lives and generally are older. Their lives and health status are more akin to the US animals that are culled from dairy or breeding herds. Such animals are in greater need of an examination by a veterinarian because the chance for health problems is greater among this population. The USDA recognizes this hazard and, like the EC, requires that these animals receive more intensive review by veterinarians.

III. US Systems of Inspection

The US has three tiers of ante-mortem inspection procedures for the three kinds of situations that exist in the US cattle industry.

1. Cull Animals

Because these animals have served multiple purposes in their lifetimes, they are usually slaughtered in unique facilities specialized in handling this type of animal. These animals undergo

a thorough examination by a veterinarian. The task is never delegated and is always done in a traditional manner by an FSIS veterinary medical officer (VMO). This means that animals are observed while at rest and in motion, on both sides.

2. Traditional Ante-mortem Inspection of Fed Animals

One hundred percent of these animals are observed at rest and in motion, on both sides, in the traditional manner, by a veterinarian or an FSIS non-veterinarian inspector. Then, either a veterinarian or an FSIS non-veterinarian inspector, who is specially trained to identify abnormal from normal animals, performs the ante-mortem inspection. Abnormal animals are segregated for an additional examination by the veterinarian who also decides the final disposition of the animal. Only normal animals proceed directly to slaughter.

3. Alternative Inspection of Fed Animals

Alternative inspection allows trained plant personnel to screen the herds and assure that only sound, healthy animals are presented for ante-mortem inspection and slaughter. Each establishment using this option must have the prior approval of the FSIS Area Supervisor, who is a veterinary medical officer. The initial screening is done by feedlot operators on a daily basis. These feedlot employees are responsible for feeding and caring for the animals and see them every day. If an animal is seen to be feeling ill or is doing poorly for some reason, that animal is removed from the competition of the large herd and raised in a smaller pen until it regains its health and strength. All fed animals in this system are under close scrutiny by the contract veterinarian who is employed by the feedlot. Following the initial screening, FSIS personnel, either a veterinarian or an FSIS non-veterinarian inspector, observe 100% of the animals at rest. Then a representative sample of the herd (5 to 10%) is selected from several lots and inspected again, this time only while in motion, and from both sides. Any abnormal animals are given another full, traditional examination by a veterinarian — at rest and in motion, and from both sides. The VMO then makes a final disposition.

IV. *Experience of the US System*

During the nine decades that these three systems have been used and refined in the US, they have proven to be highly effective in sorting and removing animals that are deemed unfit for human consumption.

US DOCUMENTATION

(Trichinosis)

Trichinae destruction requirements

Issue: What time/temperature combinations are necessary to completely destroy trichinae?

Legislation:

EC — Directive 77/96/EEC of 12/21/76, Annex IV:

- '6. The temperature in the refrigeration room must be at least -25°C .'
- '7. Meat with a diameter or thickness of up to 25 cm must be frozen for at least 240 consecutive hours, and meat with a diameter or thickness of between 25 and 50 cm must be frozen for at least 480 consecutive hours.'

US — 9CFR 308.3 (c) (2) states acceptable time/temperature relationships (tables 1 and 2).

Analysis: The problem arises from a difference in the legal requirements.

Basis for requirement:

A. US

The time and temperature relationships in table 1 have been used by the USDA for over 40 years. Those in table 2 were added in 1973. The time and temperatures in table 1 are based on work by Ransom (1920). Over the years it has been noted that Ransom worked mainly with air temperature in ordinary cold storage facilities where the rate of change in the temperature of the meat containing the parasite was relatively slow (Augustine, 1933; Blair and Lang, 1934).

Augustine (1952) and Gould (1949) concluded that trichinae could be destroyed by lowering the temperature of the product to -35°C and -37°C respectively. However to attain these temperatures with conventional, mechanical freezing techniques available at that time was highly impractical. With the advent of cryogenic materials, such as liquid nitrogen and liquid carbon dioxide, the attainment of the -35°C in pork tissues under commercial condition is feasible and practical.

With this in mind Zimmermann (1972) studied the effectiveness of these freezing materials for the destruction of trichinae and the minimum temperatures required to render the product safe for consumption without further treatment. He showed that a product temperature of -29°C rendered the product free of trichinae.

Kotula's work (1990) provides a continuum of definitive times and temperatures necessary to destroy trichinae. Since 1985, these are two of the most outstanding papers on trichinae freezing. These studies support the USDA refrigeration temperatures in table 2 as ensuring an adequate margin of safety for the destruction of trichinae. The Kotula study indicates that the safety margin of the freezing temperatures in table 2 exceeds the 99,99% upper confidence limits that the trichinae are destroyed.

The temperatures in table 2 are relatively simple and economical to attain with today's technology. In addition, they free the processor from the problems associated with long-term storage of pork to destroy trichinae.

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**A Report on the April 8—18, 1991 Visit of a United States Department of Agriculture (USDA) Team to
France Regarding the Outbreak of Trichinosis in Humans**

Team Members:

Robert Fetzner, D.V.M.; Caldwell W. Nash; Charlotte I. Miller, Ph.D.

Report Editor:

Linda Russell. M.A.

DRAFT

June 20, 1991

United States Department of Agriculture

Food Safety and Inspection Service (FSIS)

International Programs

Washington, D.C.

**Taken from the Proceedings of the 95th Annual Meeting of the United States Animal Health Association, San
Diego, California, 1991**

Information on the entry into force of the Agreement between the European Economic Community and the United States of America on Slaughterhouses ⁽¹⁾

The Agreement in the form of exchanges of letters between the European Economic Community and the United States of America on the application of the Community third country meat Directive (Council Directive 72/462/EEC) and the corresponding United States of America regulatory requirements with respect to trade in fresh bovine and porcine meat, which the Council decided to conclude on 26 October 1992, will come into force on 1 July 1994, the notifications regarding the fulfilment of the procedures required for this purpose having been completed on 13 November 1992. During the period prior to the final entry into force of the Agreement, the interim measures laid down in Annex II to the Agreement will apply.

⁽¹⁾ See page 1 of this Official Journal.