I

(Meddelelser)

RÅDET

VETERINÆRAFTALE MELLEM USA OG EF

(98/C 136/01)

(Denne tekst annullerer og træder i stedet for teksten offentliggjort i EFT C 122 af 21. april 1998)

Rådet godkendte nedenstående erklæring samtidig med vedtagelsen af afgørelsen om indgåelse af aftalen mellem Amerikas Forenede Stater og Det Europæiske Fællesskab om sundhedsforanstaltninger til beskyttelse af folke- og dyresundheden i samhandelen med levende dyr og animalske produkter [1]:

»Rådet noterer sig brevvekslingen mellem Kommissionen og De Forenede Staters Landbrugsministerium og beslutter at optage disse breve i mødeprotokollen.

Rådet understreger, at disse breve udgør et væsentligt argument for dets beslutning om at godkende veterinæraftalen mellem EF og USA.

Rådet og Kommissionen anser det politiske engagement, der gives tilsagn om i disse breve, for at være en væsentlig forudsætning for at sikre en korrekt, afbalanceret og fuldstændig iværksættelse af aftalen.

Kommissionen bekræfter, at den i overensstemmelse med artikel 4 i Rådets afgørelse vil anvende bestemmelserne i artikel 14 i aftalen ved behandlingen af ethvert problem, der opstår i forbindelse med iværksættelsen, under særligt hensyn til den betydning, som Rådet i sin afgørelse tillægger brevene fra De Forenede Stater. Kommissionen bekræfter endvidere, at den, såfremt problemer af ovennævnte art viser sig at være umulige at løse, vil tage de nødvendige retlige skridt til at sætte Rådet i stand til at handle i medfør af artikel 16 i aftalen, og den vil anvende de midler, som Fællesskabet kan påberåbe sig i medfør af artikel 2 i denne aftale.

Det er under alle omstændigheder klart, at Kommissionen skal træffe en række gennemførelsesbestemmelser i Den Stående Veterinærkomité. Kommissionen forudser, at gennemførelsen i den nationale lovgivning vil tage nogle måneder fra undertegnelsen, jf. artikel 8 i aftalen. I denne periode vil Kommissionen nøje følge USA's gennemførelse af aftalen.

Rådet beslutter at offentliggøre denne erklæring og ovennævnte breve i C-udgaven af *De Europæiske Fællesskabers Tidende*.«

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[1] EFT L 118 af 21.4.1998, s. 1, og berigtigelse i EFT L 130 af 1.5.1998.

BILAG I

March 10, 1998

Franz Fischler
Agricultural Commissioner
Commission of the European Union
Rue de la Loi 200
B-1049 Brussels

Dear Franz,

In our meeting in Oxford last January, we had a lengthy discussion of the actions we intended to take to recognize, under the terms of our draft Veterinary Equivalency Agreement (the Agreement), the animal health status of the European Community (EC). I explained to you that it would be impossible for us to publish a second proposed rule on animal health status before the EC Council voted to adopt the Agreement. However, I did promise to provide to you, before the date of the Council vote, an indication of the likely content of the proposal. This letter is in fulfillment of that commitment.

Our regionalization obligation under the Agreement extends to the seventeen diseases listed in Annex III of the Agreement. To ensure complete clarity, I would like to describe the situation with respect to each of those seventeen diseases.

For eleven of the diseases — namely, peste de petits ruminants, contagious caprine pleuropneumonia, sheep and goat pox, enterovirus encephalomyelitis, pseudorabies/aujeszky's, vesicular stomatitis, contagious bovine pleuropneumonia, bluetongue, African horse sickness, fowl plague (avian influenza), and Venezuelan equine encephalomyelitis — the United States already recognizes the EC's animal health status as defined by the Community. There is, therefore, no need for further action.

November 1997 Proposed Rule: In July 1997, the Animal and Plant Health Inspection Service (APHIS) received a request from the European Commission for the recognition of the animal health status of Member States and their regions for the remaining six diseases — swine vesicular disease (SVD), Newcastle disease (ND), rinderpest, foot-and-mouth disease (FMD), classical swine fever (CSF), and African swine fever (ASF). Based on the information which was provided, APHIS published a proposed rule in November 1997, under the terms of which the United States would recognize Belgium free of SVD; France free of SVD and ND; Greece free of rinderpest and ND; Luxembourg free of FMD, rinderpest, and ND; Portugal free of FMD, rinderpest, SVD, and ASF; and Spain free of ND.

If that rule is finalized as written, and I expect that it will be shortly, the United States will have recognized the EC's animal health status for two more diseases — ASF and rinderpest — as defined by the EC.

With respect to the other four disease, we had not received by the time of the publication of the original proposed rule sufficient information from the EU to allow us to make determinations with respect to certain Member States and regions. Information received subsequently, however, has given us a more complete picture.

Foot-and-Mouth disease: Based on the new information we have received on FMD, we are now prepared to begin the rulemaking process to recognize Greece as FMD-free. Completion of that process and finalization of the November proposed rule would mean that the U.S. disease picture for FMD would correspond with that of the EC.

Swine vesicular disease: With regard to SVD, we have nearly a complete picture. On the basis of the data provided, we are now prepared to propose the recognition of the EC disease map for all regions except for the central and southern regions of Italy for which we have not yet received sufficient surveillance data. Once we have received and evaluated such information, we would be able (if the data are satisfactory) to complete the EC picture with regard to SVD. Prompt receipt of the information could allow us to make a positive determination prior to formal publication of the proposal in the Federal Register.

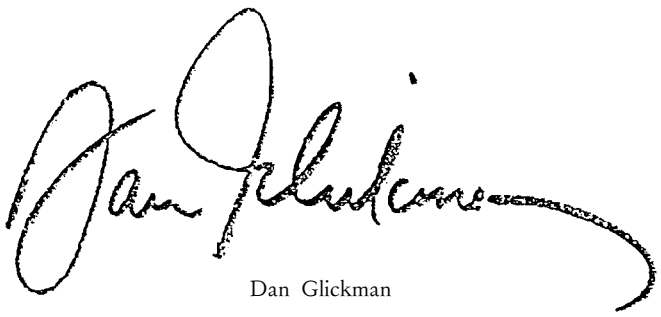
Classical swine fever and Newcastle disease: With regard to the remaining two diseases, I am frankly very concerned. The situation in Europe is far from stable, and our regulatory officials are anxious to ensure that implementation of the Agreement does not expose U.S. livestock and poultry flocks to unacceptable risks. I coming to conclusions on these two diseases, I have instructed APHIS to go as far as can be scientifically justified. However, I have also instructed them to demand full information and to make prudent judgements.

On the basis of the information we have received with respect to CSF, we are prepared to begin the rulemaking process for recognizing the EC's animal health status as defined by the EC. Moreover, we would intend to include in our proposed rule references to regionalization efforts in place in infected regions. This should facilitate the task of changing the status of those areas once the disease is eradicated. However, in light of the length, severity and repetitive nature of the outbreaks, we intend to propose two special conditions. First, in the case of future outbreaks, we would request the EC provide us with information on all shipments to the United States from the newly-infected area for 40 days prior to the outbreak. Second, we would stipulate that, in the case of this disease, infected areas would not be determined disease-free until they had completed the full six-month waiting period prescribed by the International Office of Epizootics (OIE).

With respect to ND, we have received from the Commission little information on surveillance. In addition, we are concerned by the Community's inability to identify the source of the recent outbreaks and the lack of harmonized regulations on the movement of pet birds. Therefore, we are not in a position at this time to extend the disease-free recognition for ND beyond what we have already outline in our November 1997 proposed rule. However, additional data and information obtained from he Commission supporting disease free status would allow adjustments prior to the formal publication of the proposal in the Federal Register.

I am confident that we are acting in conformity with our obligations under the draft Agreement and the Agreement on Sanitary and Phytosanitary Measures. We look forward to the adoption and implementation of the Agreement, and to working with you under the Agreement to resolve outstanding issues to the satisfaction of both parties.

Sincerely,



Dan Glickman

Secretary

BILAG II

February 24, 1998

Mr. Guy Legras
Director General
Directorate-General VI
Commission of the European Community
Rue de la Loi 200
B-1049 Brussels

Dear Mr. Legras,

I refer to the 29 January letter from David Roberts to Paul Drazek concerning the U.S. position on animal health and regionalization issues. That letter accurately identifies the main issues that arose during our recent meetings in Brussels. By way of response to that letter, I can confirm that the U.S. interpretation of the agreement is that the initial presumption in every case is that the regionalization decision taken by the other party will be accepted, allowing for exceptional cases in which, for good and justifiable reasons, the party feels that need to take recourse under the safeguard provision. Thus, in the ordinary case, we expect the agreement to operate as follows:

— In the case where the EC takes a decision to restrict an area that has previously been recognized as disease-free, the United States would accept the EU's regionalization decision without having to take further actions;

— When, subsequently, a disease incident had been appropriately dealt with and the EC lifts restrictions on that area, the United States would accept that decision without having to take further action.

In order to obviate the need for rulemaking in every instance in which the EC might take such a decision to impose or lift restrictions in an area previously recognized disease-free, USDA would include provisions in our new proposed rule on EC animal health status to the effect that animals or animal products whose free movement in the EC is restricted are similarly restricted from importation into the United States.

— Where a region that has previously been infected with a disease is being recognized as disease-free for the first time, USDA is required to proceed by rulemaking to change its recognition of disease status. This includes publishing a proposed rule based on full technical and scientific information, allowing public comment, and issuing a final rule. However, we fully anticipate that we will be able to comply with these domestic requirements to conduct rulemaking in a manner that will permit us to accept and recognize EC regionalization decisions in the ordinary case.

Our policy would be to initiate rulemaking by publishing our proposed rule during the waiting period required by the OIE before a region may be declared disease-free.

Previously, APHIS policy was to require that a country be free of disease for the entire OIE time frame or longer before it initiated rulemaking. However, in light of our agreement, we consider that it would be appropriate to initiate rulemaking once we have received thorough and complete information that the last case of the disease has been eliminated from the region, including details of the regionalization measures in place. The proposed rule would contain reference to such measures. The publication of the final rule would be contingent on the fact that no additional cases of the disease are discovered in the region during the OIE period. Normally, the required rulemaking can be conducted within the OIE waiting period.

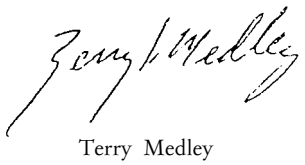
Although this response attempts to clarify our interpretation and position with respect to the obligations incorporated in Article 6 of the Agreement, it is implicit that the proper functioning of the Agreement will depend, of course, on both parties exercising their responsibilities under all provisions of the Agreement. I would note, in this regard, that we consider that the provisions of Article 6 are closely tied to the provisions of Article 10 and 11 requiring the parties to keep each other fully informed of their actions and the bases for those actions. In addition, we recognize that there may be exceptional cases — e.g., where there has been a disease outbreak which achieves significant geographical spread or which persists for a significant duration — in which the parties will not agree on what action is appropriately indicated by the circumstances, and in those cases, the obligations under Article 6 are clearly balanced by the rights and procedures contained in Article 12.

Our policy in such exceptional circumstances would be to initiate rule-making through the publication of an Interim Rule, with a public comment period. If the EC can demonstrate that the disease situation was brought under control during the comment period, the Interim Rule could simply be withdrawn and the normal regionalization provisions apply, i.e., the United States would accept the EC regionalization decision without further action.

I hope that this explanation clarifies our position. I want to reiterate that we understand our obligations under the draft agreement with respect to animal health and the recognition of regionalization decisions, and intend to honor those commitments in every respect.

I believe that we have shown considerable understanding of, and respect for, the various legal requirements which the EC must follow in the implementation of its obligations under the draft agreement. We too have certain domestic requirements that must be respected, and we appreciate your consideration in helping us to accomodate those requirements as we implement our responsibilities.

Sincerely,



Terry Medley

Administrator

BILAG III

January 28, 1998

Mr. Paul Drazek
USDA
Washington D.C.

Dear Paul,

Subject: Forthcoming Veterinary Discussions: MEGAREGs and BSE

Firstly, I would like to thank you and your team for the constructive discussions last Friday. It was most helpful to be able to run over the ground, and will enable us to be better prepared for next week's discussions in Washington.

You asked us to set out some ideas in advance, especially as regards MEGAREGs.

On the MEGAREGs, there have been no substantive discussions between the EC and the U.S.. Indeed although we had some discussion last year, as regards the SSOPs and E coli requirements, the provisions as regards salmonella and HACCP, which apply to large plants from January 1998, were not really discussed as we all expected that these discussions would take place under the provisions of Footnote 1 to Annex V.

It is evident, and not suprising, that EG legislation does not contain exactly the same provisions as those the U.S. has already imposed, and will progressively impose through to the year 2000 for the production of red meat and poultrymeat under the MEGAREGs. We are therefore ready to consider providing a guarantee that provisions at least equivalent to those set down in the MEGAREGs are applied in EC establishments which are to be listed for export to the United States, or establishments that supply such establishments.

We therefore propose the following:

All red meat and poultrymeat establishments exporting to the United States must:

1. Be EC agreed (oval stamp)

2. (a) For large establishments (more than 500 employees): apply HACCP, with the HACCP plan including microbiological testing provisions at least equivalent to those set down in the MEGAREGs for E coli and salmonella.

2. (b) For other establishments: apply SSOPs, and microbiological testing provisions at least equivalent to those set down in the MEGAREGs for E coli.

3. The U.S. agrees not to modify the provisions as regards SSOPs, HACCP, E coli or salmonella testing, as they stand at 27 January 1998, without prior discussion with the EC.

4. A procedure be agreed to initiate discussions immediately to compare, on a case by case basis, the testing and sampling provisions which are in place in the EC or which are proposed with those set down in the MEGAREGs, with a view to reaching a determination of equivalence.

This approach is intended to provide the U.S. with clear guarantees, and both sides with a process through which alternative testing and sampling methodologies may be assessed. Point 3 is simply intended to ensure that this work can move forward without sudden changes being applied without prior notice. It does not of course prevent the U.S. making changes, simply calls for advance discussion with the EC.

Turning to BSE, we regret that we had no possibility of advance discussions of the U.S. concerns that led to the action on 12 December. The Commission has taken a considerable number of measures in respect of BSE, starting in 1989 with a ban on the movement from the UK to other Member States of animals born before 1 July 1988 (the date on which the UK banned the feeding of ruminant protein to ruminants) or animals which were the offspring of BSE cases. In total, 23 Commission Decisions have been taken on the subject. These include measures to make BSE a notifiable disease, to require certain standards of treatment for waste products, to ban the feeding of mammalian protein to ruminants, to ban the export to other

Member States or third countries of bovine animals and certain bovine products from the UK, as well as to approve BSE control and eradication programmes in the UK, France, Ireland and Portugal. It should be noted that these Member States, and some others, have SRM bans in place. The Commission actions also include the Decision banning the use of specified risk materials and the subsequent Decision postponing its entry into force until 1 April 1998. Details of these Decisions are available on request.

The Commission has, in December, set up an interservice group to make an evaluation of the current state of scientific knowledge on specified risk materials, and to recommend future action to the Commission. This action may include amending the current SRM Decision (97/534/EC), but at this stage it is not possible to predict the content of any such amendment.

I must stress, as we explained during the meeting in Oxford, that the purpose of the SRM Decision is to address risks to human and animal health, not to cover 'industrial' products which do not present a health hazard. I realise that the wording of the Decision has given rise to concern that it would affect industrial products imported from third countries. However, the certification for imports is only required for products of animal origin intended for food or feed, and for medicinal, pharmaceutical and cosmetic products and their starting materials or intermediate products. It is the intention of the Commission to clarify the scope in any future amendment of the Decision to make it clear that 'industrial' products are excluded from the requirements.

The Commission's Scientific Steering Committee met last week to address the question of SRMs, and in particular on geographical risk factors and the risks associated with gelatin and tallow. The interservice group is reflecting on the outcome from the Scientific steering Committee.

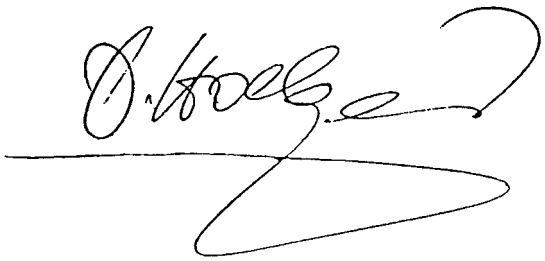
In addition, as you are aware, the OIE is also working on the question of TSEs at present, with meetings over the next two weeks and a possible decision in May. The outcome of this work will also have a bearing on the Community policy.

On the question of the BSE status of the USA, your latest submission has been passed to DG XXIV with a request for it to be examined as soon as possible by the relevant scientific group.

As far as your 'temporary suspension' of import licences for ruminants and ruminant products is concerned, we intend to comment in the coming weeks, on behalf of the Community, on the interim rule published in the Federal Register of 6 January. At this stage, I would not wish to prejudge the Community position, but I would query the restriction of the scope of the proposed rule to Europe. It seems to me that many countries outside Europe have the same risk factors which you cite to justify your current import prohibition and I would welcome an explanation of why these other countries are not subject to the same rule.

We have confirmed our travel arrangements, and will be ready to start work on the morning of 3 February in Washington. We look forward to receiving a draft agenda, following our discussions in Brussels on 23 January, and details of the location of the discussions.

Yours sincerely



Lars Hoelgaard

BILAG IV

March 3, 1998

Mr. Guy Legras
Director General
Directorate-General VI
Commission of the European Community
Rue de la Loi 200
B-1049 Brussels

Dear Mr. Legras,

In a meeting earlier this month in Washington, EC officials requested clarification of Food Safety and Inspection Service (FSIS) procedures with respect to the implementation, vis-a-vis the EC, of the Pathogen Reduction Hazard Analysis Critical Control Point Systems (PR/HACCP) rule. This letter is in response to that request.

First of all, I would like to confirm that we are in general agreement with the four-point approach laid out in Lars Hoelgaard's letter of 28 January to Paul Drazek. Further, I would like to confirm that

— FSIS, in keeping with U.S. obligations under footnote 7 to Annex V of the draft agreement, will continue to recognize decisions by the veterinary services of the Member States to add and delete approved export establishments from their list of establishments exporting to the United States;

— FSIS will accept HACCP plans developed by establishments, provided that these are equivalent to U.S. measures and are under official control and supervision; and

— FSIS will accept Salmonella testing by private establishments, provided that equivalent regulatory testing for verification and equivalent regulatory enforcement is carried out by authorized government officials.

As provided for in footnote 1 to Annex V of the draft agreement and Mr. Hoelgaard's letter, FSIS is prepared to discuss with EC and Member State officials in the coming months the implementation of PR/HACCP provisions that were put in place in January 1998 — i. e., HACCP and Salmonella performance standards and testing. We have received from Member States notification that HACCP and Salmonella standards, or equivalent alternative sanitary measures, are in place in those establishments that have 500 or more employees and are certified to export to the United States. We are reviewing those submissions in accordance with the principles of equivalence and will make every effort to reach a successful outcome.

The situation is somewhat different regarding the requirements for Sanitation Standard Operating Procedures (SSOPs) and Eshcheria coli (E. coli) testing, which were implemented in January 1997. With respect to SSOPs, FSIS has already determined that all EC Member States have complied with the requirement, or have implemented equivalent sanitary measures, in establishments which are certified to export meat or poultry to the United States.

With respect to E. coli, FSIS has approved the testing programs of most Member States. Discussions continue, however, with four Member States. Since more than a year has elapsed since domestic implementation, FSIS must now proceed in the coming weeks to bring the process to closure. If FSIS determines that the original and follow-up documentation and information provided by any of the four countries does not demonstrate that a proposed alternative sanitary measure is equivalent to the United States' E. coli testing requirement, FSIS will advise that country and the Commission of its determination. That country will then be allowed sufficient time to submit, if it chooses to do so, additional data or other information to make its case. Should FSIS still judge the country's measures not to be equivalent in regards to E. coli testing, the Agency must proceed, through notice and comment rule making, to remove the country from the group of countries listed in the United States Code of Federal Regulations as eligible to export meat or poultry to the United States.

Notwithstanding the above, we remain open to initiating general follow-on discussions on E. coli testing under the auspices of the draft agreement and point 4 of Mr. Hoelgaard's letter. We would welcome in that context any assistance the Commission could give us in resolving outstanding issues.

I can confirm that FSIS will not take any action as regards the PR/HACCP requirements against any Member State before contacting the Commission and the Member States concerned, and providing an opportunity to resolve the matter.

Let me assure you that we will do our utmost to ensure a smooth finalization of this process so that we can avoid any disruption of trade.

Sincerely,

Thomas J. Billy

Administrator

BILAG V

Mr. Thomas J. Billy
Administrator
USDA/FSIS
Washington D.C. 20250

Dear Mr. Billy,

Thank you for your letter of 3 March concerning the implementation of the Pathogen Reduction Hazard Analysis Critical Control Point Systems (PR/HACCP). The letter was discussed in detail by the Chief Veterinary Officers of the Member States meeting in the Council on 5 March.

The Commission representative was asked to clarify a number of points in the letter, and did so on the basis of the conclusions reached in our meeting in Washington at the beginning of February. The CVOs concluded by asking the Commission to obtain written clarification on three aspects of the letter.

1. That the MEGAREG rules apply only to those EC establishments that export to the U.S., and that Member States were not obliged to enact special new laws to put such arrangements in place. I would be grateful for your confirmation that this is correct.

2. The second bullet point of the second paragraph states that FSIS will accept HACCP plans provided that these are equivalent to US measures (emphasis added). In this context, does 'measures' refer to the US system of HACCP in general, or does it refer to more specific measures.

As you know, EC legislation on fresh meat and poultry meat does not at present contain requirements for HACCP, although it is the intention of my services to make a proposal for this in the near future. The proposal will be based on the full CODEX HACCP system (as are our existing HACCP legislative provisions on fishery products and milk and dairy products). Until this is adopted in legislation, EC firms may use HACCP on a voluntary basis. This is what is happening in firms exporting to the US and we need to know if application of the HACCP system as described by CODEX would be considered 'equivalent to US measures'.

3. The third point of clarification concerns the effect of the last four paragraphs of your letter on the question of the timing of actions under the MEGAREG as discussed in Washington.

In the fourth from last paragraph you state that FSIS must, in the coming weeks, bring their approval process to closure and, if they judge that a country's measures are not equivalent, they must delist that country. However, the next two paragraphs seem to indicate that the US would not delist without prior consultation. Furthermore, your final paragraph refers to avoiding any disruption of trade.

Member States asked for a moratorium from the US so that no Member State or establishment was delisted until the discussions on equivalency have taken place. Can I ask you to confirm that this de facto will be the case since it is our intention that these equivalency discussions should proceed as quickly as possible and the penultimate paragraph of your letter states that no action will be taken before an opportunity has been provided to resolve the matter.

Yours sincerely,

G. Legras

BILAG VI

March 12, 1998

Mr. Guy Legras
Director-General
Directorate-General VI, Agriculture
European Commission
Rue de la Loi 200
B-1049 Brussels

Dear Mr. Legras,

Thank you for your letter of March 6, 1998, concerning the implementation of the Pathogen Reduction Hazard Analysis Critical Control Point Systems (PR/HACCP) rule. We appreciate the opportunity to clarify three points in our letter of March 3, 1998.

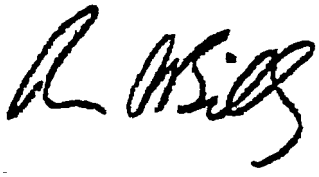
1. We concur that the PR/HACCP rule applies only to those European Community (EC) establishments that are certified to export to the United States, and that Member States are not obligated to enact special new laws to put such arrangements in place. A circular or other document sent from the Member State to the establishments that are certified to export to the United States would be an acceptable implementation instrument.

2. We concur that a HACCP system as described by Codex Alimentarius [see Codex Alimentarius, Food Hygiene Basic Texts, Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for Its Application, Annex to CAC/RCP 1-1969, Rev. 3 (1997)] would be an acceptable sanitary measure. We would, of course, expect that the HACCP plan address, among other things, certain regulatory requirements, such as adequate control of fecal contamination as evidenced by E. coli testing (or an equivalent sanitary measure), zero tolerance for visible fecal contamination, pathogen control as evidenced by the Salmonella standard (or an equivalent sanitary measure), etc.

In accordance with CAC HACCP System and Guidelines for Its Application, we would expect that the establishments validate and verify their HACCP plans. We would also expect that the controlling authority enforce this requirement.

3. We concur that prior to the removal of a Member State from the list of countries eligible to export to the United States the Food Safety and Inspection Service will give the Member State an opportunity to resolve the matter. Before proceeding, through notice and comment rule making, to remove the country from the group of countries listed in the United States Code of Federal Regulations as eligible to export meat or poultry to the United States, the Member State and/or the Commission acting on behalf of the Member State, will be allowed sufficient time to submit; if it chooses to do so, additional data or other information to make its case. We believe this objective, transparent, and measured process offers the maximum opportunity to finalize the remaining equivalence judgements without any disruption of trade. However, we cannot agree to a moratorium, since we will be bringing our equivalence approval process to closure in the coming weeks with respect to the implementation of the Escherichia coli testing provisions of the PR/HACCP final rule.

Sincerely,



Thomas J. Billy
Administrator