



APR - 5 2005

Mr. Michael Scannell  
Head of Unit, Directorate E  
Health and Consumer Protection Directorate General  
European Commission  
Brussels, Belgium

Dear Mr. Scannell:

*Michael*

On behalf of the U.S. Food and Drug Administration (FDA), Department of Health and Human Services, I want to thank you, and tell you how appreciative we all were of the friendship and cooperation extended to us during our recent meetings in Brussels. As you know, our broad goals were to achieve a better understanding of and means to accommodate differences between our approaches to the regulation of food safety. Specifically, we wanted to discuss policy and technical issues arising primarily from the 2003 EC Food and Veterinary Office (FVO) seafood and dairy audit reports that were conducted in the U.S. under the Veterinary Equivalence Agreement (VEA) with an objective to address and clarify unresolved issues contained in both reports. In large part, I do think we reached those goals. It was three days well spent.

As you know, we had several topics to discuss – all contained in the working grid developed under the leadership of Mr. Madelin and Dr. Lumpkin. I believe both sides wanted to approach the fundamental issue of equivalence – what it means, what it is intended to achieve, and how we can realistically get there, if equivalence is, indeed, the best mechanism to accomplish the desired food safety and trade outcomes. We both recognized that the mere fact we both attest to confidence in each other's food safety system is an important first step. However, finding a workable paradigm is a greater challenge, but a challenge we look forward to taking on with you.

The two audit reports issued by the Commission – dairy and seafood – as you know were disconcerting to us, and while still disappointed in them, we do now believe there is a better level of understanding of our system. While we acknowledged the same outcome goals of our system, the time we spent exchanging information and talking about the very basic process differences in our systems was of great value to both parties. We were pleased to be able to resolve the outstanding issues with the seafood and dairy audits.

Based on the outcome of our discussion, we are prepared to provide the Commission with FDA's final written responses to the June 23 to July 3, 2003 seafood audit. This information was informally provided to you during the seafood breakout session, but is also enclosed with this letter. In return, as we understand it, for seafood the Commission plans to immediately move us to level 1. Further, we understand that the EC is prepared

to also move forward towards a finding of full equivalence, but that is contingent on reaching accord on an alternative to a reciprocal determination out of consideration for your member states.

As you know, FDA believes that the equivalence obligation contained in the WTO Agreement on the Application of Sanitary and Phytosanitary Measures is intended to enable market access where such access is currently restricted. As this is not the case for seafood entering the United States from Europe, and because of the considerable time, effort, and legal considerations associated with a U.S. determination of equivalence, FDA is not prepared to move towards a reciprocal determination. While we do not agree with your position that the determinations must be reciprocal to occur, we have agreed to explore an alternative to an equivalence determination, using specific accommodations to demonstrate belief in the safety of products produced under the EU system, which in turn would allow for more flexible arrangement for EU products. The goal of such a proposal would be to create a system in which trade in both directions would flow in a similar manner (i.e. minimal encumbrances).

A driving force in our interest to obtain the equivalence determination is the possibility of the elimination of the requirement for individual export certificates. While we certainly understand that the EC has this requirement for individual export certificates, FDA does not view their issuance as being necessary for public health protection, nor does the agency have the program infrastructure to support such a non-mission critical function. Therefore, finding a path to eliminate this requirement is most desirable. We were pleased to hear the Commission confirm that it has the legal authority to propose an end to the requirement for individual seafood export certificates when a determination of full equivalence for the exporting region is reached.

Regarding the dairy audit, it is our view that all outstanding issues related to the September 18 to October 2, 2003 dairy audit were resolved. FDA agreed to provide a copy of residue monitoring plan under the Pasteurized Milk Ordinance with the industry data, and that information is enclosed.

With regard to Grade "A" dairy equivalence, FDA agreed, in principle, to consider the EC's request to be evaluated for Grade "A" equivalence and to report back to the EC on the issue after the agency consults with our States through several channels, including the National Conference of Interstate Milk Shipments (NCIMS). We also asked the EU to move towards a determination of equivalence for the US dairy products and provide a plan with the steps to be followed in the equivalence determination process or alternative solutions. It is our understanding that we will reconvene in May to determine next steps in both areas.

As you know, we jointly drafted, finalized, and signed the February 16, 2005, meeting notes outlining our thoughts on the meeting as well as our next steps. We also agreed that we would update the grid based on our work. We propose to keep these two documents as our guide to completion on all of these matters.

Michael, I was quite disappointed to learn at the end of our meeting that you are moving on to another assignment. It was, indeed, a real pleasure to work with you on these issues. Your leadership during our discussions was evident and contributed greatly to the tenor and success of our talks, and was very much appreciated by all of us on the U.S. delegation. I wish you the best with your new work and challenges.

Thank you again for your hospitality and the time and efforts of your entire team. We have truly begun a new day, and we look forward to working with you on these and other matters of shared interest.

All the best,

A handwritten signature in black ink, appearing to read "Melinda K. Plaisier". The signature is fluid and cursive, with a long horizontal stroke at the end.

Melinda K. Plaisier  
Assistant Commissioner for International Programs

Cc:

Dr. Lester M. Crawford, Acting Commissioner of Food and Drugs

Mr. Robert Madelin, European Commission

Dr. Murray Lumpkin, Acting Deputy Commissioner for International  
and Special Programs

Ms. Justina Torry, U.S. Mission, Brussels

Dr. William Steiger, Office of the Secretary (OS), HHS

Dr. Phillip Budashewitz, Office of Global Health Affairs, OS, HHS

Ms. Terry Gay, Office of Global Health Affairs, OS, HHS

Ms. Charlotte Hebebrand, Delegation of the European Commission, Washington, DC