



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

0686 5 MAY -2 P1:32

The Honorable Rob Simmons  
House of Representatives  
Washington, D.C. 20515-0702

APR 28 2005

Dear Mr. Simmons:

Thank you for the letter of March 11, 2005, regarding the proposal by the New England Lobster Coalition, which encourages the Food and Drug Administration (FDA) to provide a "voluntary custodial program" for European Union certificates.

FDA appreciates the points raised in your letter and we are considering the program. We appreciate your views on this subject. By copy of this letter we are forwarding your proposal to the docket for this issue.

Thank you again for contacting us about this matter. If you have further questions, please let us know.

Sincerely,

  
Patrick Ronan  
Assistant Commissioner  
for Legislation

cc: Dockets Management Branch, HFA-305  
(Docket Number 2004D-0510)

2004D-0510

C13/AN:

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**CONGRESSMAN ROB SIMMONS**  
HOUSE OF REPRESENTATIVES  
SECOND DISTRICT, CONNECTICUT

March 11, 2005

Mr. Lester M. Crawford  
Acting Commissioner  
Food and Drug Administration  
Parklawn Building  
5600 Fishers Lane  
Rockville, MD 20857

Dear Commissioner Crawford:

I am writing in support of the lobster industry's proposal for a Voluntary EU Export Certificate Custodial Program and ask that you consider its inclusion in the final version of your guidance.

The U.S. is the second largest exporter of live lobsters into the EU with Canada maintaining the dominant position. U.S. exporters must be able to quickly respond to the customer demands or they will lose their business to Canadian suppliers. Part of the reason the U.S. industry has been able to compete is because the FDA currently makes available to them EU Export Certificates in advance of shipments. Canadian competitors also receive certificates from their government in advance of shipment.

The FDA recently issued Guidance concerning the issuance of EU export certificates and unfortunately it does not provide for the advance issuance of certificates to live lobster exporters. I am advised that the industry has met with your staff to discuss this critical issue and as a result proposed a Voluntary Custodial Program. This proposal not only provides for the advanced issuance of EU Export Certificates, but it also proposes to increase the level of facility inspections by FDA, generates revenue by proposing a fee for each Certificate, and eliminates burdensome administrative work presently encountered by FDA district staff.

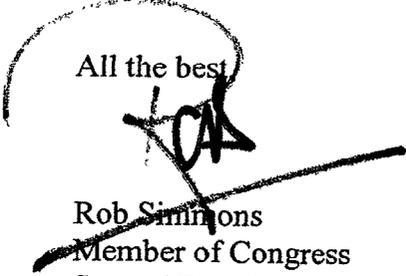
The lobster industry is very important to the state of Connecticut and I am fortunate to have the country's second largest exporter of live lobsters in my district. This business generates millions of dollars of revenue and employs more than 50 workers. I understand the sensitivities of the industry and know that a minor delay, such as waiting for export certificates to be issued, can lead to the loss of shipments and customers. If the U.S. industry can not receive EU Export Certificates in advance as they do today, they will not be competitive with Canada and business will fail. For all these reasons, I hope you will

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consider including provisions for the continuation of issuing EU Export Certificates in advance to the live lobster industry in the final version of your Guidance.

I want to thank you in advance for your serious consideration of my request.

All the best

  
~~Rob Simmons~~  
Member of Congress  
Second District, Connecticut

This is really important  
to us in CT. Thank.