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NEW ZEALAND EMBASSY

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WASHINGTON

8 July 2003

Leslye.
Original letter
also sent by
mail.

Lois Howland
New Zealand
Embassy

Ms Leslye M Fraser
Associate Director for Regulations
Mail Code HFS-4
Food and Drug Administration
Centre for Food Safety and Applied Nutrition
5100 Paint Brush Parkway
College Park, MD 20740

Dear Ms Fraser

I refer to the Federal Register Notice inviting comments on the rules proposed by the Department of Health and Human Services' Food and Drug Administration (FDA) under the *Public Health Security and Bioterrorism Preparedness and Response Act 2002 (Bioterrorism Act)* - Docket No. 02N-0277 and Docket No. 02N-0275.

The New Zealand Government welcomes the opportunity to provide comments on the proposed rules made under the Bioterrorism Act. New Zealand shares the US' concerns related to bioterrorism and supports the intention of the Bioterrorism Act to provide appropriate prevention measures against potential bioterrorism. However some aspects of the way in which the US plans to implement measures to address these concerns appear likely to add unnecessary costs or raise other difficulties for New Zealand exporters. We therefore wish to work with the US to identify ways in which the basic US concerns can be addressed in ways that minimise costs to New Zealand.
New Zealand's main concerns are listed below.

- Recognition of New Zealand's measures for food products as equivalent as provided for under the WTO Agreement on Sanitary and Phytosanitary Measures, in particular the role of another competent authority with regards to the access to required records.
- The effect time of delays, particularly in regard to perishable foods such as chilled live shellfish, if the proposed timeframes under Administrative Detention are implemented.

New Zealand's specific comments on the two dockets are contained below.

37 OBSERVATORY CIRCLE, NW WASHINGTON, DC 20008 UNITED STATES OF AMERICA
TELEPHONE (202) 328 4800 FACSIMILE (202) 667 5227
E-MAIL nz@nzemb.org INTERNET www.nzemb.org

02N-0275

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New Zealand appreciates its close working relationship with the US, including on SPS issues, and we look forward to continuing this cooperation. New Zealand hopes to work together with the US to develop measures which meets the concerns which the Bioterrorism Act is intended to address whilst doing so in a manner that minimises costs and other negative trade effects and is the least trade-restrictive as possible.

I would welcome the opportunity to discuss New Zealand's concerns with you further.

With kind regards

Yours sincerely

John Wood
Ambassador

Encl

DOCKET NO. 02N-0277

Establishment and Maintenance of Records

Section 306 of the Act would be implemented by the proposed rule which requires certain foreign facilities that manufacture, process, pack or hold food for human or animal consumption in the United States to establish and maintain record keeping.

These requirements are essentially being met by New Zealand industries at this time. However, New Zealand is concerned at the apparently intrusive nature of the means proposed for FDA inspection of this information, should the need arise. The competent authority in New Zealand requests that when FDA wishes to seek such information that the request is conveyed directly to the competent authority, the New Zealand Food Safety Authority, in the first instance. The competent authority can then carry out investigations on behalf of FDA and provide FDA with any resulting relevant information.

DOCKET NO. 02N-0275

Administrative Detention

Section 303 of the Act would be implemented by the proposed rule providing for the Administrative Detention of "perishable food" where an officer or qualified employee of FDA has credible evidence or information that an article presents a threat of serious adverse health consequences or death to humans or animals.

New Zealand has concerns with regard to the timeframes for action that FDA envisages under this proposed rule. This concern is particularly in relation to airfreight consignments of perishable foods such as chilled, live shellfish which tend to have a commercial shelf-life of some 48 hours following harvest. These items would almost certainly become unsaleable when released under the proposed timeframes. Consequently we request that the appeal process for such items be measured in hours with all attempts being made to release suitable consignments within 24 hours so as not to compromise their commercial shelf-life.