

**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES****Food and Drug Administration**

[FDA 225-98-4002]

**Exchange of Letters Between the Food  
and Drug Administration and the  
Canadian Food Inspection Agency****AGENCY:** Food and Drug Administration,  
HHS.**ACTION:** Notice.**SUMMARY:** The Food and Drug Administration (FDA) is providing notice of an exchange of letters (EOL's) between FDA and the Canadian Food Inspection Agency. The purpose of the EOL's is to enhance the exchange of information in emergency situations.**DATES:** The agreement became effective March 2, 1998.**FOR FURTHER INFORMATION CONTACT:**  
Ellen F. Morrison, Office of Regulatory  
Affairs (HFC-130), Food and Drug  
Administration, 5600 Fishers Lane,  
Rockville, MD 20857, 301-443-1240.**SUPPLEMENTARY INFORMATION:** In accordance with 21 CFR 20.108(c), which states that all written agreements and memoranda of understanding between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this EOL.

Dated: August 27, 1999.

**William K. Hubbard,***Senior Associate Commissioner for Policy,  
Planning and Legislation.***BILLING CODE 4160-01-F**



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Office of Regulatory Affairs  
Rockville MD 20857

JAN - 5 1998

Mr. Andre' Gravel  
Vice President for Programs  
Canadian Food Inspection Agency  
59 Camelot Drive  
Nepean, Ontario, Canada K1A0Y9

Dear Mr. Gravel:

The U.S. Food and Drug Administration (FDA) is pleased to cooperate with your government and the government of Mexico to enhance our collective activities in the interest of public health protection through the exchange of timely information in emergency situations where such information is believed to be a value to the other participating party in protecting the health of consumers against unsafe marketed products. Additionally, we strongly agree with the value of, and need for assisting each other, upon request and within our authority, in investigating emergency situations involving human food and animal food products manufactured in or distributed from the other country.

FDA considers any situation which involves a serious health risk for consumers or caregivers who are exposed to an unsafe product as an "emergency situation." Such situations usually, but not always, involve significant media attention and the need to coordinate a timely or extraordinary operational response.

When FDA learns of emergency situations presenting a real or potentially serious health risk and it is known or suspected that the product has been sold or distributed in Canada or Mexico, FDA will attempt to promptly provide information to the appropriate authority on matters concerning manufacture, quality control and distribution. Such information may include, where available and if pertinent, records, reports, and other information on inspections, investigations, and analysis of marketed products.

At the request of either the Canadian or Mexican government, FDA will attempt to carry out investigations of specific situations where the findings of such investigations are deemed necessary to the adequate resolution or control of an emergency situation. Information so obtained will be forwarded in a timely manner to assist cooperating authorities in resolving the emergency and implementing appropriate measures to protect consumers.

Information provided to and received from the government of Canada or the government of Mexico will be handled as provided under "Title 21, Code of Federal Regulations,

Section 20.89." This regulation governs FDA's communications with foreign governments under the Freedom of Information Act. A copy is enclosed for your information along with a copy of the Regulatory Procedures Manual Chapter that establishes procedures for implementing this regulation.

To help ensure that this information exchange continues to work well and meets respective needs, we feel it is important that meetings be arranged, at appropriate intervals, and by mutual concurrence, for the purpose of reviewing the effectiveness of this cooperation.

The FDA's contact for these activities are as follows:

Primary: Ellen Morrison

Deputy Director

Pager# 1-888-581-6480 E-mail Address-[emorriso@ora.fda.gov](mailto:emorriso@ora.fda.gov)

Secondary: Gary Pierce

Director

Pager # 1-888-471-3576 E-mail Address-[gpierce@ora.fda.gov](mailto:gpierce@ora.fda.gov)

Division of Emergency and Investigational Operations (HFC-130)

Office of Regional Operations

U.S. Food and Drug Administration

5600 Fishers Lane

Rockville, Maryland 20857

U.S.A.

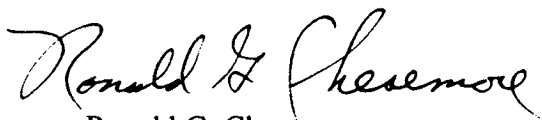
Telephone (301) 443-1240

\* 24 emergency contacts with FDA/DEIO duty officer/alternate duty officer

Fax (301) 443-3757

We look forward to continuing and enhancing the excellent cooperation that we have successfully enjoyed to this date.

Sincerely yours,



Ronald G. Chesemore

Associate Commissioner

for Regulatory Affairs

U.S. Food and Drug Administration

Enclosure:



Canadian Food Inspection Agency  
Nepean, Ontario  
K1A 0Y9

Agence canadienne d'inspection  
des aliments

225-98-4002

MAR 02 1998

Your file    Votre référence

Our file    Notre référence

Mr. Ronald Chesemore  
Associate Commissioner for Regulatory Affairs  
United States Food and Drug Administration  
Office of Regulatory Affairs  
HFC-131  
5600 Fishers Lane  
Rockville, Maryland 20857  
U.S.A.

Dear Mr. Chesemore:

Thank you for your letter of January 5, 1998 regarding information exchange in emergency situations. We also strongly agree with the need for assisting each other in investigating emergency situations involving human and animal food products.

As such, the Canadian Food Inspection Agency (CFIA) will continue the spirit of cooperation which we have had in the past. Dr. Anne MacKenzie, of our national office, has been in contact with Ellen Morrison on a number of issues relating to food emergency concerns. It is our expectation this contact will continue, and will be strengthened by our mutual agreement to meet at appropriate intervals to review the effectiveness of this cooperative effort.

The CFIA contacts for these activities are as follows:

Primary:

Dr. Anne MacKenzie  
Director General, Food Inspection Directorate  
59 Camelot Drive  
Nepean, Ontario  
K1A 0Y9  
Telephone: (613) 225-2342 ext. 4188  
Facsimile: (613) 228-6638  
Internet: "amackenzie@em.agr.ca"  
Cell: (613) 794-8521

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Canada

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**Secondary:**

Helen Spencer  
A/Manager, National Inspection Initiatives  
Food Inspection Directorate  
59 Camelot Drive  
Nepean, Ontario  
K1A 0Y9  
Telephone: (613) 225-2342 ext. 3785  
Facsimile: (613) 228-6617  
Internet: "hspencer@em.agr.ca"

With your support and assistance we can help to ensure that North America remains the world leader in food safety initiatives.

Yours sincerely,



André Gravel  
A/Vice-President  
Programs

c.c. A. MacKenzie  
H. Spencer