

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Display Date	9-3-99
Publication Date	9-7-99
Certifier	SAReese

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.

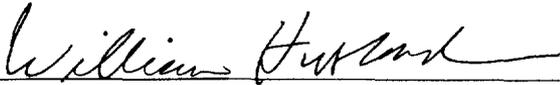
DATES: The agreement became effective March 2, 1998.

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.

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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: 8/27/99
August 27, 1999



William K. Hubbard
Senior Associate Commissioner for
Policy, Planning and Legislation

[INSERT LETTERS HERE]

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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DEPARTMENT OF HEALTH & HUMAN SERVICES

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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,

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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.

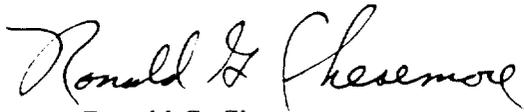
The FDA's contact for these activities are as follows:

Primary: Ellen Morrison
Deputy Director
Pager# 1-888-581-6480 E-mail Address-emorriso@ora.fda.gov

Secondary: Gary Pierce
Director
Pager # 1-888-471-3576 E-mail Address-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

Ta
JC

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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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