

**MEMORANDUM OF UNDERSTANDING
BETWEEN
THE UNITED STATES FOOD AND DRUG ADMINISTRATION
AND
THE CANADIAN FOOD INSPECTION AGENCY
CONCERNING THE SHARING OF INFORMATION AND
FACILITATION OF COLLABORATIVE RESEARCH PROJECTS**

The United States Food and Drug Administration (“US FDA”) and the Canadian Food Inspection Agency (“CFIA”), herein referred to as the “Participants”:

Wishing to develop effective collaboration with respect to food safety as it concerns the development and sharing of mutual research strategies and priorities; the research, development, and validation of microbiological and chemical detection methodologies; and the evaluation of novel and innovative technologies;

Wishing to facilitate collaboration on research projects and material transfers through subsequent instruments under this Memorandum of Understanding (MOU); and

Wishing to facilitate the sharing of food safety data and information and build on the strengths of each Participant;

HAVE COME TO THE FOLLOWING UNDERSTANDINGS:

1. PURPOSE

- (a) The purpose of this MOU is to facilitate the sharing of information and data and facilitate collaborative research projects between the Participants.
- (b) Nothing in this MOU is intended to interfere with activities under any other cooperative arrangement relating to food safety between the US FDA, on the one hand, and Health Canada, CFIA, or any other appropriate regulatory authority in Canada, on the other hand.

2. ACTIVITIES

- (a) The Participants intend to:
 - (i) Share information including, but not limited to:
 - (A) method development/research,
 - (B) planned equipment purchases,
 - (C) research/method needs,
 - (D) research data/results,

- (E) genomic sequence data,
 - (F) chemical and microbiological risk profiles,
 - (G) method validation data, and
 - (H) newly developed methods.
- (ii) Utilize this MOU as needed to facilitate collaborative research.
- (b) The Participants may co-author publications resulting from the analysis, interpretation, or consolidation of information shared.
- (c) If the Participants wish to develop intellectual property from collaborative research projects, they intend to negotiate in good faith a written arrangement to address, amongst other things, ownership and use of the resulting intellectual property.

3. FINANCIAL IMPLICATIONS

Each Participant intends to fund its own activities under this MOU, but with the understanding that participation is subject to available funding and resources.

4. INFORMATION SHARING AND CONFIDENTIALITY

- (a) Each Participant intends to share and use information under this MOU in accordance with its domestic law.
- (b) The Participants intend that any sharing of non-public information be done in reliance on, and under the terms of the *CONFIDENTIALITY COMMITMENT STATEMENT OF LEGAL AUTHORITY AND COMMITMENT FROM CANADIAN FOOD INSPECTION AGENCY NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED BY THE U. S. FOOD AND DRUG ADMINISTRATION (US FDA), U.S. DEPARTMENT OF HEALTH HUMAN SERVICES* (signed December 18, 2003) and the *CONFIDENTIALITY COMMITMENT STATEMENT OF LEGAL AUTHORITY AND COMMITMENT FROM THE UNITED STATES FOOD AND DRUG ADMINISTRATION (US FDA) UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED BY THE CANADIAN FOOD INSPECTION AGENCY* (signed December 22, 2003).
- (c) The Participants intend to discuss in good faith any potential regulatory action or any potential decisions that are taken on the basis of research data shared between the Participants and that would affect the other Participant's country prior to implementation.
- (d) Both Participants should, subject to their respective laws and procedures, endeavor to ensure that any personal information shared between Participants as part of the cooperative efforts under the terms of this MOU is not disclosed to others. "Personal information" refers to information that is linked or reasonably linkable to an identifiable individual, or information that is otherwise subject to applicable data privacy laws.

5. REPRESENTATIVES

(a) The CFIA designates the following as its representatives for this MOU:

(i) For administrative purposes:

Vice-President, Science Branch
Canadian Food Inspection Agency
Ottawa, ON

(ii) For scientific and technical purposes:

Executive Director, Food Safety Science Directorate
Canadian Food Inspection Agency
Ottawa, ON

(b) US FDA designates the following as its representatives for this MOU:

(i) For administrative purposes:

Deputy Commissioner for Foods and Veterinary Medicine
United States Food and Drug Administration

(ii) For scientific and technical purposes:

Chief Science Officer, US FDA/OC/OFVM
United States Food and Drug Administration

(c) The Participants intend to give written notice of any change in their representatives to the other Participant.

6. STATUS

(a) This MOU is not legally binding.

(b) The Participants intend that activities under this MOU be in accordance with each Participant's domestic laws, regulations, and policies, and subject to the availability of funds and personnel.

7. DIFFERENCES IN INTERPRETATION

The Participants intend to resolve any differences in the interpretation or implementation of this MOU in good faith by consultation.

8. FINAL DISPOSITIONS

- (a) This MOU is intended to come into effect on the date of its signature by the second Participant and to remain valid for five (5) years.
- (b) The Participants may extend this MOU by mutual written consent.
- (c) The Participants may modify this MOU by mutual written consent.
- (d) A Participant may cease its activities under this MOU thirty (30) days after giving written notice to the other Participant.
- (e) The Participants understand that the Confidentiality Commitments referenced in paragraph 4(b) continue beyond the cessation of activities under this MOU.

Signed in duplicate at College Park, MD on Oct 18 in the English and French languages.

FOR THE UNITED STATES
FOOD AND DRUG ADMINISTRATION:

FOR THE CANADIAN FOOD
INSPECTION AGENCY:

_____/s/_____
Stephen Ostroff, M.D.
Deputy Commissioner
Office of Foods and Veterinary Medicine

_____/s/_____
Paul Mayers
Vice President Science Branch

Place: College Park, MD

Place: College Park, MD

Date: October 18, 2017

Date: October 18, 2017