

**MEMORANDUM OF UNDERSTANDING BETWEEN THE NATIONAL CENTER FOR  
INFECTIOUS DISEASES OF THE UNITED STATES OF AMERICA, THE COORDINATING  
CENTER FOR INFECTIOUS DISEASES OF THE UNITED STATES OF AMERICA, THE  
CENTERS FOR DISEASE CONTROL AND PREVENTION OF THE UNITED STATES OF  
AMERICA AND THE SCIENTIFIC DIRECTOR GENERAL'S OFFICE AND  
ADMINISTRATION OF THE PUBLIC HEALTH AGENCY OF CANADA ON  
COOPERATION AGAINST FOODBORNE INFECTION**

The National Center for Infectious Diseases of the United States of America (NCID), the Coordinating Center for Infectious Diseases of the United States of America (CCID), the Centers for Disease Control and Prevention of the United States of America (CDC), collectively referred to as "PulseNet USA", and the Scientific Director General's Office and Administration of the Public Health Agency of Canada, hereinafter referred to as "PulseNet Canada"; PulseNet USA and PulseNet Canada hereinafter collectively referred to as the "Participants",

Whereas foodborne infections are a global problem; the trade of raw and processed food across borders within and between different regions of the world, and international travel makes it possible that the human foodborne infection may originate in a different country or region than where the illness is observed;

Whereas a critical component of the investigation of human foodborne outbreaks is the DNA "fingerprinting" of the causative organisms and comparison of the DNA "fingerprints" of strains isolated from ill persons who are considered to be part of a common source outbreak and the possible sources of the strain throughout the food-chain;

Whereas in 1996, the NCID began the PulseNet network to establish protocols to facilitate rapid, standardized DNA "fingerprinting" of human foodborne pathogens by states and local public health laboratories in the United States and the submission of those "fingerprints" into a central electronic database at the CDC; this standardization and exchange of DNA fingerprinting has assisted the NCID and its public health partners to detect and investigate outbreaks of human foodborne infections in the U.S.;

Whereas many public health laboratories outside of the U.S. are using the PulseNet network protocols locally and have shown an interest in developing protocols and principles of collaboration with PulseNet USA and other PulseNet organizations for the exchange of information respecting surveillance and control of human foodborne infections in order to assist them in early recognition of, and responding to, human foodborne outbreaks within and beyond their own regions;

Whereas PulseNet Canada and PulseNet USA wish to collaborate with each other using the protocols and principles of cooperation set out in this Memorandum of Understanding (MOU) for the exchange and use of each other's DNA "fingerprinting" of human foodborne pathogens;

Have reached the following understanding:

### **1. Nature of Arrangement**

- a) This MOU sets out the voluntary arrangement by which the Participants wish to cooperate with each other. This MOU is not intended to have any legal effect nor is it intended to create a partnership, principal-agency relationship or a joint venture.
- b) This MOU, as a voluntary arrangement between the Participants, does not constitute a financial obligation nor serve as a basis for expenditure by either Participant. Each Participant is solely responsible for the administration and expenditure of its own resources in respect of this MOU.
- c) Neither Participant is, is to represent itself as an agent, employee or other representative of the other.

### **2. Definitions**

- a) "Cluster" means two or more cases with the same or similar molecular profile seen during a period of time.
- b) "DNA fingerprint" means a DNA profile of a human foodborne pathogen obtained by separation of DNA fragments of different sizes by gel electrophoresis or by other DNA characterization methods including direct sequencing of DNA.
- c) "Outbreak" means a cluster with an established epidemiological link or common source or vehicle identified.
- d) "PulseNet International Steering Committee" means a committee made up of coordinating officials of the Participants that includes PulseNet USA, PulseNet Canada and other regional networks.
- e) "PulseNet network" means a national or regional network of laboratories dedicated to molecular surveillance of bacterial infections as defined by each network and sharing of data using PulseNet standardized methods and protocols.
- f) "Read Only" means that the existing data in the database cannot be modified by the recipient Participant.
- g) "Strain" refers to an organism within a species or variety characterized by some particular quality. In this MOU, it is referred as an isolate or a group of isolates exhibiting phenotypic and/or genotypic traits which are distinctive from those of other isolates of the same species.

### **3. Objective and Scope of MOU**

- a) This MOU establishes an understanding between the Participants for -READ ONLY access to data elements of each other as described in Appendix A for the purposes set out in this MOU.
- b) The objective of this MOU is to set out principles of cooperation between the Participants for the development of protocols and principles to exchange the data elements set out in Appendix A for the purpose of conducting standardized DNA “fingerprinting” of human foodborne disease causing bacteria so that the Participants may rapidly compare the DNA “fingerprints” of infectious agents provided by each of them.
- c) The objective of rapid comparison of standardized DNA “fingerprinting” is to:
  - i) facilitate rapid and early identification of human foodborne disease clusters and disease outbreaks outside of the regions of the Participants;
  - ii) serve as an effective early alert system for human foodborne disease outbreaks; and
  - iii) provide information that may assist the Participants in establishing policies for safer food within and outside of their regions.
- d) The scope of this MOU can be amended by the Participants in writing to include surveillance for other human pathogens such as methicillin-resistant *Staphylococcus aureus*, *Neisseria meningitidis*, *Bordetella pertussis*, and potential agents of bioterrorism such as *Yersinia pestis*, *Francisella tularensis*.

### **4. Activities of Participants**

The cooperative activities conducted by the Participants pursuant to this MOU may include:

- i) Participation as a coordinator in the PulseNet International Steering Committee;
- ii) Exchange information to standardize DNA “fingerprinting” of human foodborne pathogens;
- iii) Sharing of protocols, standards and strains of human foodborne pathogens;

- iv) Participation, coordination and implementation of quality assurance and quality control of the information that is exchanged pursuant to this MOU, including setting up proficiency testing systems to ensure comparability of profiles within and between the Participants. The profiles in the current central database of PulseNet USA are the standards against which the profiles should be compared;
- v) Participation in meetings as determined by the Participants to promote an understanding and communication of the regulations, policies and statutory obligations of each of the Participants as they relate to matters covered by this MOU, and to serve as a forum for questions and disagreements that may arise on matters covered by this MOU;
- vi) Provision, at the discretion each participant, of expertise and resources as may be requested by the other Participant on matters covered by this MOU;
- vii) Participation in research activities for the purpose of improving the use of data generated by the Participants, for the purposes of communications between Participants and for the purpose of methodological developments of DNA “fingerprinting”;
- viii) The development, evaluation and validation of new methods for standardizing DNA “fingerprinting”;
- ix) Other cooperative activities as may be determined in writing by the Participants.

## **5. Disclosure of Information**

Each Participant acknowledges that:

- i) Each of them is governed by their own government’s privacy, personal information and access to information laws, regulations and policies. Neither Participant will exchange or make available to each other or to third parties any information which is:
  - A) personal information about an identifiable individual; or
  - B) technical, commercial or scientific information received in confidence from third parties;

as those terms are defined within by the laws of their respective jurisdictions.

- ii) All other information exchanged between the Participants pursuant to this MOU is exchanged in confidence and each Participant is to maintain, respect and protect the confidentiality of the information received from the other. Disclosures of confidential information can be made only to the extent that they would be permitted by the laws of their respective jurisdictions.

- iii) Each Participant is to provide secure workstations to persons having access to data exchanged under this MOU, secure user codes and is to prevent unauthorized access to information provided by the other Participant.
- iv) Information exchanged between the Participants pursuant to this MOU is only to be used for the purposes of this MOU and except as required by the laws of the Participant's jurisdiction, is not to be disclosed to any third party, for any purpose including public communications or publications without the express prior written approval of the Participant who provided the information.
- v) Each Participant is to notify the other as soon as possible when issues on matters covered by the MOU arise.
- vi) Each Participant is to provide notice of human foodborne pathogen alerts that they issue and may, at the discretion and upon the request of the other Participant, provide technical advice to the other Participant.
- vii) Each Participant is to designate central contact persons for communications between Participants on matters covered by this MOU.
- viii) Where such information is not confidential, each Participant is to inform the other about any changes to its legislation, jurisprudence, policies, practices or procedures which relate to matters covered by this MOU, and which may impact upon the activities conducted by that Participant pursuant to this MOU.

## **6. Data Access**

Each of the Participants acknowledges that:

- i) The data elements to which PulseNet USA intends to provide READ ONLY access to -PulseNet Canada are set out in Appendix A. The data elements to which PulseNet Canada intends to provide READ ONLY access to PulseNet USA are set out in Appendix A.
- ii) The data elements may be used by the other Participant for the purposes of this MOU. Access to data elements provided by the other Participant is limited to persons whom are employees or agents of the other Participant, who have the appropriate security clearance and require the data elements to perform their duties.
- iii) Neither Participant warrants the accuracy of the data elements provided by it to the other Participant.

- v) Requests for data by a Participant is to be made in writing and provide details of the information requested, the reason for requiring the information and the use that will be made of the information. The other Participant is to respond to the request as soon as possible and provide reasons for denying any request for information.
- vi) Data elements are to be exchanged in a format mutually determined by the Participants.

## **7. Ownership of Strains and Data**

- a) This MOU, as a voluntary arrangement between the Participants, does not create, nor is it intended to result in the development of any intellectual property or other property rights in the recipient Participant to the data elements provided by the other Participant. Ownership of strains and data elements submitted by a Participant to the other Participant remains with the submitting Participant.
- b) Data generated by the recipient Participant using strains or data elements submitted by the other Participant is not to be used for any activities other than set out in the MOU without the express permission of the submitting Participant.

## **8. PulseNet International Steering Committee**

- a) The purpose of the PulseNet International Steering Committee (the Committee) is to provide guidance and make recommendations to the Participants respecting the exchange of information between them including:
  - i) development and maintenance of methods, protocols and strain collections;
  - ii) development of principles for quality assurance and control of information exchange; and methods by which and by whom to perform typing; and
  - iii) distribution of activities for development projects, such as quality assurance proficiency testing and monitoring of progress for such projects.
- b) The Committee is comprised of an equal number of representatives of each Participant as designated by that Participant. The Committee is chaired by the Chief, Laboratory Units, Foodborne and Diarrheal Diseases Branch of PulseNet USA and the representative from PulseNet Canada is to be the Chief of Enteric Diseases Program.
- c) The Committee makes recommendations upon a majority consensus.


## **9. Coming into Effect, Duration and Termination**

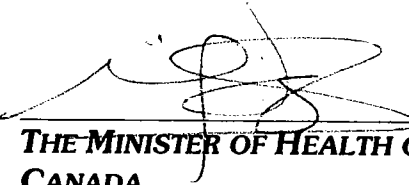
- b) This MOU may be extended past the date referred to in sub-paragraph a) by mutual consent of the Participants expressed in writing.
- c) This MOU may be terminated by either Participant by giving 60 days written notice to that effect to the other Participant.
- d) Upon termination or expiration of this MOU, the Participants are to destroy all electronic or other materials, and copies of such materials obtained from the other Participant under this MOU.

**10. Amendments to MOU**

This MOU may only be amended in writing by mutual consent of the Participants.

Signed in duplicate at Winnipeg, on the 12th day of August 2005, in the English and French languages.

  
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**THE AMBASSADOR OF THE UNITED  
STATES OF AMERICA**

  
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**THE MINISTER OF HEALTH OF  
CANADA**

## **APPENDIX A**

Minimum information fields associated with DNA fingerprints that should be made accessible to all partners in PulseNet International:

SourceCountry

SourceType - Human, Animal, Environment

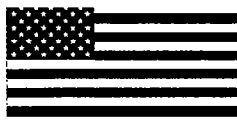
IsolatDate - if available

ReceivedDate - if available

UploadDate

Serotype - if available

PFGE-<enzyme>-pattern



**PROTOCOLE D'ENTENTE ENTRE LE NATIONAL CENTER FOR INFECTIOUS DISEASES  
DES ÉTATS-UNIS D'AMÉRIQUE, LE COORDINATING CENTER FOR INFECTIOUS  
DISEASES DES ÉTATS-UNIS D'AMÉRIQUE, LES CENTERS FOR DISEASE CONTROL  
AND PREVENTION DES ÉTATS-UNIS D'AMÉRIQUE ET LE BUREAU ET  
L'ADMINISTRATION DU DIRECTEUR SCIENTIFIQUE DE L'AGENCE DE SANTÉ  
PUBLIQUE DU CANADA SUR LA COLLABORATION DANS LA PRISE EN CHARGE DES  
INFECTIONS D'ORIGINE ALIMENTAIRE**

Le National Center for Infectious Diseases des États-Unis d'Amérique (NCID), le Coordinating Center for Infectious Diseases États-Unis d'Amérique (CCID), les Centers for Disease Control and Prevention États-Unis d'Amérique (CDC), appelés collectivement « PulseNet USA », et le Bureau et l'administration du directeur scientifique de l'Agence de santé publique du Canada, ci-après appelé « PulseNet Canada »; PulseNet USA et PulseNet Canada, ci-après appelés collectivement les « participants »,

Attendu que les infections d'origine alimentaire constituent un problème d'envergure mondiale; les échanges commerciaux transfrontaliers d'aliments crus et d'aliments transformés entre différentes régions et à l'intérieur d'une même région du monde, ainsi que les déplacements internationaux peuvent donner lieu à des maladies infectieuses humaines d'origine alimentaire qui se manifestent dans une région ou dans un pays autre que celui où elles ont pris naissance;

Attendu que un élément essentiel des enquêtes sur les éclosions de maladies infectieuses humaines d'origine alimentaire est la détermination de l'empreinte génétique des organismes responsables et la comparaison des empreintes génétiques des souches isolées à partir de malades considérés comme appartenant à une éclosion d'origine commune et des sources possibles de la souche dans la chaîne alimentaire;

Attendu que en 1996, le NCID a institué le réseau PulseNet afin d'établir des protocoles en vue de faciliter la détermination rapide et normalisée de l'empreinte génétique d'agents pathogènes pour l'humain d'origine alimentaire par les laboratoires de santé publique étatiques et locaux des États-Unis, ainsi que le classement de ces empreintes génétiques dans une banque centrale de données dans les CDC; cette normalisation et cet échange de renseignements sur les empreintes génétiques ont aidé le NCID et ses partenaires en santé publique à détecter et à étudier les éclosions de maladies infectieuses d'origine alimentaire aux États-unis;

Attendu que de nombreux laboratoires de santé publique de l'extérieur des États-Unis utilisent les protocoles du réseau PulseNet localement et ont exprimé un intérêt à élaborer des protocoles et des principes de collaboration avec PulseNet USA et d'autres organisations de PulseNet pour l'échange de renseignements sur la surveillance et le contrôle des infections alimentaires humaines afin d'être mieux à même de reconnaître rapidement les éclosions de maladies infectieuses d'origine alimentaire dans leur région et à l'extérieur et de prendre des mesures en vue de les endiguer;

Attendu que PulseNet Canada et PulseNet USA souhaitent collaborer mutuellement en utilisant les protocoles et les principes de collaboration énoncés dans le présent protocole d'entente, en vue de l'échange et de l'utilisation de renseignements sur leurs empreintes génétiques d'agents d'origine alimentaire pathogènes pour l'humain;

Ont décidé de ce qui suit :

### **1. Nature de l'entente**

- a) Le présent protocole d'entente (PE) définit l'engagement des participants à travailler en collaboration. Le PE n'a aucune valeur juridique; il ne vise pas non plus la création d'un partenariat, d'une relation mandant-mandataire ni d'une entreprise commune volontaire.
- b) Le présent PE, en tant qu'entente volontaire entre les participants, ne constitue pas une obligation financière ni une justification de l'engagement de dépenses. Chaque participant est uniquement responsable de l'administration et de l'utilisation de ses propres ressources dans le cadre du présent PE.
- c) Aucun des participants n'est ou ne se présentera comme étant un mandataire, un employé ou un représentant de l'autre participant.

### **2. Définitions**

- a) « Grappe » désigne deux ou plusieurs cas qui présentent un profil moléculaire identique ou similaire et surviennent durant une période donnée.
- b) « Empreinte génétique » s'entend du profil d'ADN d'un agent d'origine alimentaire pathogène pour l'humain obtenu par la séparation de fragments d'ADN de différentes tailles par électrophorèse ou par d'autres méthodes de caractérisation de l'ADN, y compris le séquençage direct.
- c) « Écllosion » se rapporte à une grappe pour laquelle on a établi un lien épidémiologique ou déterminé une source commune ou un véhicule commun.
- d) « Comité directeur de PulseNet international » renvoie à un comité constitué de fonctionnaires coordonnateurs des participants qui comprend PulseNet USA, PulseNet Canada et d'autres réseaux régionaux de PulseNet.
- e) « Réseau PulseNet » désigne un réseau national ou régional de laboratoires qui se consacrent à la surveillance moléculaire d'infections bactériennes définies par chaque réseau et au partage de données à l'aide des méthodes et des protocoles normalisés de PulseNet.
- f) « mode Lecture seule » signifie que les données existantes dans la base de données ne peuvent être modifiées par le participant qui en est le destinataire.
- g) « Souche » désigne un organisme au sein d'une espèce ou d'une variété caractérisé par une certaine qualité particulière. Dans le présent PE, ce terme désigne un isolat ou un groupe d'isolats qui présentent des caractéristiques phénotypiques ou génotypiques distinctives de celles d'autres isolats de la même espèce.

