# Technical Guidelines for United States—Mexico Coordination on Public Health Events of Mutual Interest

## 1. Introduction

In 2002, within the framework of the United States—Mexico Binational Commission, representatives from the U.S. Department of Health and Human Services and Mexico's *Secretaria de Salud* established a binational group on Epidemiologic Surveillance and Information Exchange to address issues of interest to both countries. With the objective of better defining how the two countries should collaborate on epidemiologic events of mutual interest, the present document has been elaborated by federal and state public health officials from both countries to provide a set of shared guidelines.

The United States and Mexico have a rich tradition of collaboration on epidemiologic events involving the two countries, including infectious disease outbreaks, diseases associated with products from the other country, and the continuity of care for patients with tuberculosis and other key diseases, traveling between the two countries. A joint Border Infectious Disease Surveillance project has been in place since 1999, and an Early Warning Infectious Disease Program was initiated in 2004. In addition, the TB Crossborder Management and Referral Project facilitates healthcare provider access to information on TB patients traveling between the two countries to ensure continuity of therapy. The Laboratory Response Network, providing diagnostic support for select pathogens, includes public health laboratories from both Mexico and the United States as members. Facilitated by the close ties resulting from these and other collaborations, public health professionals from the two countries have regularly sought to keep their counterparts apprised of relevant epidemiologic events.

However, clear guidelines have not yet been formally adopted for what information should be shared and how the sharing should take place. Public health officials from the two countries chose to formulate such a set of guidelines with the objectives of better institutionalizing the exchange of information on epidemiologic events of mutual interest, and promoting collaborative responses when appropriate.

Recognizing that productive collaboration already occurs between many 'sister cities' along the United States—Mexico border and between neighboring states, it should be emphasized that the present *Technical Guidelines for United States—Mexico Coordination on Public Health Events of Mutual Interest* (Guidelines) should facilitate the continuation of existing binational cooperation, while at the same time fostering more systematic and comprehensive sharing of information at all levels of government. These Guidelines focus primarily on coordination between the public health agencies/units that have primary responsibility for epidemiologic surveillance. They do not seek to define coordination between agencies/units with major regulatory functions, for which arrangements have already been established.

These Guidelines are being formally adopted following the entry into force in 2007 of the International Health Regulations (IHR). The IHR (http://www.who.int/ihr/9789241596664/en/index.html) provide a legally binding global

framework for the detection of, and response to, Public Health Emergencies of International Concern (PHEIC) requiring member nations to notify the World Health Organization (WHO) of any potential PHEIC.

Given the very specific definition of what represents a PHEIC, the present Guidelines cover a broader scope of Public Health events than the IHR, addressing all Public Health events of interest to both the United States and Mexico, not being limited to public health emergencies. In addition they are based on bilateral coordination to address the Public Health event of interest, without a requirement to involve WHO or the Pan-American Health Organization. However, for any such event involving the two countries and that constitutes a PHEIC, the terms of the IHR prevail. In addition, Public Health events qualifying as a PHEIC such as the 2009-10 influenza pH1N1 pandemic illustrate how binational cooperation prior to and during the PHEIC can contribute to global response.

The Guidelines are further consistent with and supportive of the IHR by representing a response to several of its articles regarding interactions between nations.

- Article 21 Ground Crossings "States Parties sharing common borders should consider entering into bilateral or multilateral agreements or arrangements concerning prevention or control of international transmission of disease at ground crossings in accordance with Article 57"
- Article 44 Collaboration and Assistance which encourages State Parties to collaborate on "the detection and assessment of, and response to, events", "the provision or facilitation of technical cooperation and logistical support, particularly in the development, strengthening and maintenance of the public health capacities", "the mobilization of financial resources to facilitate implementation of their obligations" and "the formulation of proposed laws and other legal and administrative provisions for the implementation of these Regulations"
- Article 57 Relationship with other International Agreements which asserts that States Parties "having certain interests in common owing to their health, geographical, social or economic conditions," may develop "special treaties or arrangements in order to facilitate the application of IHR," in particular "the direct and rapid exchange of public health information between neighboring territories of different States", and the application of health measures at common frontiers.

These Guidelines regard binational public health events as those affecting individuals or populations who translocate between the two countries. This concept recognizes that the rich and complex migration dynamics between the two countries extends beyond the United States-Mexico border area – currently considered 100 km (62 miles) at each side of the borderline, into the territories of Mexico and the U.S – and determines the risk of propagation of infectious diseases and other public health threats.

This document has adopted the term binational case for referring to a confirmed or probable case of disease or other health event in an individual:

• who has recently traveled or lived in the neighboring country, or had recent contact with persons who lived or traveled in the neighboring country; or

- who is thought to have acquired the disease in the neighboring country or have been in the neighboring country during the incubation period of an infection and was possibly contagious during this period; or
- who is thought to have acquired the disease from a product or other exposure in the other country; or
- whose case requires the collaboration of both countries for the purposes of disease investigation and control, regardless of the presumed site of infection or exposure

These Guidelines are meant to provide guidance for public health agencies or institutions and their staff in responding to public health events of shared interest to both countries. While the Guidelines are not binding, it is planned they will lead to the development of shared protocols to facilitate their full implementation.

# 2. General Principles

The guidelines of this document are based on the following principles:

## 2.1. The Need to Share Information

The primary mission of public health agencies or institutions of the United States and Mexico is to protect and promote the health of their citizens. Public health events involving both countries – by geographic proximity, by translocation of their citizens, by exchange of their products, or by concurrent presentation of events – require the sharing of information between counterpart institutions. Such sharing has the objectives of providing information about potential risks and facilitating an appropriate response for the protection of the health of the public, in whichever country they reside. Adequate preparation for the risks of bioterrorism or other public health emergencies further requires that well-functioning, clearly defined channels of communication be established prior to the occurrence of such an event, to facilitate effective sharing of crucial information, and articulation of coordinated responses to ensure the greatest protection possible of the public's health.

In addition to sharing information to directly protect the public's health, counterpart agencies are also expected to share information on other public health matters affecting both countries, such as revised policies, advisories or alerts on travel or imported products from the other country. Such alterations in one country's positions create important demands on the public health agency of the other country, for which they should be as well prepared as possible to respond.

## 2.2. Timely Sharing of Information

The value of epidemiologic information is closely linked to its timeliness. When needed, the sharing of such information between the United States and Mexico should occur in a time frame which allows the other country to respond to the specific health need in as timely a manner as possible, maximizing the potential for effective public health action to prevent avoidable disease, disability and mortality. As such, information shared may be preliminary in nature and subject to change as events evolve. Preliminary information should be clearly communicated as such.

## 2.3. Quality of Information

The value of the epidemiologic information being shared depends on its accuracy and completeness. The national and state public health authorities of both countries need to commit to providing the most comprehensive and current epidemiologic information available.

## 2.4. Communication Pathways

Clearly defined pathways between public health agencies or institutions of the United States and Mexico for communication of such epidemiologic information should be established to ensure rapid delivery to the appropriate agency and a high potential for action based on the information.

Information exchange between the two countries should be reciprocal and favor symmetry in the participation of different levels of government of the two countries. When a specific need for binational information exchange arises, public health agencies at the local, state or federal levels of one country should communicate with their counterpart agency of the same level in the other country (i.e., local–local, state–state, or federal–federal). This should be conducted in parallel with communication to federal partners, as defined by national policies. Federal public health agencies or institutions or officials who intervene, participate, facilitate, or promote binational exchange of information between state or local public health agencies, regarding a particular public health event, should communicate with their federal counterparts in the neighboring country before directly interacting with state and local levels of that country.

While communications transmitted in the language of the other country are encouraged, communications in the language of the provider country are acceptable means of information exchange for the purposes contemplated in these Guidelines.

#### 2.5. Confidentiality, protection of privacy, and dissemination of information

Epidemiological information may be sensitive in nature. Inappropriately handled information may expose individuals, communities and countries to stigma or discredit, affecting their stability, security and wellbeing. Therefore, both countries should protect the information shared by the neighboring country and establish secure mechanisms and tools for transmitting and storing all information shared by the other country.

Information exchange discussed in this document aims to facilitate effective and timely public health action. This information should not be disseminated outside the purview of relevant public health authorities unless by mutual agreement or if it has been made public by the provider country. If public health agencies or institutions of the country receiving the information are obligated to share data beyond its original purpose because of legal requirements – such as judicial order or freedom of information acts – or they become aware of an unintentional leak of information, they should warn as soon as possible the relevant public health agencies of the provider country.

## 2.6. Joint Action to Respond to an Public Health Event

When an epidemiologic event occurs involving both countries and both have an interest in investigating the event (such as an outbreak investigation), the two countries should make a determined effort to conduct the investigation together. In this situation, the national public health agency of the country in which the study will take place should assume the coordinating role in accordance with its jurisdiction. At all times, the receiving country has the prerogative of cancelling an invitation or finalizing the joint investigation of a particular public health event. In Mexico inviting or declining the collaboration of another country's health officials is an attribution reserved to the federal government, whether or not federal health agencies or personnel participate in epidemiological investigations or disease control measures of a particular public health event.

Each country should be expected to provide the technical and financial support needed for its participation, recognizing that this will be subject to the availability of funds and the applicable provisions of the respective country. Sharing of resources, e.g. laboratory testing, may be necessary, is highly encouraged, and should be negotiated in a timely fashion. The timeliness of the investigation should be accorded a high priority by both countries. When rapid action is appropriate, the deployment of a team of the country where the outbreak is occurring should not be slowed by the delayed mobilization of the corresponding team from the other country; that is, the response to the event by the affected country should not be delayed pending arrival of the team of the other country.

## 2.7. Differences between Health Systems

The roles of public health agencies or institutions of the United States and Mexico at the different levels of government are not always the same. In the United States, the public health sector is primarily state-based. In Mexico, although states are legally competent for performing some public health activities, these are subject to the overall direction of the *Secretaria de Salud* of the Federal Government. Such differences should be taken into consideration in mounting the necessary responses when the two countries face an epidemiologic event requiring collaboration.

#### 2.8. Respect for the Sovereignty and Laws of Each Country

The responsibility for all public health responses to binational events lies with the public health agencies or institutions of the country where the respective activities will take place. All parties recognize the need for these same public health agencies or institutions to operate within the legal framework established by that country. If legal or other barriers are identified which limit the capacity of public health agencies or institutions to collaborate with counterpart agencies of the other country in the most effective way, the public health agencies should investigate possible solutions to such barriers.

## 3. Legal Framework

The following section reviews the legal framework currently in place for implementing these Guidelines, from the perspective of the U.S. federal and state governments and the Government of Mexico.

#### Federal and State Governments of the United States

The Public Health Service Act (42 USC § 241 et seq.) provides the Department of Health and Human Services (HHS) with a broad authority to conduct activities relating to the

prevention and control of diseases and injuries. It also authorizes HHS to participate with other countries in cooperative endeavors to advance health sciences and improve the health of Americans (42 U.S.C. § 242*l*). Requirements for disease reporting are typically defined in laws at the state and local level. The Centers for Disease Control and Prevention (CDC), however, together with the Council of State and Territorial Epidemiologists (CSTE) have defined a list of nationally notifiable diseases and conditions, and states provide information about these to CDC's National Notifiable Diseases Surveillance System and other CDC surveillance systems. In addition, ships and airlines are required by federal regulation to report deaths or ill passengers to CDC quarantine stations. CDC also operates various surveillance systems that track particular disease problems of national interest.

The Privacy Act of 1974 (5 USC § 552a) establishes a code of fair information practices that governs the collection, maintenance, use, and dissemination of information about individuals that is maintained in systems of records by federal agencies. A system of records is a group of records under the control of an agency from which information is retrieved by the name of the individual or by some identifier assigned to the individual. The Privacy Act requires that agencies give the public notice of their systems of records by publication in the Federal Register. The Privacy Act prohibits the disclosure of a record about an individual from a system of records absent the written consent of the individual, unless the disclosure is pursuant to one of twelve statutory exceptions. The Act also provides individuals with a means by which to seek access to and amendment of their records, and sets forth various agency record-keeping requirements. While the Act sets controls on the terms by which federal agencies can gather, maintain, and disseminate personal information, it also defines circumstances in which disclosure of information is permissible without the subject's consent. This includes disclosure "to a person pursuant to a showing of compelling circumstances affecting the health or safety of an individual" if notice of the disclosure is transmitted to the individual's last known address and pursuant to a routine use as defined in the system of records published by the agency. The system of records applicable to most of CDC's surveillance projects, "Epidemiologic Studies and Surveillance of Disease Problems" authorizes, among other things, disclosure to "cooperating medical authorities."

The Freedom of Information Act (FOIA, 5 USC § 552) provides that any person has a right to obtain access to federal agency records, except to the extent that such records (or portions of them) are protected from public disclosure by one of nine exemptions or by one of three special law enforcement record exclusions. It applies only to federal records, though U.S. states have their own equivalent statutes. The FOIA provides access to all federal agency records except for those records (or portions of records) that are protected from disclosure.

The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule regulates how "covered entities" – e.g. healthcare providers, health plans, health billing services – use and disclose certain individually identifiable health information known as "protected health information" (PHI). While CDC is not considered a "covered entity," some state and local health departments may be. The HIPAA Privacy Rule recognizes the legitimate need for public health authorities and others responsible for ensuring public health and safety to have access to PHI to carry out their public health mission. The Privacy Rule permits covered entities to disclose PHI, without authorization from the subject, to public health authorities (e.g., CDC, State and local health departments) that are legally authorized to receive such reports for purposes of preventing or controlling disease, injury, or disability. This includes, for example, reporting of disease or injury; reporting vital events, such as births or deaths; and conducting public health surveillance, investigations, or interventions. At the direction of a public health authority, covered entities may disclose PHI to a foreign government agency that is acting in collaboration with a public health authority (45 CFR 164.512(b)(1)(i)). Covered entities may only disclose the minimum PHI necessary to accomplish the permitted purpose (45 CFR 164.502(b)(1)). However, the covered entity may reasonably rely on the representation of a public official requesting the information that it constitutes the minimum necessary (45 CFR 164.514(d)(3)(iii)(A)).

Under the U.S. federal system, each state enacts health and safety laws within their jurisdictions. Each state must review its laws relating to these Guidelines to determine whether legal authority exists to exchange public health information and to collaborate in other ways with counterparts in Mexico on public health issues of mutual interest. Some states have examined their legislation, seeking to identify potential barriers to the sharing of epidemiologic information with Mexico.<sup>1,2</sup> All states are encouraged to complete an analysis of their laws for this purpose. In those cases where barriers are identified, states are encouraged to consider new legislation that would provide such authority, based on the value of such collaboration for the improvement of public health in our countries. Mexico's local, state and federal health agencies reserve the right to limit sharing of information with those states whose legal barriers limit the exchange of epidemiologic information.

In summary, U.S. federal legislation permits the sharing of epidemiologic information by federal agencies with a foreign country for the prevention or control of disease, with necessary restrictions based on confidentiality. Each state needs to review its own legislation to determine whether barriers exist to the exchange of such information. If present, this legislation should be reconsidered to ensure that state public health officials have the needed authority to improve the public's health through the sharing of such information. With the requisite authority under state law, states would be constitutionally permitted to enter into cooperative arrangements with each other and with Mexican states for the purpose of sharing epidemiologic information.

#### Federal Government of Mexico

The legal framework of Mexico for epidemiologic surveillance and health information is composed of a set of legal arrangements that include the Mexican Constitution, laws, regulations, decrees, secretarial agreements, norms, agreements and guidelines of the National Epidemiologic Surveillance Technical Sectorial Committee Specialized in Health (Annex 1). Among the most prominent are the following.

<sup>&</sup>lt;sup>1</sup> Barriers to Binational Cooperation in Public Health between Texas and Mexico, Office of Border Health, Texas Department of Health, 2001

<sup>&</sup>lt;sup>2</sup> Annual Border Health Status Report, 2001: Barriers to California-Mexico Collaboration in Public Health, California Office of Binational Border Health, California Department of Health Services

The Political Constitution of the United Mexican States, in its Article 4, Paragraph 4, establishes the right of health protection . Article 73, Section XVI, first basis, establishes the General Public Health Council (GPHC), a body of the Mexican State directly dependent of the President of the Republic, chaired by the Secretary of Health. The GPHC has authority to issue mandatory provisions in public health. The Council is the second health authority in the country, preceded only by the President of the Republic.

The General Health Law (GHL) describes the terms for the application of the universal right to health protection established in Article 4 of the Constitution. This law is mandatory for all public and private entities and individuals in Mexico. The GHL defines General Public Health and determines the respective competencies and collaboration of the Federal and State governments in the matter.

The Federal Law of Transparence and Access to Public Governmental Information (FLTAPGI) establishes the rules and mechanisms to assure persons have access to information stored by the Federal Government or autonomous institutions, except for information that is classified as reserved. All 32 states in Mexico have similar bylaws.

The reform of FLTAPGI, published in the Official Journal of the Federation on July 5, 2010, defines the mode in which personal data will be handled and establishes principles and procedures to store, transmit, and limit access to data containing private or confidential information of persons. Although this law generally inhibits transmission of nominal data, it contemplates the use of such information for specific technical purposes of governmental agencies, provided the appropriate mechanisms are observed to avoid unintentional transmission of information beyond the intended agencies and purposes.

The Mexican Official Norms for Epidemiologic Surveillance (NOM 017-SSA2-1994) and Health Information (NOM 040-SSA2-2004) determine institutional responsibilities and procedures to conduct surveillance, including notification, data integration and communication.

The Mexican constitution in Article 117, Fraction I, states that "the States cannot, under any circumstance, sign agreement, treaty or coalition with another State or foreign power..." [but, similarly to the United States, they may be able to sign non-binding agreements].

In summary, no part of relevant Mexican laws contemplates sharing public health information with other countries but also does not forbid sharing of such information internationally. Mexican law determines disease prevention and control in Mexico to be an exclusive attribution of Mexican health authorities, but allows the Federal Government to establish specific collaboration agreements with other parties, including international agencies and other governments.

#### Other United States-Mexico Collaborations

These Guidelines are also consistent with other terms agreed to between public health authorities of the two countries. In March 2008, HHS and SSA established a Memorandum of Understanding on Cooperation in the Fields of Public Health and Science, providing a "framework to encourage bilateral cooperation" in which efforts are meant to "foster collaboration where areas of mutual interest exist." Among the areas cited for cooperation is "the detection, surveillance, and reporting of infectious and chronic diseases, to enable better tracking and analyses of prevalence and trends, so as to improve the prevention and care of, and the response to these diseases." In 2007, a mutual assistance agreement also was adopted by the United States, Mexico and Canada for addressing public health emergencies, referring to the sharing of information, and implementation of protocols for laboratory collaborations, among other areas.

Other existing mechanisms for collaboration between governments of the two countries on public health issues include the United States – Mexico Border Health Commission, the United States–Mexico Food Safety Cooperative Agreement, the Border Governor's Conference, the Pan American Health Organization (PAHO) El Paso Field Office, border state Memoranda of Understanding, and Binational Health Councils of border Sister Cities. Joint public health collaborations are in place between the two countries in the areas of tuberculosis (Ten Against TB, Binational TB Card), infectious disease surveillance (Border Infectious Disease Surveillance – BIDS, Early Warning Infectious Disease Surveillance – EWIDS), influenza and others.

In conclusion, the legal frameworks of the two countries at the national level allow for the exchange of information, as proposed in these Guidelines. States or federal entities that are part of each of the countries will need to analyze their own local legal framework in order to verify that its arrangements are aligned with and complement the Guidelines provided here. Numerous interfaces are already in place between health authorities of the United States and Mexico, reflecting the need and desire to assist each other in confronting shared public health challenges.

#### 4. Scope of Public Health Events

The purpose of this chapter is to characterize the scope or range of public health events for which both countries determine that exchange of epidemiologic information is appropriate. It is understood that the information to be shared by one country has the objective of leading to or facilitating action in the second country which will be of direct benefit to the health of the population of one or both countries. This would include:

- A. Cases of disease identified in one country for which there is evidence or reason to suspect an epidemiologic link to the other country, including diseases detected in animals, or that such a link may occur in the future due to expected travel to the neighboring country;
- B. Similarly, the identification of risk factors for disease in one country that may lead to disease in the other country. When a country identifies risk factors for

disease in a location outside its territory that may affect the neighboring country, efforts should be done to timely share relevant information with the potentially affected country.

Types of public health events that meet these criteria include, but are not limited to:

- A probable or confirmed case of any severe or otherwise important infectious disease with high potential for spread to the other country
- Infections in animals or vectors with potential for spread of severe or potentially severe disease to humans
- A probable or confirmed case of severe or potentially severe disease suspected of having been intentionally spread
- Disease outbreaks involving both countries at the time of discovery or which have a significant potential for spread to the other country
- Outbreaks of disease associated with travel or migration to the other country
- Outbreaks of disease or chemical contamination associated with food or other products originating in the other country
- Environmental health emergencies potentially or actually affecting both countries
- Binational cases of pre-established/or agreed notifiable diseases

There is a tremendous interaction between the United States and Mexico, reflected by almost 128 million visitors from Mexico to the United States and almost 95 million US visitors to Mexico in 2005.<sup>3</sup> While border region traffic makes up the majority of such travel, travel occurs between all regions of Mexico and the United States. For example, over 65% of US air travelers to Mexico in 2010 flew to Mexico City, Cancun and Guadalajara. Therefore, the potential of a public health event to be binational should be considered throughout the full reach of both countries.

## 5. Specific Guidelines

This section presents specific guidelines for different types of events and for different areas of collaboration.

## 5.1. Binational Public Health Events

Binational public health events are those potentially or actually affecting individuals or populations in both countries. Binational events encompass cases, outbreaks, threats and risks, exposures and, generally, all relevant public health situations of concern to both countries.

## **Binational Cases**

As stated earlier, a binational case refers to an individual who is a confirmed or probable case of an infectious disease or ailment, notifiable in either country, who may have

<sup>&</sup>lt;sup>3</sup> North American Transportation Statistics, http://nats.sct.gob.mx/nats/sys/tables

acquired or may transmit the disease in the other country, or who may require binational collaboration for investigation, management or control.

An example of a binational case is a person with tuberculosis (TB) under treatment who crosses the border during the course of his or her medical care and public health followup. Such a binational TB case is thus at risk for interruptions in treatment with the consequent possibility of transmitting TB to others, as well as of developing drug resistant tuberculosis. Based on the "Need to Share Information" (General Principle 2.1 of these guidelines) identification of binational cases by public health authorities warrants the sharing of relevant information with counterparts of the neighboring country to assist in finding exposed individuals and other cases, to limit the risks of further disease transmission, and to ensure adequate control of the disease among identified cases.

- 1. Identification of Binational Cases The determination of whether or not a person with a notifiable disease is a binational case requires obtaining information that currently is not routinely gathered. States should encourage health professionals making disease notifications of the need to explore whether cases are binational, especially in settings where this is more likely to occur (locations with considerable travel between the countries, migrant populations, etc.). In the future, public health authorities should consider the value of incorporating information specifically designed to identify binational cases along with the other information to be routinely reported. A list of potential diseases defining binational cases and questions designed to elicit such information should be prepared as part of the implementation phase of these Guidelines, being careful not to exclude unknown or unspecific events that are binational by nature (eg. environmental exposures, infectious disease pandemics, etc.).
- 2. Notification of Binational Cases Recognizing that binational cases, by definition, imply a public health risk to the neighboring country and usually require prompt public health action, binational cases of notifiable infectious diseases should be promptly reported to the appropriate public health official(s) in the neighboring country. Public health authorities of both countries should become familiar with the list of conditions that are notifiable in each country. The questions contained in the decision tool of the IHR Annex 2 may help to assess whether a particular condition in an individual should be regarded as a binational case, as well as whether it is considered notifiable under the IHR.
- 3. Information on Binational Cases When necessary, the information shared on binational cases should be sufficient to allow appropriate public health follow-up of the case to take place. In some circumstances, this may entail sharing patient identifying information. Following the public health laws and privacy regulations of both countries, information exchange needs to be handled confidentially. Health officials receiving identifying information should use it responsibly for the sole purpose of instrumenting public health action.
- **4. Timely Reporting of Binational Cases** Time frames should be established by both countries for reporting binational case to public health authorities. Urgently

notifiable conditions, as defined by the relevant agencies, should be reported within 24 hours following a first identification.

- **5. Procedures for Notification of Binational Cases** Clear mechanisms of notification should be established by public health officials of both countries, at the different levels of government, which specify:
  - Counterpart agency and corresponding office to notify
  - Channels, tools and formats of for communication that minimize delay in receiving the notification and assure safe and confidential transactions (e.g. telephone, fax, email, electronic file, secure web-based systems, etc.)
  - Information to be included regarding the binational case(s)
- 6. Follow-up Information on Binational Cases The two countries should exchange follow-up information on binational cases so that the effectiveness of binational case notification and coordinated case management and investigations can be determined. Public health officials of both countries should agree on protocols for case follow-up.

## **Binational Outbreaks**

The term outbreak refers to an increase in the expected number of cases of a specific disease or other health problem in a given population over a defined time period. The number of cases required to consider a cluster of disease cases an outbreak thus obviously depends on historical epidemiologic data and diagnostic criteria and laboratory resources. A single case of a rare disease, such as cholera, or an eradicated disease such as smallpox, may constitute an outbreak, while numerous cases of more common diseases such as HIV/AIDS or tuberculosis may be required to be considered an outbreak. Newer diagnostic capabilities, such as molecular fingerprinting techniques, can identify a cluster of illnesses with indistinguishable molecular characteristics; epidemiological investigation is then used to find links between these cases in the cluster. This combination of molecular characterization of microbes and epidemiological investigation has identified numerous outbreaks, including widely dispersed outbreaks that would otherwise have gone undetected. An outbreak is considered binational:

- when disease exposures occur in one country to visitors or migrants of the other country,
- when disease is associated with products from the other country
- when environmental/ecologic exposures causing disease simultaneously affect both countries, or
- when cases appear in border settings involving the population from both countries.

Upon recognition of a binational outbreak, if new cases continue to appear or exposure to causal agents persists, a rapid response should be organized to accurately diagnose the illness, to determine the scale of the outbreak, to identify significant risk factors, or to implement appropriate preventive and control measures. Coordination between public health agencies or institutions of the two countries is essential for meeting the needs of all relevant parties and to achieve the most effective use of available resources.

- 1. **Preparing for Binational Outbreaks** Pre-event preparations that should be implemented include:
  - Exchange updated lists of binational contact information at the local, state, and federal levels, including information that provide for round-the-clock availability
  - Establish mechanisms for communication in both Spanish and English
  - Define and practice communication protocols for notification to public health officials
  - Plan for needed responses for diverse kinds of public health threats
  - Establish mechanisms for the transportation of specimens or needed supplies through U.S. and Mexican customs
- 2. Communications among Health Authorities during Binational Outbreaks Once a binational outbreak is identified, the appropriate public health officials should be notified, following a pre-defined communications protocol. The public health authorities from each country should share the available data, and take a decision on the most appropriate response, including a decision whether or not to initiate a binational investigation.
- 3. Collaborative Investigations of Binational Outbreaks Upon binational concurrence to conduct a binational investigation or response effort, a binational oversight team of public health officials from the two countries should meet. Unless defined otherwise, the coordination of the investigation will be the responsibility of the lead public health authority where the outbreak is to be investigated. Agreement of the Mexican Federal Public Health authorities is always required when a binational team is expected to work in Mexican territory. The oversight team should be responsible for or coordinate:
  - choosing the members of the binational field investigation team, including a team leader from each country
  - field work preparation, including arrangements for any necessary travel, personal protective gear, prophylaxis, and availability of supplies and equipment
  - planning and implementation of the investigation
  - content of health alerts and press releases
  - determination of control measures based on information provided by field staff
  - administrative arrangements and logistics to support the binational team
- 4. Resources for Collaborative Investigations Each country is responsible for funding the travel of participants of that country in the investigating team. Primary resources needed for the investigation itself should be the responsibility of the lead public health agency where the investigation takes place. In the absence of needed supplies or investigative capacity (e.g. select laboratory exams), sharing of technical resources between counterpart agencies is strongly encouraged.

5. Binational Cooperation in Sharing Public Health Resources – National and state public health agencies or institutions are encouraged to share informational and other resources designed to strengthen the epidemiology and response capacity of binational counterparts. Joint participation by multinational agencies (e.g. PAHO/WHO) and NGOs (e.g. TEPHINET) may provide additional opportunities to identify such needs and appropriately collaborate with the U.S. and Mexican Public Health authorities.

## 5.2. Foodborne Disease Outbreaks

Contaminated foods are responsible for many infections and toxic exposures. Within the United States, foodborne diseases are estimated to be responsible annually for 48 million illnesses and 3,000 deaths. The growing international trade of agricultural products has correspondingly been associated with outbreaks due to pathogens transmitted by foods imported from another country. The United States and Mexico have collaborated in responding to several such outbreaks.

The organization of governmental roles in food safety often includes multiple agencies in both the health and agricultural sectors, and at the federal, state and local levels. To facilitate needed collaboration, a clear definition of the different roles of such agencies must be understood by neighboring countries, including the responsibility of each in responding to outbreaks of foodborne diseases.

At the national level within the United States, the CDC is responsible for surveillance of human illness caused by foodborne disease and for epidemiological and laboratory investigation of outbreaks of foodborne illness. The United States Department of Agriculture (USDA) is responsible for regulating meat, poultry, and processed egg products. The Food and Drug Administration (FDA) is responsible for regulating all other foods, which includes seafood, dairy products, fruits, vegetables, and shell eggs, among other products.

At the state level in the United States, the foodborne illness surveillance and investigation responsibility rests with the health agency at the state and local level, while the regulatory responsibility may rest with the agriculture department or the health department at the state level or the local health agency at the local level. When states want assistance from the CDC for foodborne outbreak investigations, state officials must make a formal request to CDC because CDC does not send investigators without an invitation from state officials. In the event of an inter-state or international foodborne outbreak, the FDA and/or USDA would be contacted in order to cooperate with multiple jurisdictions in coordinating the outbreak investigation, including traceback, trace-forward and potential product recall.

At the local government level in the United States, there is wide variation in food safety roles and responsibilities among the 3000 local health agencies. In many localities, sanitarians have the primary responsibility for investigating reports of foodborne illness related to food service establishments, whereas in other localities reports of foodborne illness are investigated by state officials and the local sanitarians serve in a secondary support role.

Within Mexico, the National Service for Agro-alimentary Health, Safety and Quality (SENASICA) is a decentralized organ of the Ministry of Agriculture, Livestock, Rural Development, Fisheries and Food (*Secretaria de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación*). The Federal Commission for Protection against Sanitary Risks (COFEPRIS) is the decentralized organ of the *Secretaria de Salud*, with jurisdiction over control and public health surveillance of food and drinks, pesticides, plant nutrients, toxic or otherwise dangerous substances, biotechnology products, food supplements, raw materials and additives used in manufacturing of these products, among others. When informed by any domestic or international party of a foodborne disease outbreak associated with a product from Mexico or other country, COFEPRIS coordinates internally and externally with other government agencies, according to the nature of the event.

The complexity of institutional organization on food safety in both countries creates an important need for collaboration between federal, state, and local authorities across international borders.

Foodborne disease outbreaks often imply the need for two or more stages of investigation. The first stage is the primary epidemiologic and environmental investigation which aims to identify the agent, the food vehicle and how the food became contaminated. Traceback of the food vehicle will indicate whether it is a domestic or imported product. In the latter case, and if the food product is suspected to have been contaminated at its point of origin, further traceback investigation of the implicated food product should determine its source. Additional investigation may identify how the food product became contaminated, where the most effective opportunity for future prevention exists and the need for regulatory action. These investigations represent important opportunities for collaboration between the two countries.

- 1. Regulatory Responsibilities in Foodborne Disease Outbreaks Given that public health actions related to products fall under the legal responsibility of regulatory agencies, sharing of information should be conducted in accordance with the policies of those agencies and within the framework of the existing arrangements between the food regulatory agencies in Mexico and the United States.
- 2. Trade-related Implications Recognizing that foodborne outbreaks can have significant effects on trade, each country should conduct investigations and other activities in compliance with any applicable trade obligations. Epidemiologic conclusions should be based on highly reliable scientific methods providing results which are shared with counterpart agencies in the other country.
- **3.** Advanced Diagnostic Technologies The use of advanced technologies (e.g. pulsed field gel electrophoresis) for subtyping of human and food isolates should be encouraged, as well as the sharing of findings from such technologies with counterparts in the two countries.
- 4. Confidentiality and Information Sharing Public health agencies or institutions and food safety regulatory agencies in both countries are obliged to

maintain the confidentiality of patient identification and trade secret information in accordance with their respective laws, practices and policies. Quick sharing of specific information among relevant agencies in both countries on the number and locations of persons who have become ill, the associated epidemiologic information implicating food vehicles, as well as the point of origin and total distribution of the implicated foods, is important to the rapid, appropriate and effective response to a binational outbreak of foodborne disease. The parameters that define which data should be shared and the conditions under which data sharing can legally occur should be determined in advance for binational food safety emergencies.

#### 5.3 Potential Terrorist Events of Public Health Importance

The possibility of introduction of biologic, chemical, radiological, or nuclear agents by way of the United States-Mexico border or the intentional release of an agent in one country with transmission to the other makes this an issue of interest to both countries. Such a scenario could include the appearance of cases in the border region which would require close binational coordination.

The suspicion or identification of such an event as being intentional would lead to the application of legal arrangements other than those addressed in these Guidelines and potential participation of other agencies outside the health sector, with which national public health agencies or institutions would need to cooperate, as defined in their respective national emergency response plans.

Since disease arising by intentional spread may well appear without previous notice, health officials should be aware of suggestive features of such an incident, including the following:

- An outbreak of an unusual syndrome or disease, compatible with agents associated with bioterrorism, especially when occurring in a discrete population.
- Many cases of unexplained diseases or deaths
- More severe disease than is usually expected for a specific pathogen or failure to respond to standard therapy
- A disease that is unusual for a given geographic area or transmission season.
- Multiple simultaneous or serial epidemics of different diseases in the same population
- Unusual strains or variants of organisms or antimicrobial resistance patterns different from those circulating
- Similar genetic typing of agents isolated from distinct sources at different times or locations
- Intelligence of a potential attack, claims by a terrorist or aggressor of a release, and other evidence suggesting terrorist intent
- Other unusual situations<sup>4,5</sup>

<sup>&</sup>lt;sup>4</sup> Recognition of Illness Associated with the Intentional Release of a Biologic Agent, MMWR 2001 Oct 19;50(41):893-897.

<sup>&</sup>lt;sup>5</sup> <u>Recognition of Illness Associated With Exposure to Chemical Agents — United States, 2003</u>, MMWR 2003 Oct 3;52(3):938-940.

- 1. Emergency Communications Channel The program units for public health emergencies in the two countries, including their directors and directories, should be known to each other. Both program units should have a mechanism permitting direct contact on a continuous basis (i.e. 24 hours/day, 7 days/week, 365 days/year).
- 2. Communication of a Suspected Incident Suspicion of any intentional health incident which presents a risk to citizens of the other country should be urgently communicated to the counterpart agency responsible for such emergencies.
- **3. Ongoing Information Exchange** As such an incident evolves, information should be regularly exchanged at commonly decided intervals between corresponding public health emergency program units of both countries.
- 4. Resource Sharing in Emergencies In preparation for such potential events, arrangements should be established between the public health authorities of the two countries including local, state and federal levels regarding the sharing of health resources during public health emergencies, together with expedited clearance procedures for cross–border transfer of such resources by immigration and custom officials, when such a public health emergency is formally declared.
- 5. Adherence to Outbreak Guidelines Cooperation in the investigation of such incidents is strongly encouraged and should follow the same guidelines as for naturally occurring outbreaks.
- 6. Quarantine or Isolation of Foreign Citizens In the event that quarantine or isolation are considered necessary by the public health agency of a country that will include citizens of the other country, subject to all other treaty or international law obligations, this decision should be communicated urgently to the counterpart public health agency of the other country. The public health agency enacting the quarantine or isolation should recognize the special needs of citizens of the other country who are caught outside their place of residence, while still ensuring the effectiveness of the quarantine or isolation measure.

#### 5.4 Laboratory Issues

Laboratories serve a unique role in both surveillance and investigation of health problems. The purpose of this section is to establish guidelines for laboratories when significant health events of binational interest occur that will benefit from a collaborative response by both nations.

The availability of laboratories and the complexity of testing that those laboratories are capable of performing vary along the length of the border in the two countries. This may lead to periodic use of laboratories by border clinicians or patients in the neighboring country. In addition, disease outbreaks or emergency preparedness plans may lead to decisions to share laboratory resources. In such cases, minimizing the time required for laboratory diagnosis and confirmatory testing is critical to timely identification of health problems and disease outbreaks so that appropriate and timely control measures can be

implemented. This is particularly important when considering bioterrorism events and outbreaks of highly communicable diseases such as pandemic influenza or Severe Acute Respiratory Syndrome (SARS) which have the potential to cause substantial health, social, and economic problems.

Each of the specific items detailed below should be addressed in establishing an efficient, highly functional, binational framework for laboratories to develop the needed capabilities for responding effectively to disease outbreaks and other health challenges impacting both countries.

- 1. Binational Reporting of Notifiable Diseases When a laboratory in one country analyzes or examines specimens from a person residing in the other country, and obtains a positive result for a reportable condition, this information should be routinely communicated to the appropriate public health officials where the tested individual resides. The mechanism for making this communication should be determined by the respective state public health agencies working in coordination with relevant public and private laboratories and with its counterparts in the neighboring country.
- 2. Transport of Laboratory Samples through Customs In cases where specimens of public health interest need to be carried across the border for testing in a laboratory of the other country, mechanisms should be established to assure expedited passage through customs, since excessive delay may compromise the quality of the specimen and the ability to obtain an accurate diagnosis. This is likely to require the stimulus of prior coordination among the involved agencies, including the customs authority, specifying a clearly defined protocol to be followed for the rapid, cross-border transport of a set of specimens.
- 3. Standards for Sample Transport Specimens being sent for testing in the neighboring country should follow national and international standards for the labeling, packaging and transport of such material. In laboratories that may participate in such collaborative testing, specific training on implementation of these standards should be provided to responsible personnel in these areas, together with written instructions.
- 4. Authorized Request for Laboratory Testing Submission of samples for diagnostic testing by a laboratory of the neighboring country should be preceded by communication between authorized public health officials of the two countries, with approval of the receiving laboratory. Upon arrival of the specimen, confirmation should be sent to the agency submitting the specimens for testing. In situations where there is potential for the receiving laboratory to be sent a large number of specimens, a triaging policy should be established in anticipation to define the priority of received samples for urgent testing, and inform referring agencies of this policy.
- **5. Reporting of Laboratory Results** Laboratory results should be communicated promptly to the requesting public health agency on a confidential basis. The agency submitting specimens for testing should be responsible for any public

release of findings. When appropriate, specific protocols may be agreed upon which dictate alternate procedures.

6. Binational Laboratory Collaboration – Collaborative activities between crossborder laboratories is encouraged to enhance the scope of diagnostic capabilities available and the quality of the services provided. This may include training, provision of equipment, supplies and/or reagents, and participation in quality assurance programs. For cross-border transport of specimens, agreements between regulatory, public health agencies and customs authorities should be promoted to define protocols which facilitate the passage of such material. Roles of national and state public health agencies for coordination of such activities should be defined by each country.

#### 5.5 Public Health Risk Assessment and Communications

#### 5.5.1 Risk assessment

Risk assessment is a fundamental element of effective public health response. Assessing the risk of public health events involves both quantitative and qualitative efforts to estimate the probability of harmful effects to populations from certain disease events or human activities. Risk assessments are formally conducted for Public Health Emergencies of International Concern reported to WHO using the International Health Regulations decision algorithms and by each country's health agencies for a variety of situations, for example outbreaks that may lead to travel advisories, or emergency events caused by radiation. Each country should make every effort to share risk assessments for situations potentially affecting the neighboring country. In certain situations, such as events in border sister cities, joint risk assessments may be appropriate. Each country should make an effort to be responsive to a request from the neighboring country for a risk assessment on a situation for which that country indicates concern. Mechanisms for sharing risk assessments and making joint risk assessments when appropriate should be established.

#### 5.5.2 Communications

As expressed throughout this document, successful binational exchange of epidemiologic information for public health depends on timely and clear communication of accurate information between appropriate public health authorities of the U.S. and Mexico. Failure to do so can result not only in an inadequate public health response to prevent and control disease among binational populations, but also to misunderstandings between officials and the populations of both countries. Such misunderstandings can undermine mutual trust and confidence and can create distorted and unequal perceptions of the epidemiologic situation affecting the two countries. For these reasons, establishing clear mechanisms and protocols for public health communications between the two countries is of paramount importance.

#### Communications between Public Health Agencies or Institutions

- 1. Existing Information Sources To facilitate the exchange of information recommended in this document, public health agencies should consult and subscribe to those information outlets provided by the other country (e.g. publications, press releases, *Boletín Epidemiología*, Health Alert Network, Epi-X).
- 2. Communications between Public Health Agencies or Institutions Direct communications between corresponding programs and staff of counterpart public health agencies or institutions of the neighboring country should be encouraged (e.g. to contact a known staff member in the measles unit to report a case of binational interest). However for cases in which program staff are not known or cannot be reached, or for emergencies and other broader issues of common interest, counterpart agencies of the two countries should each have a preestablished mechanism (telephone contact number and email address) which is staffed at all times for such communications. In the case of binational events requiring continued collaboration, the communications offices of counterpart agencies should be in regular contact, exchanging relevant information and coordinating the release of information to the public.

## Release of Information to the Public

- **3.** Harmonization of Public Information In cases of binational epidemiologic events, information released to the public by the two countries regarding the event, risk factors and preventive measures should be consistent, based on the best available scientific evidence of the event itself, and the pathogens or substances involved. Ideally, the population of each country should receive such information from their public health authorities in the same time period, to avoid creation of unexpected demands on public health authorities from one-sided releases, and to reinforce their credibility to the public.
- 4. Sharing of Information for the Public In the case of a binational public health emergency or outbreak affecting the population of both countries, copies of information made available to the public by the respective public health agency should be shared with the counterpart agency of the other country. In non-emergency circumstances, such information should be made available on request.
- 5. Travel Notices Travel notices are posted by public health authorities to provide information to travelers, the public, healthcare providers and public health authorities regarding outbreaks of disease of public health significance. The character of the notification is based on four criteria relating to disease transmission, containment measures, quality of surveillance, and quality and accessibility of medical care. In the case of such travel notices or other communications to the public which could have negative impact on trade, tourism or other industries, the counterpart agency should be given prior notice of the action to be taken and the evidence supporting that decision for their review and,

if appropriate, their response. The IHR (2005) should be always considered when making these decisions.

## 6. Next Steps

The intent of the two countries is that the completion of these Guidelines be followed by the elaboration of a set of protocols to guide the implementation of these recommendations by the public health agencies or institutions of each country. This process should be undertaken with broad binational participation of the major public health agencies or institutions at the state and federal levels.

Finally, based on the experience accumulated in the functional implementation of the Guidelines to date, it appears likely that they will evolve over time, and new or revised needs will be identified. In anticipation of this, a binational technical working group should review this document annually, to assess its continued validity, and to update the Guidelines as needed. Nevertheless, these Guidelines will remain applicable as long as no other document of a similar nature modifies them.

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#### Annex: Mexico's Legal Framework for Epidemiologic Surveillance

#### 1. Constitution of Mexico

Article 4. Fourth paragraph.

#### 2. Laws

General Health Law. Articles: 17B, 133, part II, Chapter II of "Infectious Diseases" 134 to 157, 181, 353, 358, 359, 360 and 408 and others relating to epidemiologic issues.

Federal Law for the Control of Chemical Precursors, Essential Chemical Products and Machinery for Producing Capsules, Tablets and Pills Official Journal of the Federation 26 Dec 1997.

Biosafety Law on Genetically Modified Organisms Official Journal of the Federation 18 Mar 2005.

Customs Law Official Journal of the Federation 15 Dec 1995.

Organic Law of Federal Public Administration Official Journal of the Federation 29 Dec 1976 Last Alteration Official Journal of the Federation 17 Jun 2009.

Federal Law of Transparency and Access to Public Governmental Information Official Journal of the Federation 11 June 2002 Last Alteration Official Journal of the Federation 05 Jul 2010.

General Law of Civil Defense Official Journal of the Federation 12 May 2000 Last Alteration Journal of the Federation 24 Apr 2006.

Federal Law for Protection of Personal Data Held by Individuals Official Journal of the Federation 05 Jul 2010.

#### 3. Regulations

Regulation of the General Health Law regarding International Sanitary Issues. Official Journal of the Federation 18 Feb 1985. Errata Official Journal of the Federation 10 Jul 1985.

Regulation of the General Health Law regarding Sanitary Control for the Disposition of Organs, Tissues, and Human Cadavers. Official Journal of the Federation 20 Feb 1985. Errata Official Journal of the Federation 09 Jul 1985. Alterations Official Journal of the Federation 26 Nov 1987. Regulation of the General Health Law regarding Delivery of Medical Care Services. Official Journal of the Federation 14 May 1986. Alterations Official Journal of the Federation 04 Dec 2009

Regulation of the General Health Law regarding Health Research. Official Journal of the Federation 06 Jan 1987.

Regulation of the General Health Law regarding Public Health Control of Activities, Establishments, Products and Services. Official Journal of the Federation 18 Jan 1988. Alterations Official Journal of the Federation 28 Apr 2004

Regulation on Health Supplies Official Journal of the Federation 04 Feb 1998. Corrections Official Journal of the Federation 05 Aug 2008.

Regulation on Public Health Control of Products and Services. Official Journal of the Federation 09 Aug 1999. Alterations Official Journal of the Federation 6 Apr 2006

Regulation on Registrations, Authorizations of Importation and Export Certificates of Insecticides, Plant Nutrients and Substances and Toxic or Dangerous Materials. Official Journal of the Federation 28 Dec 2004.

Regulation on Customs Law Official Journal of the Federation 06 Jun 1996 Last Alteration Official Journal of the Federation 28 Oct 2003.

Regulation on the Law of Biosecurity for Genetically Modified Organisms Official Journal of the Federation 19 Mar 2008 Last Alteration Official Journal of the Federation 02 Jun 2009

Regulation on the Federal Law for the Control of Chemical Precursors, Essential Chemical Products and Machinery for Producing Capsules, Tablets and Pills Official Journal of the Federation 15 Sep 1999

Regulation on the Federal Law of Transparency and Access to Public Governmental Information Official Journal of the Federation 11 Jun 2004

Internal Regulations of the Secretariat of Health Official Journal of the Federation 19 Jan 2004 Last Alterations Official Journal of the Federation 29 Nov 2006, 02 Feb 2010, 10 Jan 2011.

#### 4. Plans and Programs

National Development Plan 2007-2012. Official Journal of the Federation 31 May 2007.

Health Sector Program 2007-2012 Official Journal of the Federation 17 Jan 2008.

#### 5. Decrees

Decree which establishes the basis of coordination for the Secretaries of Commerce and Industry, of Agriculture and Water Resources, of Urban Development and Ecology and of Health, that should be observed in regard to Insecticides, Fertilizers, and Toxic Substances.

Official Journal of the Federation 15 Oct 1987.

Decree by which is created the National Vaccination Council Official Journal of the Federation 24 Jan 1991. Corrections Official Journal of the Federation 05 Jul 2001.

Decree by which is changed the National Council for AIDS Prevention and Control. Official Journal of the Federation 05 Jul 2001.

Decree by which is created the National Bioethics Council. Official Journal of the Federation 07 Sep 2005.

#### 6. Executive Agreements

Agreement by which is created the Inter-Institutional Commision on Health Research. Official Journal of the Federation 19 Oct 1983.

Agreement by which is created the National Committee for Health Security Official Journal of the Federation 23 Sep 2003.

Agreement by which is established the Integration and Objectives of the National Health Council. Official Journal of the Federation 27 Jan 2009.

#### 7. Secretarial Agreements

Agreement Number 43. By which is created the Health Research Committee. Official Journal of the Federation 11 Jan 1985.

Agreement by which instructions are made known for the uniform and comprehensive procedure to which is subjected the Secretaries of Commerce and Industry, of Agriculture and Water Resources, of Urban Development and Ecology, in the resolution of requests for authorizations for licenses, permissions, and registries of insecticides, fertilizers, and toxic substances.

Official Journal of the Federation 07 Dec 1988.

Agreement Number 130. By which is created the National Committee for Epidemiologic Surveillance.

Official Journal of the Federation 06 Sep 1995.

Agreement that establishes the classification and coding of merchandise whose importation is subject to regulation by those agencies which make up the the Inter-Secretarial Commision for the Control of the Process and Use of Inecticides, Fertilizers, and Toxic Substances.

Official Journal of the Federation 29 Mar 2002.

Last modifications Official Journal of the Federation 01 Apr 2005, 26 May 2008, 25 Aug 2010.

Agreement by which is established certification of the geographic areas that have achieved elimination of transmission of canine rabies. Official Journal of the Federation 16 Mar 2004.

Agreement by which is established certification of the geographic areas which have achieved elimination of transmission of malaria. Official Journal of the Federation 16 Mar 2004.

Agreement by which is created the National Committee of the Tuberculosis Action Program.

Official Journal of the Federation 16 Mar 2004.

Agreement by which is made known the instructions and forms for the authorization of importation and exportation of insecticides, plant nutrients and dangerous substances and materials.

Official Journal of the Federation 15 Sep 2005.

Agreement by which is made known the instructions and forms for the authorization of importation and exportation of insecticides, plant nutrients and dangerous substances and materials.

Official Journal of the Federation 15 Sep 2005.

Agreement through which all the institutions of the national health system in its public, social, and private levels of medical services, must immediately notify the Secretariat of Health of probable cases of influenza meeting the case definition established by the Secretariat of Health.

Official Journal of the Federation 02 May 2009

Agreement which establishes the classification and codification of merchandise and products whose importation, exportation, entrance or exit is subject to the sanitary regulation of the Secretariat of Health. Official Journal of the Federation 27 Sep 2007

Modification Official Journal of the Federation 01 Jun 2010

#### 8. Decisions of the General Public Health Council

Agreement by which is established that public institutions of the national health system should purchase interchangeable generic medications. Official Journal of the Federation 07 Jun 2002.

Basic List and Catalog of Medications, Edition 2010. Official Journal of the Federation 13 May 2011. First Update Official Journal of the Federation 10 Jun 2011 Second Update Official Journal of the Federation 20 Jul 2011 Third Update Official Journal of the Federation 11 Aug 2011 Fourth Update Official Journal of the Federation 24 Oct 2011

Basic List and Catalog of Biological Products and Reagents of the Health Sector 1997.
Official Journal of the Federation 29 Sep 1997.
First update Official Journal of the Federation 16 Mar 1998.
Second update Official Journal of the Federation 20 Jul 1998.
Third update Official Journal of the Federation 06 May 1999.
Fourth update Official Journal of the Federation 22 Dec 1999.
Fifth update Official Journal of the Federation 03 Nov 2000.
Sixth update Official Journal of the Federation 12 Apr 2002.
Eighth update Official Journal of the Federation 06 Aug 2002.

Catalog of Interchangeable Generic Medications Official Journal of the Federation 17 Aug 1998. And its subsequent updates published in the Official Journal of the Federation

Agreement by which is established the Prevention and Health Promotion Strategy during the Stages of Life. Official Journal of the Federation 23 Oct 2003.

Basic List and Catalog of Diagnostic Materials, Edition 2010. Official Journal of the Federation 09 May 2011. First update Official Journal of the Federation 07 Sept 2011.

Agreement by which is established the Commission for Definition of Treatments and Medications Associated with Diseases that Result in Catastrophic Costs. Official Journal of the Federation 28 Apr 2004.

Agreement by which is established the obligatory application in the public and private institutions of the National Health System, of the substantive and strategic components and components of the Action Program Start Out Even in Life and of epidemiologic surveillance of maternal deaths.

Official Journal of the Federation 01 Nov 2004.

Agreement by which are established the general obligatory measures for the prevention, care and control of HIV/AIDS in the public institutions of the National Health System.

Official Journal of the Federation 12 Nov 2004.

#### 9. Official Mexican Norms

Included here are all the Official Mexican Norms emitted to the present, but as per federal law, these are in effect for five years from the date of emission, in which time they need to be revised or will become inactive.

# A) National Advisory Committee on Standardization of Public Health Regulation and Promotion. SSA1.

Official Mexican Norm NOM-003-SSA2-1993, on the use of human blood and its components for therapeutic ends. Official Journal of the Federation 18 Jul 1994. Errata Official Journal of the Federation 23 Feb 1996. Clarification Official Journal of the Federation 08 Sep 1994.

Official Mexican Norm NOM-230-SSA1-2002, Environmental health. Water for human use and consumption, public health requirements that private and public supply systems of water should follow. Public health procedures for sampling. Official Journal of the Federation 12 Jul 2005.

Official Mexican Norm NOM-020-SSA1-1993,Environmental Health. Criteria for evaluating air quality in regard to ozone (O<sub>2</sub>). The level of ozone concentration defined as a measure of protection of the population's health. Official Journal of the Federation 23 Dec 1994. Project Modification Official Journal of the Federation 31 Jul 2000.

Official Mexican Norm NOM-022-SSA1-1993 Environmental Health. Environmental criteria for evaluating air quality in regard to sulfur dioxide (SO<sub>2</sub>). The level of sulfur dioxide (SO<sub>2</sub>) in ambiental air as a measure of protection of the population's health. Official Journal of the Federation 23 Dec 1994.

Official Mexican Norm NOM-59-SSA1-1993, good production practices for chemicalpharmaceutical establishments engaged in the production of medications. Official Journal of the Federation 31 Jul 1998. Clarification Official Journal of the Federation 01 Feb 1999.

Official Mexican Norm NOM-115-SSA1-1994, Goods and Services. Method for determining the presence of staphylococcus aureus in foods. Official Journal of the Federation 25 Sep 1995.

Official Mexican Norm NOM-199-SSA1-2000, Environmental Health. Levels of lead in blood and actions as criteria to protect the health of populations exposed occupationally. Official Journal of the Federation 18 Oct 2002.

Official Mexican Norm NOM-220-SSA1-2002, Installation and operation of pharmacosurveillance.

Official Journal of the Federation 15 Nov 2004.

#### B) National Advisory Committee of Standards for Disease Prevention and Control.

Official Mexican Norm NOM-006-SSA2-1993 for the prevention and control of tuberculosis in primary health care. Official Journal of the Federation 26 Jan 1995. Modification Official Journal of the Federation 31 Oct 2000. Modification Project Official Journal of the Federation 02 Sep 2004. Modification Official Journal of the Federation 27 Sep 2005.

Official Mexican Norm NOM-010-SSA2-1993, for the prevention and control of HIV infection. Official Journal of the Federation 17 Jan 1995. Modification Project Official Journal of the Federation 22 Sep 1999. Modification of the Norm Official Journal of the Federation 21 Jun 2000.

Official Mexican Norm NOM-011-SSA2-1993, for the prevention and control of rabies. Official Journal of the Federation 25 Jan 1995. Modification Official Journal of the Federation 24 Jan 2001.

Official Mexican Norm NOM-016-SSA2-1994, for the surveillance, prevention, control and treatment of cholera. Official Journal of the Federation 05 Oct 2000.

Official Mexican Norm NOM-017-SSA2-1994, for epidemiologic surveillance. Official Journal of the Federation 11 Oct 1999.

Official Mexican Norm NOM-021-SSA2-1994, for the surveillance, prevention, and control of the tenia/cysticercosis complex in primary health care. Official Journal of the Federation 21 Aug 1996. Modification Project: Official Journal of the Federation 11 Sep 2000.

Official Mexican Norm NOM-021-SSA2-1994, for the prevention and control of the teniasis/cysticercosis in primary health care. Modification Official Journal of the Federation 21 May 2004.

Official Mexican Norm NOM-022-SSA2-1994, for the prevention and control of brucellosis in man in primary health care. Official Journal of the Federation 30 Nov 95. Modification Project: D.O.F: 27 Jun 2000. Modification Official Journal of the Federation 02 Feb 2001.

Official Mexican Norm NOM-026-SSA2-1998, for epidemiologic surveillance, prevention and control of nosocomial infections. Official Journal of the Federation 26 Jan 2001. Notice of Cancellation Official Journal of the Federation 26 Nov 2003. Official Mexican Norm NOM-027-SSA2-2007, for the prevention, control and elimination of leprosy. Official Journal of the Federation 12 Aug 2009

Official Mexican Norm NOM-029-SSA2-1999, for epidemiologic surveillance, prevention and control of leptospirosis in man. Official Journal of the Federation 02 Feb 2001.

Official Mexican Norm NOM-032-SSA2-2002, For the epidemiologic surveillance, prevention and control of vector-borne diseases. Official Journal of the Federation 21 Jul 2003.

Official Mexican Norm NOM-036-SSA2-2002, Prevention and control of diseases. Application of vaccines, toxoids, sera, antitoxins, and immunoglobulins in man. Official Journal of the Federation 17 Jul 2003. Clarification Official Journal of the Federation 20 Jan 2004.

Official Mexican Norm NOM-039-SSA2-2002, For the prevention and control of sexually transmitted infections. Official Journal of the Federation 19 Sep 2003.

Official Mexican Norm NOM-041-SSA2-2002, For the prevention, diagnosis, treatment, control and epidemiologic surveillance of breast cancer. Official Journal of the Federation 17 Sep 2003.

Official Mexican Norm NOM-042-SSA2-2006, For the prevention and control of diseases. Public health specifications for canine veterinary services.

Official Mexican Norm NOM-045-SSA2-2005, For epidemiologic surveillance, prevention and control of nosocomial infections. Official Journal of the Federation 20 Nov 2009.

#### **10. Other Juridical Orders**

Criteria for the certification of geographic areas that have achieved elimination of canine rabies transmission. Official Journal of the Federation 19 Aug 2005.

Criteria for the certification of geographic areas that have achieved the elimination of malaria transmission. Official Journal of the Federation 10 Apr 2006.

General rules regarding exterior commerce for 2011. Official Journal of the Federation 29 Jul 2011.

## **11. International Decisions**

Decree by which is approved Prohibition of the Development, Production and Storage of Bacterial Weapons (Biologic) and Toxins and on their Destruction; approved during the XVI normal session during the United Nations General Assembly. Official Journal of the Federation 04 Apr 1973.

Enactment Decree of the Convention on the Prohibition of the Development, Production, Storage and Use of Chemical Weapons and on their Destruction. Official Journal of the Federation 05 Oct 1994.

Decree by which is approved the Cartagena Protocol on the Security of Biotechnology of the Convention on Biologic Diversity, adopted in Montreal, on January 21, 2000. Official Journal of the Federation 01 Jul 2002.