

International Health Regulations

Revised for Today's World

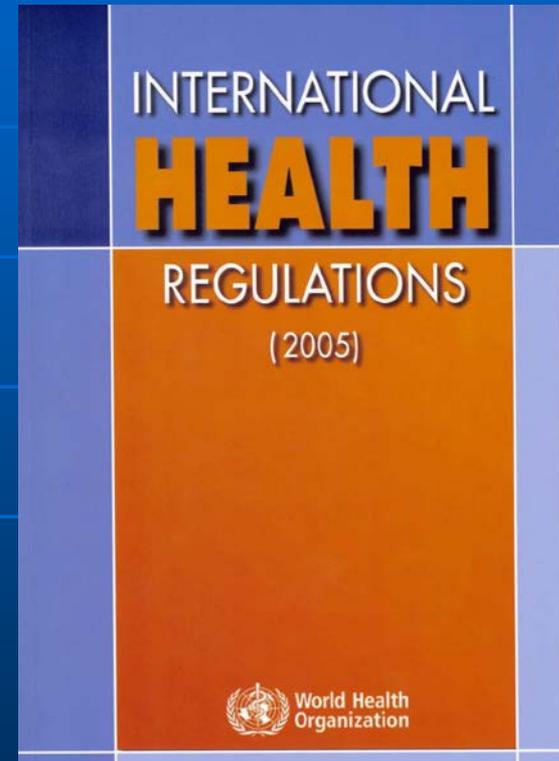
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IHR in Context

International Health Regulations (IHR)

- **What?** – formal code of conduct for public health emergencies of international concern
- **Why?** – a matter of responsible citizenship and collective protection
- **How?** – the U.S. national, tribal, territorial, state, and local roles
- **Who?** – all World Health Organization (WHO) Member Countries
- **When?** – July 18, 2007



Revised IHR

What

- International agreement giving rise to international obligations
- Focuses on serious public health threats with potential to spread beyond a country's borders, to other parts of the world
 - Such events are defined as a Public Health Emergency of International Concern (PHEIC)
- Outlines assessment, management, and information sharing for PHEICs



IHR Serves a Common Interest

why

- **Serious and unusual disease events are inevitable.**
- **A health threat in one part of the world can threaten health anywhere or everywhere.**
- **A formal code of conduct:**
 - **helps contain or prevent serious risks to public health**
 - **discourages unnecessary or excessive traffic or trade restrictions, for “public health purposes”**





Revised IHR

key changes from old (1969) IHR

Member Countries must:

- **Notify WHO of events meeting defined criteria – beyond prescribed list**
- **Enhance their events management – especially alert and response actions**
- **Meet minimum core capacities – notably in surveillance, response, and at points of entry**





International Health Regulations

in brief

Are:

- **Written in legal language**
- **Supported by guidelines to aid compliance**
- **Intended to contain public health threats and minimize economic disruption**

Are not:

- **Self-explanatory**
- **Recommendations for safe travel**
- **A scientific consensus on everything possible to prevent disease spread**



United States Accepts the IHR

- **The United States accepted the IHR with a reservation and three understandings.**
 - **Entered into force in the United States on July 18, 2007**
- **United States is encouraging local and state governments to aid compliance.**
 - **Secretary Leavitt's letter to Governors**
 - **CSTE position statement in support**



United States Accepts IHR

how

- **Reservation**

The U.S. will implement the IHR under the principles of federalism.

- **Federalism**

The system of government in which power is divided between a central authority (U.S. federal government) and constituent political units (local and state governments).





United States Accepts IHR

how

Understandings

- Under the IHR, incidents that involve the natural, accidental or deliberate release of chemical, biological, or radiological materials must be reported.
- Countries that accept the IHR are obligated to report, to the extent possible, potential public health emergencies that occur outside their borders.
- The IHR do not create any separate private right to legal action against the Federal government.



United States Accepts IHR

how

- HHS Secretary's Operations Center is the U.S. National Focal Point to the WHO.
- WHO access to IHR information will be "24 / 7".
- CDC assumes a lead role in IHR implementation as it relates to human disease.
 - Detection, prevention, and control
- One major role for CDC is to support existing health monitoring systems that identify and report.
 - Local, state, and federal public health authorities need to collaborate to improve the ability of national health monitoring systems to report possible PHEICs under IHR provisions.



IHR: Practically Correct

why

As we have seen recently with SARS and H5N1 avian influenza, diseases respect no boundaries. In today's world, a threat anywhere means danger everywhere.

December 13, 2006

HHS Secretary Michael O. Leavitt
on occasion of official United States
acceptance of revised IHR



IHR: Practically Correct

why

*When the world is collectively at risk,
defense becomes a shared
responsibility of all nations.*

Dr. Margaret Chan, Director-General, World Health Organization, World Health Day 2007

(Rodier G, et al. Global Public Health Security, EID, Vol 13, October 2007, <http://www.cdc.gov/eid/content/13/10/1447.htm>)



2007 CSTE Position Statement 07-ID-06

- **Title:** *Events that May Constitute a Public Health Emergency of International Concern*
- Supports implementation of IHR (2005)
- CDC will work with all stakeholders (e.g., CSTE) to develop criteria and processes for contacting CDC about potential PHEICs.
- CDC will evaluate reported events using the decision instrument in Annex 2.
- Invites reporting of events as soon as feasible using formal (e.g., NEDSS and NNDSS) and informal processes, including the CDC Emergency Operations Center at 770-488-7100 or eocreport@cdc.gov





Homeland Security Presidential Directive HSPD-21

Calls on HHS to "establish an operational national epidemiologic surveillance system for human health, **with international connectivity where appropriate**, that is predicated on State, regional, and community-level capabilities and creates a networked system to allow for two-way information flow between and among Federal, State, and local government public health authorities and clinical health care providers."





Establish a Work Group with CSTE Representation

- Perform WHO and national U.S. case definition comparisons
- Develop guidance for interpretation of Annex 2 for use at the local, county, state level of public health
- Develop a CDC Surveillance Program Registry
 - Identify gaps in surveillance for IHR implementation
 - Identify changes to surveillance systems in to support implementation of the IHR (2005)
- Develop case studies
 - To pilot test the federal PHEIC report form



IHR in a Small World

why



Assessing the Threat under IHR

Always Notifiable

- Smallpox
- Poliomyelitis, wild-type
- Human influenza, new sub-type
- SARS

PHEIC

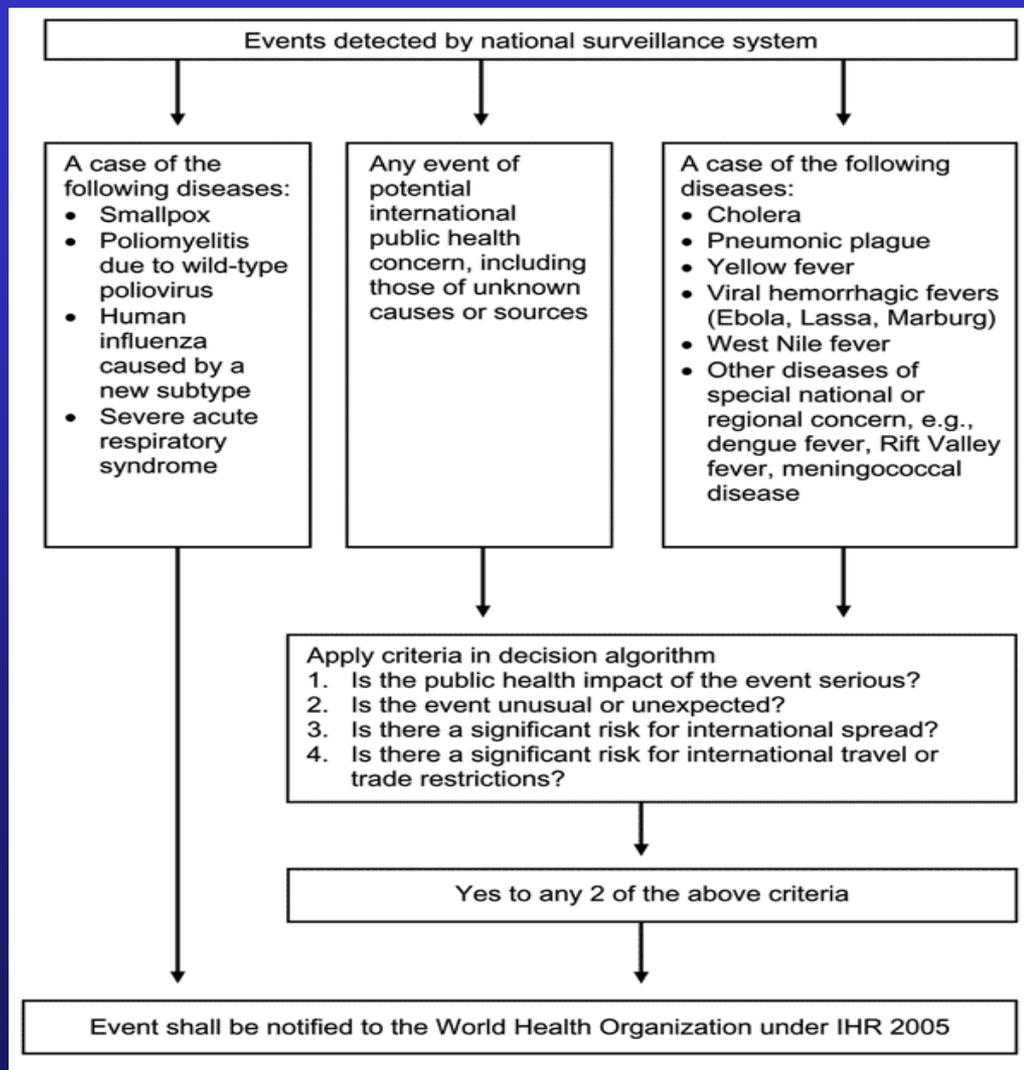
Other Events Potentially Notifiable

- Examples: cholera, pneumonic plague, yellow fever, viral hemorrhagic fevers, and West Nile fever
- Other biological, radiological, or chemical events may fit the decision algorithm and be reportable



PHEIC Decision Instrument

*annex 2**



* Baker MG, Fidler DP. Global public health surveillance under the new International Health Regulations. *EID*; July 2006, Vol. 12. <http://www.cdc.gov/ncidod/eid/vol12no07/05-1497.htm>



Making the Determination

PHEIC

Criteria for Notification from Annex 2

- Is the public health impact of the event serious?
- Is the event unusual or unexpected?
- Is there a significant risk of international spread?
- Is there a significant risk of international travel or trade restrictions?

WHO makes the final determination that a PHEIC exists



Serious Impact on Public Health?

- There is potentially high morbidity and/or mortality
 - The geographic scope is large or spreading over a large area (e.g. multi-state or regional); is in area of high population density
 - The agent is highly transmissible/pathogenic
 - The event has compromised containment or control efforts
 - Therapeutic/prophylactic agents are unavailable, absent, or ineffective
 - Cases occurring among health care staff
-
- Event requires assistance from WHO or other countries for investigation & response



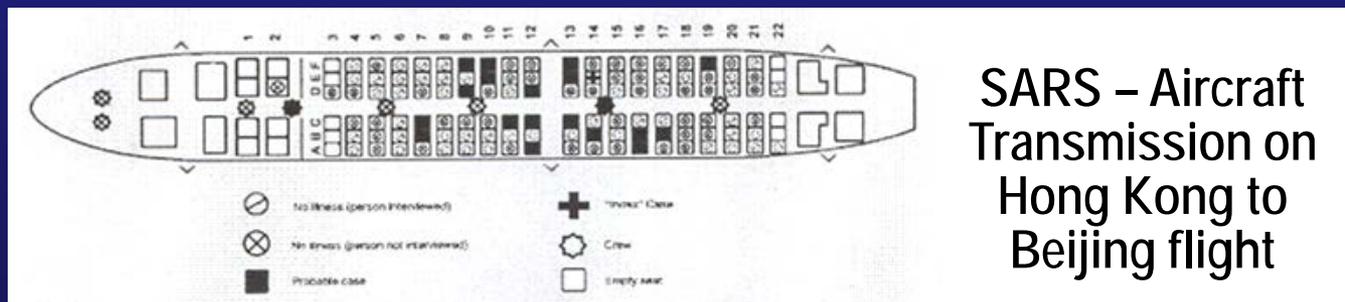
Unusual or Unexpected?

- The disease-causing agent is yet unknown or a new (emergent) pathogen
- The population affected is highly susceptible
- The event is unusual for the season, locality or host
- There is a suspicion that this may have been an intentional act
- Agent had been eliminated or never reported in U.S.



Significant Risk for International Spread?

- Epidemiologic link to a similar event outside the United States
 - International travel or gathering
 - Contact with traveler or mobile population
- Potential cross-border movement of pathogen/agent/host
- Conducive transmission vehicles: air, water, food or environmental



Risk for Trade or Travel Restrictions?

- There is a history of similar events in the past that have resulted in restrictions
- The event is associated with an international gathering or a tourist area
- The event is or has gained significant government or media attention
- There is a zoonotic disease or the potential for an epizootic event, or exported/imported food/water-related





Making the Determination

PHEIC

In summary ...

- **Local situational assessment required**
 - **Decision instrument available**
- **WHO will also assess before any publication or formal response**

Criteria from Annex 2





Global Health and IHR

IHR mandate

Shared responsibility – to establish core capacities:

- **Surveillance and response**
- **Points of entry**
- **Country-specific procedures—key element of WHO's strategy for global health security**



Global Health and IHR

IHR mandate

Robust National Response Effort is Expected

- **Context-specific**
- **Flexible**
- **Interventional health measures permitted**

Entrance Screening Permissible

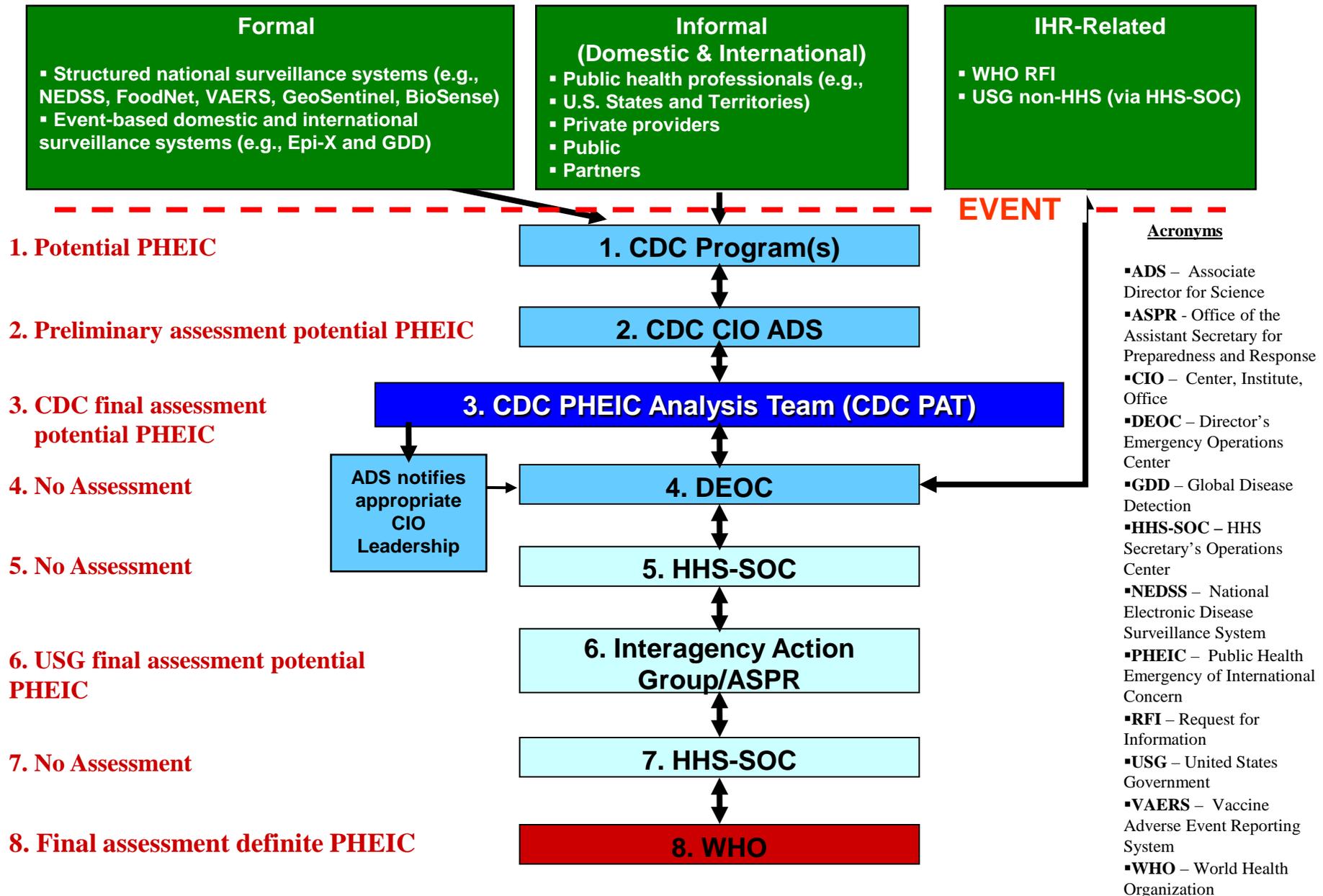
- **Medical exams and interviews**
- **Vaccination and other measures by consent**
- **Quarantine/isolation – respect for human rights**

Who Makes the Decision at CDC to Report a Potential PHEIC?

CDC Preliminary Assessment:
ADS (or CIO designee)

CDC Final Assessment:
CDC PHEIC Analysis Team (CDC PAT)

PHEIC Assessment and Reporting Protocol





IHR in Practice

reporting timeline

48-hour Time Requirement

- After a U.S. Governmental Agency (USGA) learns of a potential PHEIC in a U.S. state or territory, it must assess the event within 48 hours.

24-hour Time Requirement

- The USGA has 24 hours to notify WHO after it believes that a potential PHEIC may exist.



Who is Responsible at CDC?

ADS (or designee)

- Educates the programs about the IHR (2005), analysis and notification requirements
- Makes preliminary assessment of potential PHEIC
- Participates in CDC PAT quorum
- Submits final USG IHR Report Form after CDC PAT determination
- Notifies CDC Leadership about the event

CDC PAT

- Makes the CDC final assessment of a potential PHEIC
- Is a resource for programs reporting events to CDC

Global Disease Detection Operations Center (GDDOC)

- Oversight and advisory role for CDC PAT
- Recipient of copies of the USG IHR Report Form



USG IHR Report Form

Appendix 4 – USG IHR PHEIC Report Form

SOP No. IHR 1.0
Page 17 of 20
Effective Date: October 2007

SOP No. IHR 1.0
Page 18 of 20
Effective Date: October 2007

U.S. Government International Health Regulation (IHR) Public Health Emergency of International Concern (PHEIC) Report Form

Date/Time _____ Event _____
Location _____
Source of Report (for internal USG use only) _____

Step 1: Indicate why this event may be a potential Public Health Emergency of International Concern (PHEIC)*

- A. Disease is one of the following:** SARS, polio, smallpox, human influenza caused by a new subtype (e.g., H5N1)

Skip to Step 2 if checkbox A is checked. For each of the four major PHEIC criteria listed below, fill in the circle next to any sub-item that applies. If any circle is filled in, check the corresponding criterion checkbox.

- B. Event (biological, chemical or radiological) meets the following criteria:**

1. Serious Impact on Public Health

- there is high or potentially high morbidity and/or mortality
- the geographic scope is large or spreading over a large area (e.g. multi-state or regional); is in area of high population density
- the agent is highly transmissible/pathogenic
- the event has compromised containment or control efforts
- therapeutic/prophylactic agents are unavailable, absent, or ineffective (e.g., XDR-TB)
- cases occurring among health care staff
- the event has compromised containment or control efforts
- other: _____

- 2. Unusual or Unexpected Event**

- the disease-causing agent(s) is yet unknown or a new (emergent) pathogen
- the population affected is highly susceptible
- the event is unusual for the season, locality or host
- there is a suspicion that this may have been an intentional act
- other: _____

- 3. Significant risk for international spread**

- epidemiologic link to a similar event outside the U.S.
- potential cross-border movement of pathogen/agent/host
- conducive transmission vehicles: air, water, food or environmental
- other: _____

- 4. Risk for trade or travel restrictions**

- there is a history of similar events in the past that have resulted in restrictions
- the event is associated with an international gathering or a tourist area
- the event is or has gained significant government or media attention
- there is a zoonotic disease or the potential for an epizootic event
- other: _____

Continue with Step 2 if at least two checkboxes (1 – 4) are checked; else, this event does not meet the requirements of a potential PHEIC.

Step 2: Are there human cases of illness associated with the event?

If yes, fill out BOX 1, paying particular attention to report the items listed in BOX 1.

If no, fill out BOX 2, paying particular attention to report the items listed for BOX 2.

Complete the appropriate boxes as best as possible, and include any other event-related information.

BOX 1. HUMAN DISEASE / SYNDROME

PROVIDE AVAILABLE INFORMATION FOR THE FOLLOWING:

Name of pathogen/agent (etiology), if known; clinical signs and symptoms; new or emerging pathogen/agent; case definition; vector or reservoir; cases and deaths; population at risk; laboratory test results and location/name of lab performing analyses; scale— local or widespread; control measures implemented; association with international travel; therapy or containment compromise; infrastructure strain; intentional or unintentional; unusual/atypical conditions

BOX 2. ENVIRONMENTAL/FOOD CONTAMINATION OR ANIMAL INFECTIONS

PROVIDE AVAILABLE INFORMATION FOR THE FOLLOWING:

Agent/pathogen; source; vehicle/mode of dispersion; population at risk; laboratory test results and location/name of lab performing analyses; distribution of agent/product/animals; control measures implemented; scale-local or widespread; intentional or unintentional; potential for human exposure to toxic or infectious agent

The IHR Timeline

when

- **May 2005:** World Health Assembly approved revised IHR
- **December 2006:** United States accepted the revised IHR (with reservation and understandings)
- **June 15, 2007:** Initial start-date for revised IHR
- **July 18, 2007:** United States starts adherence to revised IHR
- **June 2009:** Within 2 years after IHR enters into force, Member Countries complete assessment of the ability of their national structures and resources to meet minimum core capacities*
- **2012:** Within 5 years after IHR enters into force, Member Countries achieve the required minimum level of core capacities, unless WHO grants an extension
- **2014:** End of 2-year extensions on achieving core capacity, unless an exceptional circumstance exists and a further extension is granted by WHO
- **2016:** End of final 2-year extensions (for exceptional circumstances) on achieving core capacities

*Core capacities as listed in Annex 1 of the IHR



IHR References

- WHO IHR website: <http://www.who.int/csr/ihr/en/>
- HHS Global Health website: <http://www.globalhealth.gov/ihr/>
- HHS Announcement the U.S. accepted the IHR (2005):
<http://www.hhs.gov/news/press/2006pres/20061213.html>
- CDC IHR website: <http://www.cdc.gov/cogh/ihrefregulations.htm>
- Baker MG, Fidler DP. Global public health surveillance under the new International Health Regulations. EID; July 2006, Vol. 12.
<http://www.cdc.gov/ncidod/eid/vol12no07/05-1497.htm>
- CSTE Position statement:
<http://www.cste.org/ps/2007ps/2007psfinal/id/07-id-06.pdf>
- The NNDSS notifiable diseases website:
<http://www.cdc.gov/epo/dphsi/nndsshis.htm>



International Health Regulations

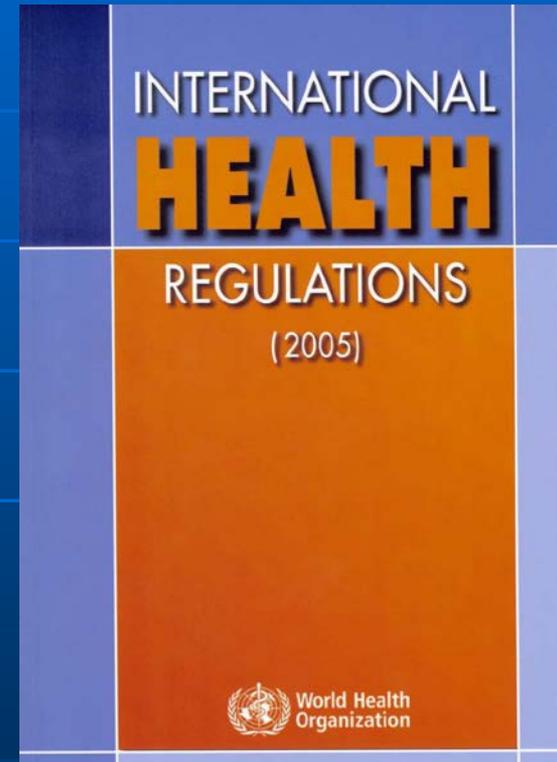
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Thank you

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