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International Health Regulations (2005)

**A brief introduction to
implementation
in national legislation**

January 2009

International Health Regulations
Coordination



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Introduction

The International Health Regulations (2005) ("IHR (2005)" or "Regulations") are the international legal instrument designed to help protect all States from the international spread of disease. The IHR (2005) entered into force on 15 June 2007. They are currently legally binding upon 194 States Parties around the world (including all WHO Member States).

This document provides a brief introduction to legislative implementation of the IHR (2005) to assist States Parties in initiating such processes. Since the scope of the IHR (2005) is very broad and cuts across a number of public health and other subject areas, it is proposed that this document be brought to the attention of officials and legal advisers within all the relevant ministries and departments, as well as other relevant authorities, at all governmental levels (including national, intermediate and local) with functions or responsibilities affected by the IHR (2005) (see Box II below).

This brief introductory document was developed by the Secretariat of the World Health Organization (WHO) in response to requests for guidance on these legal issues. More detailed guidance on legislative implementation of the IHR (2005) as well as the *International Health Regulations (2005): Areas of work for implementation* and other documents developed by the WHO Secretariat are available at www.who.int/ihr/en/.

Unless the context indicates otherwise, the term "legislation, regulations and other instruments" (at times shortened to "legislation" to avoid undue repetition) is used generally in this document to refer to the broad range of legal, administrative or other governmental instruments, whether legally binding or non-binding, and which may be available for States Parties to implement the IHR (2005). Such instruments may thus not be limited to those adopted by the legislature.

The terms "national" or "domestic" in this document refer to all the governmental levels (national, intermediate (e.g. state, provincial, regional) and local), unless otherwise indicated.

This document provides introductory guidance on the implementation of the IHR (2005) in national legislation. How the IHR requirements are to be implemented is up to each State Party in light of its own domestic legal and governance systems, socio-political contexts and policies. Each State Party should therefore determine the extent to which the different aspects of this guidance may be relevant or appropriate to their particular circumstances.

1. What are the IHR (2005)?

The IHR (2005) are the international legal instrument designed to help protect all States from the international spread of disease, including public health risks and public health emergencies.

The purpose and scope of the IHR (2005) are very broad, focusing upon almost all serious public health risks that might spread across international borders. According to Article 2, the purpose and scope of the Regulations are:

"to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade." (emphasis added)

To this end, the IHR (2005) contain rights and obligations for States Parties (and functions for WHO) concerning national and international surveillance; assessment and public health response; health measures applied by States Parties to international travellers, aircraft, ships, motor vehicles and goods; public health at international ports, airports and ground crossings (together referred to as "points of entry"); and many other subjects (see Box I below).

In light of the expansive definitions of "disease", "event", "public health risk" and other relevant terms in the IHR (2005), the coverage of the Regulations includes much more than a list of specific infectious diseases. Accordingly, the IHR (2005) cover a wide range of public health risks of potential international concern:

- whether biological, chemical or radionuclear in origin or source, and
- whether potentially transmitted by:
 - persons (e.g. SARS, influenza, polio, Ebola),
 - goods, food, animals (including zoonotic disease risks),
 - vectors (e.g. plague, yellow fever, West Nile fever), or
 - the environment (e.g. radionuclear releases, chemical spills or other contamination).

The IHR (2005) differ thus importantly from their previous 1969 version.¹ The latter were limited primarily to the notification of cases of only three diseases (cholera, plague and yellow fever) and the implementation of specified maximum measures in response to those diseases.

Box I
Organization of IHR (2005) State Party provisions by subject matter

To facilitate the identification or location of State Party provisions in the IHR (2005) on particular key subjects, the articles and annexes may be organized by subject matter in the following ten categories:

- A. **General provisions** (purpose and scope; principles; transparency, promptness and non-discriminatory implementation of health measures; general requirements) (Arts. 2, 3, 42, 44.1)
- B. **Responsible authorities including National IHR Focal Points (NFPs) and competent authorities** (in particular Arts. 4 and 22, and Annex 7.2(f))
- C. **Notification and reporting of events to WHO** (Arts. 5.1-.2, 6.1-.2, 7, 8, 9.2, 10.1-.2 and 46, and Annex 1)
- D. **Public health response** (Arts. 13.1, 13.5, and 46, and Annex 1. See also articles and annexes listed under section E below.)
- E. **Public health emergencies of international concern (PHEIC)**, temporary recommendations and related national capacities (see articles and annexes listed under sections C and D above and Arts. 10.3, 12, 13.4, 15, 17, 18, 43, 48-49, and Annex 1)
- F. **Points of entry** (international ports, airports and ground crossings) (Annex 1B, Arts. 19-23)
- G. **International goods, containers and container loading areas** (Arts. 23.1(b), 33-35, 41)
- H. **Conveyances** (international aircraft, shipping, ground vehicles) **and conveyance operators** (Arts. 23.1(b), 24-28, 35, 37-39, 41, 43, and Annexes 3-5, 8 and 9)
- I. **International travellers (persons)**: applying health measures and traveller protections (including human rights) (Arts. 3.1, 23, 30-32, 35-36, 40, 43, 45, Annexes 6 and 7)
- J. **National core capacity requirements** (surveillance, response and designated points of entry) (Arts. 5.1, 13.1, 19(a), 20.1, 21, and Annex 1)

For further detail see the IHR (2005) and the legislative reference and assessment tool developed by the WHO Secretariat (see endnote 3).

2. Which governmental functions and subject areas may be affected by IHR (2005) implementation?

The implementation of the Regulations can impact governmental functions and responsibilities across many ministries, sectors and governmental levels. For example, implementation can involve governmental or related activities at the ministerial (or higher) levels, as well as specific operational functions (such as legal provisions authorizing inspection of ships) (see Boxes II and III below).

Box II.

Subject areas affected by IHR (2005) implementation

Subject areas affected by IHR (2005) implementation include:

- environment
- public health
- international ports, airports, ground crossings (including quarantine)
- customs
- food safety
- agriculture (including animal health)
- radiation safety
- chemical safety
- transportation (including dangerous goods)
- collection, use and disclosure of public health information
- public health activities of authorities or other relevant entities at the intermediate (e.g. state, provincial or regional) and local levels.

Box III.

Selected governmental functions implementing international and national aspects of IHR (2005)

Among others, the IHR (2005) affect governmental functions concerning:

- *international* traffic, communications and collaboration including
 - legislation, regulations and other instruments;
 - activities concerning virtually all aspects of international traffic (travellers, transport and trade); and
 - international communications (e.g. reporting public health events to WHO and collaborating in assessment and response);

and

- *national* capacities and activities including
 - national legislation, regulations and other instruments;
 - development of national public health capacities for surveillance and response throughout the State territory and capacities at specific international points of entry (ports, airports, and ground crossings); and
 - coordination of public health communications and assessment across relevant ministries, departments and levels (e.g. national, state or regional, local) of government.

3. Why are national legislation, regulations and other instruments relevant for IHR (2005) implementation?

Note:
The term "legislation, regulations and other instruments" (at times shortened to "legislation") is used in this document generally to refer to the broad range of legal, administrative or other governmental instruments which may be available for States Parties to implement the IHR (2005) and which are not necessarily limited to instruments adopted by the legislature.

An adequate legal framework to support and enable all of the varied IHR (2005) State Party activities is needed in each State. In some States, giving effect to the IHR (2005) within domestic jurisdiction and national law requires that the relevant authorities adopt implementing legislation for some or all of the relevant rights and obligations for States Parties. However, even where new or revised legislation may not be explicitly required under the State Party's legal system for implementation of one or more provisions in the IHR (2005), revision of some legislation, regulations or other instruments may still be considered by the country in order to facilitate performance of IHR activities in a more efficient, effective or otherwise beneficial manner.

Additionally, from a policy perspective, implementing legislation may serve to institutionalize and strengthen the role of IHR (2005) capacities and operations within the State Party. A further potential benefit from such legislation is that it can facilitate necessary coordination among the different entities involved in implementation and help to ensure continuity.

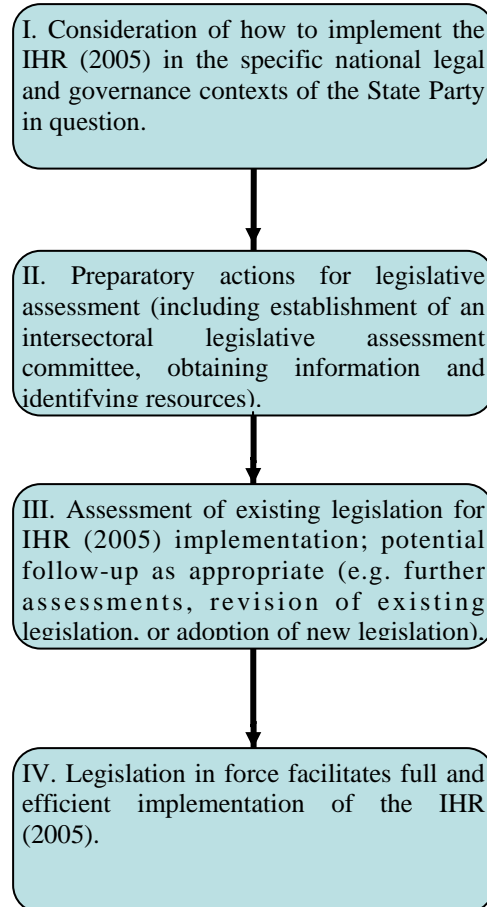
For these reasons, States Parties to the IHR (2005) should consider assessing their relevant existing legislation to determine whether they may be appropriate for revision in order to facilitate full and efficient implementation of the Regulations.²

4. How is the process of implementing the IHR (2005) in national legislation, regulations and other instruments?

As noted above, implementing the IHR (2005) in national legislation facilitates full and efficient implementation of the Regulations. An overview of the process of legislative implementation is presented in the chart below. The process usually starts with the general consideration of how the IHR (2005) are to be implemented in the legal and governance contexts of the State Party concerned. The process then continues with the assessment of existing legislation, regulations and other instruments to determine whether their revision, or adoption of new ones, is appropriate to facilitate the full and efficient implementation of the Regulations. These initial stages of the process are discussed further below in this document. For additional information on these and other aspects of legislative implementation of the Regulations consult the more detailed guidance materials developed by the WHO Secretariat.³

Chart

Overview of the process of implementing the IHR (2005) in national legislation



5. How are the IHR (2005) to be implemented within the legal and governance contexts of each State Party?

How the rights and obligations for the States Parties in the Regulations are to be implemented in each State Party is up to each State in light of its own domestic legal and governance systems, socio-political contexts and policies.

Important variables in considering legislative implementation of the IHR (2005) include:

- The manner in which each State chooses to implement its international legal obligations within its domestic legal system.
- The relevant domestic governmental structures (national, regional and/or local), constitutional arrangements, legal or regulatory systems, and socio-political environments. In particular, legal structures applicable to public health functions vary among IHR (2005) States Parties.
- The extent to which the legislation, regulations, and other instruments in various areas may (or may not) need to be adjusted to facilitate full and efficient implementation of the Regulations.

In State practice, the modalities of incorporating the IHR (2005) into national legal system include the adoption of:

1. legislation, regulations and other instruments incorporating or giving effect to the various IHR (2005) requirements in each relevant area; and/or
2. legislation mandating the automatic applicability of the IHR (2005) within the national legal system. Such legislation may, for example, simply state that the IHR (2005) must be complied with and potentially annex the text of the Regulations or incorporate them by reference.

6. How may an assessment of national legislation, regulations and other instruments for IHR (2005) purposes be conducted?

Suggested preparatory actions:

- Consider establishing an intersectoral committee for legislative assessment that represents all the sectors which may be affected by IHR (2005) implementation (see Box II above). Distribute the legislative reference and assessment tool and relevant guidance materials developed by WHO Secretariat to the committee members.⁴
- Obtain information on national legislation, regulations and other instruments, requirements and practices.
- Identify and mobilize, if needed, technical, governmental, financial, personnel or other resources.
- Contact other States Parties to the IHR (2005) that are preparing, or have recently successfully conducted, legislative assessment or reform for IHR (2005) implementation, for collaboration.
- Consult the relevant guidance materials developed by the WHO Secretariat, in particular the Toolkits for implementation in national legislation.⁵

Key legislative assessment tasks:

- Identify all legislative subjects and operational functions at all governmental levels relevant for your State Party to implement the IHR (2005).
- Identify all existing domestic legislation, regulations and other instruments relevant to each of the subject areas and functions covered under the IHR (2005). This includes any legislation adopted to implement the prior IHR (1969), as amended, keeping in mind the broader scope and other differences in this 2005 version.
- Specify any legislation, regulations and other instruments which may potentially interfere or conflict with full or efficient IHR (2005) implementation.
- Specify any necessary enabling or authorizing legislation which may be relevant for the State Party to exercise rights or fulfil obligations.
- With regard to these tasks, pay particular attention to:

Note:
The term "legislation, regulations and other instruments" (at times shortened to "legislation") is used in this document generally to refer to the broad range of legal, administrative or other governmental instruments which may be available for States Parties to implement the IHR (2005) and which are not necessarily limited to instruments adopted by the legislature.

- the priority subject areas for implementation indicated in Box IV below;
 - the mandatory IHR (2005) requirements (provisions that use the term "shall"); and
 - the rights and obligations in the IHR (2005) particularly relevant to your State's individual context, including public health infrastructure and priorities; trade, transport and travel profile; and economic and geographical characteristics.
- Cross reference other WHO guidance documents on the Regulations.⁶
 - Keep a written record of the results of the assessment.
 - Agree on follow-up action when revision of existing legislation, regulations and/or other instruments, or adoption of new ones, is considered appropriate.

Box IV

Selected priority subject areas for IHR (2005) implementation

- National IHR Focal Points: designation and operation
- Detection, reporting, verification, and control of events, as well as related communications, domestically and internationally
- Communication and collaboration with WHO
- Implementation of IHR (2005) documents:
 - Ship Sanitation Certificate (Annex 3)
 - International Certificate of Vaccination and Prophylaxis (Annex 6)
 - Maritime Declaration of Health (Annex 8)
 - Health Part of Aircraft General Declaration (Annex 9)
- Designation of Points of Entry (ports, airports and ground crossings) for development of core public health capacities
- Identification (and informing WHO) of ports authorized to issue Ship Sanitation Certificates and provide related services

Further information and guidance

- *International Health Regulations (2005)*. Second edition, Geneva, World Health Organization, 2008, available at http://www.who.int/ihr/IHR_2005_en.pdf.
- *International Health Regulations (2005). Toolkit for implementation in national legislation. Questions and answers, legislative reference and assessment tool and examples of national legislation*. Geneva, World Health Organization, January 2009, available at <http://www.who.int/ihr/en/>.
- *International Health Regulations (2005). Toolkit for implementation in national legislation. The National IHR Focal Point*. Geneva, World Health Organization, January 2009, available at <http://www.who.int/ihr/en/>.
- Examples of national legislation, regulations and other instruments adopted by States Parties to the IHR (2005) and which refer to the Regulations, are summarized and published in the WHO International Digest of Health Legislation (IDHL), available at www.who.int/legislation. (search by keyword "IHR"). States Parties may find such examples of interest when assessing or revising their legislation.
- See, in general, the IHR (2005) dedicated webpage www.who.int/ihr/en/ which contains information and guidance documents on legal and technical aspects of IHR (2005) implementation, among other subjects.

¹ *International Health Regulations (1969), as amended in 1973 and 1981*. Third annotated edition. WHO: Geneva 1983, available at <http://whqlibdoc.who.int/publications/1983/9241580070.pdf>.

² At the same time, it is important to bear in mind that each State Party has been responsible for complying fully with the IHR (2005) since they entered into force in 2007, irrespective of how the Regulations may or may not have been specifically incorporated into its national legal order. There is no requirement in the IHR (2005) that States Parties must adopt or revise domestic legislation relating to the Regulations, provided that they comply with their obligations thereunder.

³ See, in particular, *International Health Regulations (2005). Toolkit for implementation in national legislation. Questions and answers, legislative reference and assessment tool and examples of national legislation*, WHO: Geneva January 2009, available at <http://www.who.int/ihr/en/>.

⁴ *Ibid.*

⁵ *Ibid.*

⁶ See guidance documents available at www.who.int/ihr/, or at applicable WHO Regional Office websites.