

## Part I: Questions and answers on implementation of the IHR (2005) in national legislation, regulations and other instruments

### I.1 What are the IHR (2005)?

The IHR (2005)<sup>3</sup> 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.<sup>4</sup>

The initial WHO International Sanitary Regulations of 1951<sup>5</sup> were revised and renamed the International Health Regulations in 1969.<sup>6</sup> In response to the increased and changing risks of international transmission of disease, the Regulations were substantially revised over a 10-year process ending in 2005. The revised Regulations were adopted by the WHO Member States at the 58<sup>th</sup> World Health Assembly on 23 May 2005.<sup>7</sup> In accordance with the Constitution of WHO, the Regulations entered into force on 15 June 2007<sup>8</sup> and are currently legally binding upon 194 States Parties around the world (including all WHO Member States).<sup>9</sup>

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)

---

<sup>3</sup> *International Health Regulations (2005)*. Second edition, WHO: Geneva 2008, available at [http://www.who.int/ihr/IHR\\_2005\\_en.pdf](http://www.who.int/ihr/IHR_2005_en.pdf).

<sup>4</sup> See, in general, [www.who.int/ihr/en/](http://www.who.int/ihr/en/).

<sup>5</sup> *International Sanitary Regulations*, adopted on 25 May 1951, reproduced in *World Health Organization Technical Reports Series* No. 41. WHO: Geneva, July 1951, available at [http://whqlibdoc.who.int/trs/WHO\\_TRS\\_41.pdf](http://whqlibdoc.who.int/trs/WHO_TRS_41.pdf).

<sup>6</sup> *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>.

<sup>7</sup> WHA58.3, adopted on 23 May 2005, available at [www.who.int/gb/ebwha/pdf\\_files/WHA58/WHA58\\_3-en.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA58/WHA58_3-en.pdf). See also Art. 21(a) of the WHO Constitution, reproduced in *Basic Documents*, Fifty-sixth ed., WHO: Geneva 2007, p. 1, available at <http://www.who.int/gb/bd>.

<sup>8</sup> According to Article 22 of the WHO Constitution, Regulations adopted by the Health Assembly "shall come into force for all Members after due notice has been given of their adoption by the Health Assembly except for such Members as may notify the Director-General of rejection or reservations within the period stated in the notice." *Ibid.*, Art. 22.

<sup>9</sup> A list of the States Parties to the IHR (2005) and related information is available at [http://www.who.int/ihr/states\\_parties/en/index.html](http://www.who.int/ihr/states_parties/en/index.html).

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.

In light of the expansive definitions of "disease", "event", "public health risk"<sup>10</sup> 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).

Given the comprehensive scope of the IHR (2005), the range of national legal and administrative regimes which may be affected by the provisions in the IHR (2005) is similarly broad (see Box I below).

---

<sup>10</sup> IHR (2005) definitions of "disease", "event" and "public health risk":

"disease" means an illness or medical condition, irrespective of origin or source, that presents or could present significant harm to humans;  
"event" means a manifestation of disease or an occurrence that creates a potential for disease;  
"public health risk" means a likelihood of an event that may affect adversely the health of human populations, with an emphasis on one which may spread internationally or may present a serious and direct danger (IHR (2005), Art. 1.1).

See also Table II of this document reproducing selected key IHR (2005) definitions.

Box I.

**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, regional, local) of government.

## I.2 Why are national legislation, regulations and other instruments relevant for IHR (2005) implementation?

The IHR (2005) are legally binding on virtually all (i.e. 194) States worldwide, and impact governmental functions and responsibilities across many ministries, sectors and governmental levels. They also can involve governmental activities at the ministerial (or higher) levels, as well as very specific operational functions (such as legal provisions authorizing inspection of ships). Accordingly, there needs to be an adequate legal framework to support and enable all of these varied activities within all States Parties.

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, such legislation may also 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 governmental and non-governmental entities involved in implementation and help to ensure continuity.<sup>11</sup>

For these reasons, States Parties to the IHR (2005) should consider assessing their relevant existing legislation, regulations and other instruments to determine whether they may be appropriate for revision in order to facilitate full and efficient implementation of the Regulations. Since 2005, resolutions of the World Health Assembly (WHA) have emphasized the need to make legislative and administrative assessments to implement the Regulations.<sup>12</sup> The IHR (2005) themselves expressly require States Parties to collaborate with each other in developing national legal, regulatory and administrative provisions for implementation of the IHR (2005).<sup>13</sup>

---

<sup>11</sup> On these issues, see e.g. *Tools for advancing tobacco control in the 21<sup>st</sup> century: Tobacco control legislation: an introductory guide*, WHO: Geneva 2004, p. 49, available at [www.who.int/tobacco/research/legislation/tobacco\\_cont\\_leg/en/index.html](http://www.who.int/tobacco/research/legislation/tobacco_cont_leg/en/index.html). On legislation issues generally, see other references in the Appendix: Selected secondary sources on drafting, revising and implementing public health legislation, at the end of this document.

<sup>12</sup> WHA58.3, operative paragraph 5(4), available at [www.who.int/gb/ebwha/pdf\\_files/WHA58/WHA58\\_3-en.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA58/WHA58_3-en.pdf), and WHA59.2, operative paragraph 4(11), available at [http://www.who.int/gb/ebwha/pdf\\_files/WHA59/WHA59\\_2-en.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA59/WHA59_2-en.pdf).

<sup>13</sup> IHR (2005), Art. 44.1(d).

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 explicitly 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.

### **I.3 How are the IHR (2005) to be implemented within the legal and governance contexts of each State Party?**

While the IHR (2005) mandate the rights and obligations for States Parties, *how* these 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.

In many countries, different public health risks (e.g. infectious disease, food safety, risks of chemical accidents or contamination, radionuclear safety, animal health issues which may affect humans) are addressed in different laws or regulations, and often by different ministries, departments and governmental levels. All of these risks (and others) are covered by the obligations of the IHR (2005) depending upon the specific circumstances. Hence, a multiplicity of different ministries, departments and governmental levels should be part of any assessment and possible revision process of legislation, regulations and other instruments.

In considering the roles that national legal, administrative and policy environments can play in how each State Party arranges and incorporates IHR (2005) provisions into its legal rules and governmental structure, important variables 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 and sub-national (e.g. state, provincial, regional, 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 (see examples in Part III below); 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 (see examples in Part III below).

The manner in which this may be done will depend upon the particular legal system. Additional implementing legislation may need to be adopted if specific IHR (2005) provisions cannot be otherwise directly applied within the national legal system.

In addition, even where the IHR (2005) are incorporated in whole or in part by reference (or other similar legislation is adopted), States are also likely to need to consider adopting more specific regulations or other administrative instruments in order to carry out operationally the particular IHR (2005) requirements in the context of the State's unique circumstances.

Box II below provides a summary overview of legislation, regulations and other instruments to assist in choosing the appropriate type of instrument among the range of legal or other governmental instruments which may be available depending upon the specific context.

## Box II

### Summary overview of legislation, regulations and other types of instruments

One of the challenges in evaluating approaches to revision of national legislation, regulations and other instruments in the context of the IHR (2005) implementation is choosing the appropriate type of instrument among the range of governmental instruments which may be available depending upon the specific purpose and legal/governmental contexts of the State concerned.

These various instruments can vary widely as to:

- their legal nature (legally binding vs. non-legally binding);
- the procedural or other formalities they require to be enacted;
- the officials or bodies which can adopt or issue them;
- their potential effectiveness or enforceability; and
- their applicability for the different types of legal requirements implicated in the IHR (2005) (e.g. high-level legislation, specific administrative or regulatory requirements, or guidelines and standards).

In general, these instruments can be divided into the following categories:

*Legally binding instruments*, which often include constitutions, legislation, decrees, acts, orders, ordinances and regulations. This category may include *emergency* legislation or instruments, which can often be faster to adopt than standard legislation but may be of limited duration or application.

*Legally non-binding instruments*, which often include guidelines, standards, operating rules, or other non-binding administrative procedures or rules. These can be faster to adopt and revise than legally binding instruments and are therefore often considered more flexible. Depending on the context, non-binding instruments may be less authoritative than legally binding instruments.

*Other types of instruments*, which may include those not clearly in either above category, such as governmental actions in the nature of protocols or committee resolutions; and inter-sectoral, interministerial or inter-governmental agreements (i.e. agreements between or among national, state or provincial, and/or local authorities).

Importantly, these categorizations are highly variable, depending upon the particular context and legal system of the State Party.

## I.4 How do the IHR (2005) provisions differ by their legal nature?

For implementation of the IHR (2005), it is important to understand the legal nature of provisions in the Regulations. Many (but not all) State Party provisions generally fall into one of three categories:

- (1) legally binding obligations (using the word "shall"),
- (2) authoritative advice agreed by States Parties concerning appropriate actions under the IHR (using the word "should"), and
- (3) provisions indicating discretion or authorization of States Parties to take certain steps under the Regulations (using the word "may").<sup>14</sup>

Table I

**Selected terms concerning the legal nature of IHR (2005) provisions: "shall", "should", "may"**

Nature	Term	Explanation	Example
<b>(1) Legally binding obligations</b>	<i>shall</i> <i>shall</i> <i>not</i>	The word "shall" is used for legally binding obligations, i.e., to indicate mandatory requirements set out in the Regulations (such as affirmative obligations and prohibitions).	"Each State Party <b>shall</b> assess events occurring within its territory..." (Art. 6.1)  "Such measures <b>shall not</b> be more restrictive of international traffic and not more invasive or intrusive to persons than reasonably available alternatives..." (Art. 43.1)
<b>(2) Authoritative advice</b>	<i>should</i>	The word "should" is used in provisions where the States Parties have agreed on appropriate actions for their consideration in certain circumstances.	"States Parties sharing common borders <b>should</b> consider..." (Art. 21.2)
<b>(3) Discretion or authorization</b>	<i>may</i>	The word "may" is used where the aim is to indicate discretion or potentially an authorization.	"Where justified for public health reasons, a State Party <b>may</b> designate ground crossings..." (Art. 21.1)

<sup>14</sup> The ultimate determination of the legal nature or meaning of these and other provisions in the Regulations requires consideration of the entire text of these provisions, other content of the IHR (2005), the context and other relevant factors.