

User's guide

The *International Health Regulations (2005) - Toolkit for implementation in national legislation* was developed by the Secretariat of the World Health Organization (WHO) in response to requests for guidance on these legal issues. This toolkit complements other related legal guidance documents on legislative implementation of the International Health Regulations (2005) ("IHR (2005)" or "Regulations"), as well as the *International Health Regulations (2005): Areas of work for implementation* and other guidance developed by the WHO Secretariat to assist States Parties with the IHR (2005) implementation process.

In addition, other guidance documents on technical aspects of implementation are in preparation and will be available concerning development of national core public health capacities in surveillance and response (Annex 1A); ports, airports and ground crossings (Annex 1B); ship sanitation certification (Annex 3); and national public health laboratory capacities.¹

Unless the context indicates otherwise, the term "legislation, regulations and other instruments" (at times shortened to "legislation") is used generally in this document 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). Such instruments may thus not be limited to those adopted by the legislature. More specifically, the term "legislation, regulations and other instruments" used in this document should be understood to include:

- *legally-binding instruments*, including constitutions, legislation, decrees, acts, orders, ordinances, and regulations;
- *legally non-binding instruments*, which may include guidelines, standards, operating rules, or other non-binding administrative procedures or rules; and
- *other types of instruments*, which may not fall clearly in either above-mentioned category, such as governmental protocols, committee resolutions or other similar actions; and inter-sectoral, interdepartmental, interministerial, or intergovernmental agreements (i.e. agreements between or among national and sub-national (e.g. state, provincial, regional and local) authorities).

Note that the above descriptions and categories, and their relevant characteristics, will vary substantially among States Parties depending upon the particular governmental, legislative, administrative, and socio-political contexts.

The terms "national" or "domestic" in this document refer to *all* the above-mentioned governmental levels (national and sub-national (e.g. state, provincial, regional and local)), unless otherwise specified.

¹ See at <http://www.who.int/ihr/en/>.

This toolkit consists of three parts:

- Part I provides States Parties with guidance on key questions on legislative implementation of the IHR (2005), including the role of national legislation, regulations and other instruments in the implementation of the State Party provisions in the IHR (2005).
- Part II discusses legislative assessment and potential follow-up actions. It provides a legislative reference and assessment tool for evaluation of the State Party's existing legislation, regulations and other instruments against the specific rights and obligations for States Parties to carry out under the IHR (2005). This part will also help States Parties determine whether revisions may be appropriate to facilitate full and efficient implementation of the Regulations.
- Part III contains a compilation of examples of national legislation, regulations and other instruments adopted by States Parties which refer to the Regulations.

The scope of the IHR (2005) is very broad and cuts across a number of public health and legal subject areas.² It is therefore proposed that this document be brought to the attention of officials and legal or legislative advisers within all ministries and departments, as well as other relevant authorities, with functions or responsibilities involving the following and other relevant subject areas:

- public health
- environment
- 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 health-related information
- public health related activities of authorities or other relevant entities at the sub-national (e.g. state, provincial, regional, local) levels.

This toolkit provides guidance on the implementation of the IHR (2005) in national legislation. How the 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 toolkit, including examples of national legislation, regulations and other instruments adopted by States Parties, may be relevant or appropriate to their particular circumstances.

² See section I.1 below.