

WORLD HEALTH ORGANIZATION
Regional Office for the Eastern Mediterranean
ORGANISATION MONDIALE DE LA SANTE
Bureau régional de la Méditerranée orientale



مَنْظَرُ الصِّحَّةِ الْعَالَمِيَّةِ
المكتب الإقليمي شرق المتوسط

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**International Health Regulations—update on the
revised version**

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1. Introduction

International travel and trade are major factors in the international spread of infectious diseases. People and goods are crossing national borders in massive numbers, unparalleled in human history. While some countries may still opt for extreme protectionism, agents of diseases never respect borders and importation of diseases is always difficult to prevent. Prevention of international spread of infectious diseases has been addressed through a multilateral initiative by countries to provide a legally binding set of regulations and code of measures that harmonize the protection of public health without unnecessary disruption of trade and travel.

The need for such regulations was translated into action at the first International Sanitary Conference in 1851. This conference came in response to the epidemics of cholera that overran Europe between 1830 and 1847. The International Sanitary Conference in 1892 adopted the International Sanitary Convention, which was restricted to cholera. In 1897, another International Sanitary Convention, dealing with preventive measures against plague was adopted. However, these conventions never came into force, as the multilateral institutions necessary to enforce them did not exist. Subsequently, the International Sanitary Bureau in Washington, for the American States and L'Office International d'Hygiène Publique (International Bureau of Public Health), in Paris, for the European States, and the Health Office of the League of Nations in Geneva, were established independently of each other, and enforced conventions and agreements within their respective areas.

Following the establishment of the World Health Organization (WHO) and enactment of the WHO Constitution in 1948, in 1951 Member States adopted the International Sanitary Regulations which were renamed the International Health Regulations in 1969. These regulations were slightly modified in 1973 and 1981. The current International Health Regulations reflect this long history of application, change and modification of the various conventions, recommendations and regulations put in place over more than 15 decades. Both the current International Health Regulations and the previous International Sanitary Regulations have, for more than 50 years, provided WHO Member States and the transportation industry with a regulatory framework to support public health security by preventing the international spread of human diseases that can be carried by aircraft, ships and ground transport in the form of infected passengers or crew, insects, rodents or contaminated cargo or goods.

The objective of the International Health Regulations is to harmonize public health, trade, and the movement of people, animals, and goods, and today it remains the only compulsory set of regulations for global surveillance of infectious diseases by the Member States of WHO. The International Health Regulations comprise the only internationally binding legislation on the reporting of epidemics. They are intended to ensure maximum protection against the international spread of diseases with minimum interference with world traffic, and constituted the first multilateral initiative to develop an effective framework for preventing the trans-border transmission of disease.

2. Shortcomings in the current International Health Regulations

Constant worldwide increase in population movements, changes in methods of food processing, growth in international trade, and the continuous emergence of serious pathogens mean that the appearance of an infectious disease in one country poses potential concern to the whole world. In recent years the current International Health Regulations, as a global tool for public health protection, have been shown to have shortcomings. The major weaknesses can be attributed to the limited scope of the regulations, their dependence on passive country notification, the lack of mechanisms for collaboration between countries in preventing disease spread and the lack of power of the regulations. The current International Health Regulations require the reporting of cholera, plague and yellow fever only. This not only stigmatizes those diseases but does not provide for the emergence of new infectious diseases, such as severe acute respiratory syndrome (SARS) which afflicted the world in 2003. Moreover, the current International Health Regulations entirely depend on the affected country to make an official notification to WHO, without consideration of other sources of information. This is no longer appropriate given the revolution in information technology, and could cause delay in disease identification and international response. At present, there is little in the regulations to foster

collaboration between WHO and a country in which an infectious disease with a potential for international spread is occurring. It is also worth mentioning that the present International Health Regulations lack power and effective incentives to encourage compliance by Member States. Within the current regulations, WHO lacks the capacity to proscribe reactions that extend far beyond the measures necessary from a public health point of view. In the meantime, many countries are reluctant to report outbreaks for fear of the economic repercussions in the form of trade and travel embargos.

3. What should be addressed by the new regulations?

The proposed revised version of the International Health Regulations needs to address all public health risks that could threaten the international community, taking into consideration emerging diseases. They need to ensure immediate availability of information through mandatory, immediate reporting of health risks of international concern by the affected countries, as well as the use of sources of information other than official notification by the country. The revised International Health Regulations must emphasize the need for stronger national, regional and international capacity for surveillance and response, and for national surveillance systems that are sensitive enough to detect new or re-emerging risks. There is demand for a mechanism for collaboration between WHO and the affected Member State to ensure immediate action and international support, when needed. There is also demand for a mechanism for protecting the international community from the spread of diseases, while protecting the notifying countries from unnecessary reactions.

Based on experience gained from the operation of WHO's Global Outbreak Alert and Response Network (GOARN), it was proposed that the revision of the International Health Regulations should cover the following two main areas: maintenance of a reliable system to prevent the extension of public health risks through the application of updated and broader routine public health measures for transport of persons and goods; and reporting of any potential public health emergency (by both countries and the WHO network) and evaluation of the information in collaboration with the Member State concerned to establish whether it is of urgent international importance and, if this is the case, ensuring that appropriate international public health measures are recommended by WHO.

4. The revision process

In order to deal with the threat posed by the substantial increase in international travel and the potential for the rapid spread of infectious diseases, especially through air transport, in 1995 the World Health Assembly adopted resolution WHA48.7 on the Revision and updating of the International Health Regulations, requesting revision of the regulations. In 2001, the Health Assembly adopted resolution WHA54.14 on Global health security: epidemic alert and response, which linked the revision of the regulations to WHO activities in identifying, verifying and responding to health emergencies of international concern. In 2002, the principles and key changes were identified and consulted upon and the Health Assembly again reiterated the need to revise the regulations in WHA55.16. In 2003, resolution WHA56.28 urged Member States to give high priority to the work on the revision of the International Health Regulations and to provide resources and cooperation necessary to facilitate the progress of such work. In 2004 began the process of global consultation with all Member States through the regional offices. This process has now been completed and a final draft will be presented to the Inter-governmental Working Group in Geneva in November 2004. The final draft will be presented to the World Health Assembly in 2005 for adoption by the Member States.

Revision of the International Health Regulations was undertaken in close collaboration with other key stakeholders: the International Civil Aviation Organization (ICAO), the International Maritime Organization (IMO), and industry associations like the International Air Transport Association (IATA), the Airports Council International (ACI) and the International Shipping Federation (ISF), since the Regulations have an impact on their operations.

The approach to the revision was grounded in three specific principles: to ensure that all risks to public health that are of international importance, including but not limited to infectious diseases, are reported as stipulated in the regulations; to prevent stigmatization, unnecessary harm to travel and

trade, and unfounded reports from sources that are not the official sources of the Member States, which can have serious economic repercussions for the countries; and to ensure that the system is sensitive enough to detect new or re-emerging public health events.

5. Main changes in the revised International Health Regulations

In the proposed revision of the International Health Regulations, notification will no longer be limited to a known list of diseases. There will be a requirement to notify WHO of “public health emergencies of international concern”, which refers to events identified according to certain criteria: seriousness, unexpectedness and potential for international spread. For the International Health Regulations to be effective, Member States should agree on a consensus definition of public health to avoid any variation or ambiguity in the interpretation of the concept “public health”. It is worth mentioning that in 2003 the Regional Committee for the Eastern Mediterranean in resolution EM/RC50/R.2 endorsed the following definition of public health: “The science and art of promoting, protecting and/or restoring the physical, mental and social well-being of the people through prophylactic, diagnostic, therapeutic and rehabilitative measures, applied to human beings and their environment”.

An important change proposed for the International Health Regulations is the addition of a “real-time” process for dealing with international public health emergencies that could affect Member States and the transport industry. The revised regulations will consider information from sources other than official notification by the Member States. In order to implement the revised International Health Regulations, Member States will need to have core capacities for rapid detection and response in order to contain disease events or public health risks, prevent potential spread and minimize the need for international control measures.

6. The review process in the Eastern Mediterranean Region

The Regional Office for the Eastern Mediterranean held two regional consultation meetings on the International Health Regulations. The first was held for high level officials of ministries of health in Cairo, Egypt (1–3 March 2004). The objectives were: to introduce the proposed revised version of the International Health Regulations; to increase awareness of the proposed revision of the regulations and associated documents in all Member States; to discuss the sensitive issues that might be raised in relation to the proposed revised regulations; and to develop national plans for developing national consensus on the proposed revised regulations. The meeting was followed by national workshops in Member States which were attended by representatives of ministries of health and other key sectors in the respective countries. The national consensus of Member States was presented at the second regional consultation held in Damascus, Syrian Arab Republic (20–22 June 2004), which was attended by national representatives, whether from ministries of health or from other key sectors, from all countries of the Region, as well as staff from the Regional Office and WHO headquarters. The objectives of the second meeting were: to provide an opportunity for Member States to assess the areas on which broad agreement and difference of opinion existed on the proposed revised International Health Regulations; to define and agree on a process to narrow the differences in opinion on the proposed International Health Regulations and that would accommodate national consensus proposals from all Member States in the Region; to provide input to the WHO Inter-Governmental Working Group (IGWG) on the proposed revised International Health Regulations; to improve transparency of reporting of epidemic-prone and other communicable diseases; and to minimize over-reaction of countries in the Eastern Mediterranean Region to outbreaks of communicable diseases.

The two consultations discussed, *inter alia*, issues related to the scope of the regulations, the need for a list of diseases to support the decision instrument, the definition of the term “Public Health Emergency of International Concern”, the role of the national focal points, the procedures for emergency and review committees, and the relationship between the proposed revised version of the International Health Regulations and other international agreements. The interaction of the regulations with World Trade Organization Agreements, in particular the Agreement on Application of Sanitary and Phytosanitary Measures (SPS), were also discussed throughout the process. In the period between the consultations all countries in the Region except one held a series of meetings and workshops to discuss

the proposed revisions. Member States used the Arabic, English or French versions of the proposal as appropriate, each being equally authoritative. In Afghanistan, the proposed revised version of IHR was translated into *Dari*. Seven countries agreed and accepted the revised version without reservations or changes (Afghanistan, Djibouti, Morocco, Qatar, Somalia, Sudan and Tunisia). Member States raised many points regarding the Arabic translation in relation to the English version, and regarding the definitions of many key words in the revised version, and made suggestions for additions and deletions. The Arabic translation of the revised International Health Regulations has since been thoroughly revised.

Three phases of the International Health Regulations revision process were identified from the Region: enactment, enforcement and implementation. In regard to enactment, the issues identified principally related to the need to revise legislation at national level, where applicable. In regard to enforcement, issues identified included: the lack of awareness of public health emergencies of international concern; low political commitment; weak intersectoral coordination and cooperation; and the risk of trade and tourism embargo which might lower political commitment further. In regard to implementation, problems were anticipated relating to: weakness of national surveillance and response systems in the Region for communicable and noncommunicable diseases as well as for public health emergencies of international concern; inadequacy of national epidemiological services; notification of noncommunicable diseases owing to lack of case definitions; low capacity to respond promptly and to carry out necessary measures; points of entry; and lack of coordination with health authorities.

7. Challenges

The challenges encountered during the revision of the International Health Regulations were many. Implementation of the revised regulations will mean that all public health risks (including but not limited to infectious diseases) of urgent international importance, will have to be reported. This approach goes beyond notification based solely on specific diseases, although a list of diseases may be provided as a supplementary guide. There is need for mechanisms to avoid stigmatization and unnecessary negative impact on international travel and trade as a result of invalid and unreliable reporting from sources other than official sources.

International efforts will be needed to evaluate and address epidemic outbreaks and to contain them. Since 1996 WHO has sought to strengthen its global alert and response capacity by setting up a mechanism actively to collect information on reported public health risks, to verify it confidentially with Member States, and then to ensure that appropriate containment measures are taken. A great deal of information on public health risks, originating from formal laboratory and epidemiology networks and from electronic discussion groups and diverse media, has been collected through GOARN. This network aims to ensure that the best expertise is harnessed wherever and whenever it is needed, as cost-effectively as possible. GOARN provides coordinated mechanisms for epidemic alert and response to maintain global public health security. Since 1997, when the mechanism became fully operational in WHO, 745 reports have been investigated in direct collaboration with the countries concerned, and the network is being continually extended to reduce currently existing gaps in coverage, mainly in developing countries where epidemiological and laboratory capacity is being reinforced. In addition to information on public health risks, this network could also provide information on noncommunicable diseases and environmental, chemical or nuclear risks. Hence, proposals now being made within the framework of the revision of the International Health Regulations include the use of GOARN as an additional source of information on public health risks of urgent international importance together with reports from countries.

Member States need to be fully aware that the strengthening of epidemiological and laboratory surveillance and of disease control activities at national level (i.e. where the diseases occur) is the main defence against the international spread of communicable diseases. Syndromic reporting, although valuable within a national system, is not appropriate for use in the context of a regulatory framework, because syndromes cannot be linked to preset rules for control of spread. Member States will need to upgrade their capacities in the different elements of surveillance, including those of public health laboratories. Another challenge of the revised International Health Regulations concerns the

updating of the existing measures relating to the carrying out of routine environmental provisions that reduce the spread of disease. These measures essentially apply to airports and ports, and upgrading surveillance capacities in these locations should not be overlooked. Detailed guidelines for inspection of ships are being prepared.

Transparency in reporting is a major challenge, but greater transparency will prevent over-reaction of the type that has been seen in the past. As trade has often been adversely affected by the occurrence of certain public health risks, links with the World Trade Organization (WTO) Agreements will have to be studied. The issue of compensation for affected countries that comply with the International Health Regulations has been raised but the issue has not been resolved and is not within the scope of the WHO to resolve.

Although the concept of public health emergencies of international concern is good, relying solely on non-specific public health emergencies of international concern is considered insufficient and many countries requested the addition of a list of defined, known, serious communicable diseases that have the potential for creating public health emergencies of international concern. It was also suggested that the list be reviewed periodically.

The scope and role of national focal points for the International Health Regulations are subject to interpretation in the proposed revision. The role expected of the national focal point needs further clarification.

Systematic collection by national health authorities of all outbreak information, from both formal and informal sources, is essential. However, it may create difficulties in distinguishing credible reports from rumour. Similarly, utilization of sources other than official notification systems will require mechanisms for verifying the accuracy of information.

The rights of individuals in complying with visa requirements is also a challenge to be resolved. Health authorities in some countries may demand vaccination or prophylactic treatment for unvaccinated visitors as a requirement for issuing an entry visa. There is need to clarify internationally acceptable procedures in the case of a traveller at risk who refuses vaccination or prophylaxis at the entry point of a destination country.

8. Final stage

An Inter-Governmental Working Group, open to all Member States, will meet in Geneva in November 2004 to review and recommend a draft revision of the International Health Regulations for consideration by the World Health Assembly. The draft revised regulations should be adopted by the 58th World Health Assembly in 2005. Member States should give high priority to the work on the revision of the International Health Regulations and provide the resources and cooperation necessary to facilitate the progress of such work.

9. International Health Regulations revision process retrospective summary

May 1995	World Health Assembly passes resolution WHA48.7 requesting the revision of the International Health Regulations
December 1995	Meeting of international experts decides to pursue syndrome notification, to try and capture all important disease events
1996–1997	Informal Working Group of internal and external experts established. The group recommends the use of disease syndromes and to continue existing public health requirements in the 1969 version of the International Health Regulations
October 1997	Initiation of Syndrome Notification Pilot Study in 21 countries selected by WHO regional offices
January 1998	Preliminary International Health Regulations draft distributed to Member States for review and comment
May 1998	Progress report to the World Health Assembly
November 1998	Meeting of the Committee on International Surveillance of Communicable Diseases (CISCD)
January 1999	Small working group meets to analyse outcome of CISCD meeting and propose future changes
March 1999	Syndrome Notification Pilot Study terminated
August 1999	International Health Regulations revision team strengthened New concepts elaborated and developed 21 meetings held with collaborating Member States Electronic virtual discussion forum initiated with participants from some 70 Member States Collaboration with relevant international agencies pursued International Health Regulations policy paper discussed by WHO cabinet Synergy between the International Health Regulations and Agreement on Application of Sanitary and Phytosanitary Measures explored
November 2000	Report by the Secretariat to the 107th Session of the Executive Board on Global Health Security: epidemic alert and response requesting the Executive Board to support the continuing work on the revision of the International Health Regulations
April 2001	Report by the Secretariat to the 54th World Health Assembly on Global health security: epidemic alert and response, inviting the Health Assembly to adopt resolution EB107.R13
2001	Resolution WHA54.14 on Global health security: epidemic alert and response is adopted by the Health Assembly expressing its support for the ongoing revision process and urging Members States to designate focal points for the International Health Regulations. Through WHA54.14 the Health Assembly links the International Health Regulations to global health security, notification of public health emergencies of international concern and national focal points
2002	Principles and key changes identified and consulted upon. Resolution WHA55.16 Global public health response to natural occurrence, accidental release or deliberate use of biological and chemical agents or radionuclear material that affect health

- 2003 Report to Executive Board and establishment of procedures for finalization, preliminary (non-regulatory) draft, first regulatory draft; World Health Assembly adopts Executive Board resolution
- 2003–2004 Global consultation and regional consultation meetings
- 2004 Inter-Governmental Working Group meets to discuss final draft for submission to World Health Assembly in 2005

Annex 1

Recommendations of the first regional consultation on the International Health Regulations

Introduction of the revised International Health Regulations

Cairo, Egypt, 1–3 March 2004

Focal persons

1. The participants of the current meeting should serve as the National Focal Points for their respective countries throughout the initiation process, which continues until June 22, 2004.
2. All Member States should officially notify the WHO, Eastern Mediterranean Regional Office (EMRO) with the official nominations of at least two focal persons for the implementation phase.
3. Countries should notify WHO/EMRO of the full contact numbers for the appointed focal persons.
4. Countries should notify WHO/EMRO of any changes in naming or contact numbers of the focal persons.
5. Each country's focal point should submit to EMRO monthly progress reports on the Plan of Action to be used for the review process of the proposed revision of the International Health Regulations.

Translation of International Health Regulations (IHR)

6. WHO/EMRO should revise the Arabic translation of the proposed revision of the International Health Regulations.
7. The revision of the translation should be done within the Region.
8. The revision should be completed and mailed to all Member States as soon as possible.

Support to Member States

9. EMRO should support the review process of the proposed revised International Health Regulations in Member States by:
 - a) sending a letter to the Minister of Health in all Member States from the Regional Director, EMRO, to support the review process;
 - b) sending a letter to the WHO Representatives in the Eastern Mediterranean Region to brief them about the importance of the review process and request their inputs to facilitate the review process within countries;
 - c) immediately recruiting a full time qualified officer (Short-term professional) to support the review process at the regional level;
 - d) promptly replying to all enquiries raised by the focal persons in Member States;
 - e) procuring appropriate funds to enhance the review process within countries;
 - f) making all technical documents and guidelines related to International Health Regulations available to ministries of health, other ministries and other related agencies as requested by the focal person for the respective Member State.

Capacity-building for the revised International Health Regulations

10. WHO/EMRO should assist in needs assessment and capacity-building for surveillance activities within countries.
11. WHO/EMRO should organize training workshops for training of trainers for surveillance and response officers working at points of entry, borders, etc. and assist in rehabilitating inadequately functioning units within countries.

12. The International Health Regulations should be implemented in phases and countries need to define needs for capacity-building accordingly.
13. Member States should retain trained persons whenever possible in the right position.

Implementation of the revised International Health Regulations

14. The revised International Health Regulations should be implemented in three phases:
 - a) enactment, as implementation of the current International Health Regulations is non-existent in some countries;
 - b) enforcement to combat lack of awareness of Public Health Emergencies of International Concern, low political commitment and weak international collaboration; and
 - c) implementation of activities “to ensure a maximum security against the international spread of diseases with a minimum of interference with world traffic”.

Annex 2

Recommendations of the second regional consultation on the International Health Regulations

Damascus, Syrian Arab Republic, 20–22 June 2004

WHO

The International Health Regulations review process

1. WHO Regional Office for the Eastern Mediterranean (EMRO) should finalize compilation of the summary report on the national consensus meetings in the Eastern Mediterranean Region on the proposed revised version of the International Health Regulations (IHR) based on the reports received from the Member States of the Region and send it to headquarters.
2. EMRO should provide countries with updates and developments on the review process as they occur throughout the review process.
3. WHO should take into consideration during the revision of the International Health Regulations all the comments from the Eastern Mediterranean Region.

Scope and the objectives of the Regulations

4. The scope and the objectives of International Health Regulations should be further elaborated and clearly stated.
5. The relationship should be identified and clearly stated between the International Health Regulations and other international regulations, e.g. regulations of the International Civil Aviation Organization (ICAO), the International Maritime Organization (IMO), and industry associations like the International Air Transport Association (IATA), the Airports Council International (ACI) and the International Shipping Federation (ISF) and other international organizations, Codex Alimentarius Commission, International Office of Epizootics (OIE), World Trade Organization (WTO) etc.
6. The revised International Health Regulations should include easy reference to articles in other international regulations that relate to respective articles of the Regulations.

List of notifiable communicable diseases

7. A list of notifiable communicable diseases of international concern should be incorporated in the International Health Regulations in defining public health emergencies of international concern (PHEIC).
8. The decision on the number and diseases to be listed should be based on the recommendations of a Global Technical Committee (GTC).
9. The list of diseases should be reviewed, updated or modified periodically by the GTC as needed.

Implementation process

10. There should be provision for progressive implementation of the recommended core capacity requirements for surveillance and response (Annex 1 of the International Health Regulations).
11. WHO should develop clear terms of reference for the national focal points and clearly define the relationship between the focal points and WHO.

Response to public health emergencies of international concern (PHEIC)

12. WHO should ensure good geographical representation of Member States in all global technical committees related to the International Health Regulations formed by the Director-General of WHO.
13. Committees should always include representatives from the affected countries.
14. WHO should develop clear guidelines on methods of verification of unofficial sources of information.
15. WHO should always contact Member States before public release of information.
16. WHO should identify regional and other international reference laboratories, e.g. WHO collaborating centres.
17. WHO should facilitate shipment of biological specimens to appropriate laboratories through good coordination with the International Air Transport Association (IATA).

Funding for implementation of the International Health Regulations

18. WHO should identify additional funds or funding sources to:
 - enable Member States to fulfil their obligations during the implementation of the International Health Regulations;
 - support national programmes in capacity building, epidemiological surveillance of communicable diseases of international concern, and laboratory and environmental surveillance.

Compensations

19. WHO, in collaboration with the United Nations, should consider means to compensate countries affected by excessive measures exercised by other Member States as a result of those countries' transparency and collaboration with WHO.
20. WHO should support countries in efforts to overcome the difficulties attributed to excessive measures exercised by other Member States.

Capacity-building

21. WHO should organize training courses for:
 - National focal points for the International Health Regulations
 - national staff at ports of entry associated with IHR implementation
 - trainers in surveillance
22. Develop guidelines, indicators and other technical material to:
 - strengthen programmes on surveillance of communicable diseases and PHEIC
 - develop clear and better guidelines for inspection of aeroplanes, ships, containers etc.
23. WHO should support establishment of field epidemiology training programmes (FETP) in high priority countries in the Region.
24. EMRO should create a Regional Rapid Response Team to support Member States within the Region during major outbreaks or PHEIC.



WORLD HEALTH ORGANIZATION

INTERGOVERNMENTAL WORKING
GROUP ON THE REVISION OF THE
INTERNATIONAL HEALTH REGULATIONS

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International Health Regulations

Working paper for regional consultations

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Member States

National commitment

25. Member States should send full reports on the review process to EMRO as soon as possible.
26. Health authorities in Member States should harmonize activities with other ministries and agencies at the national level.
27. Member States should ensure that there is no contradiction between the International Health Regulations and their national regulations.
28. Member States should support sharing of information, transparency and networking in surveillance activities.

Capacity-building

29. Member States should develop preparedness plans that include various components of response.
30. Member States should allocate more resources for capacity-building and consider the local needs both qualitatively and quantitatively.