# WORLD TRADE

# **ORGANIZATION**

# G/SPS/GEN/59

5 March 1998

(98-0857)

**Committee on Sanitary and Phytosanitary Measures** 

Original: English

#### THE REVISION OF THE INTERNATIONAL HEALTH REGULATIONS (IHR)

<u>Submission by the World Health Organization</u> <u>Division of Emerging and Other Communicable Diseases Surveillance and Control</u>

### Background

- 1. The current International Health Regulations were adopted by the Twenty-second World Health Assembly in 1969, and were amended in 1973 and 1981. The need to inspect and control the movement of ships and cargos to prevent the spread of disease dates from as early as 1377, and the International Sanitary Regulations, adopted by the World Health Assembly in 1951, was the first omnibus international legislation designed for this purpose. The IHR are binding on all WHO Member States but one, and they are often referenced in national public health and quarantine legislation. The IHR describe the obligations of Member States regarding notifications for disease outbreaks (currently limited to cholera, yellow fever and plague); health organisation at frontiers, and the required health documents for the international movement of persons, ships, aircraft and other conveyances.
- 2. The IHR are being revised in accordance with WHO resolution WHA 48.7, adopted in 1995. The purpose of the revision is to adapt the Regulations to the present volume of international traffic and trade and take account of current trends in the epidemiology of communicable diseases, including emerging and reemerging disease threats.

#### WHO Position

- 3. Both the World Trade Organization Sanitary and Phytosanitary Measures Agreement (SPS) and the World Health Organization International Health Regulations (IHR) are committed to the principle of protecting health while interfering as little as possible with international trade. Potential strengthening of each of these documents through mutual acceptance and acknowledgement must be explored.
- 4. The revised draft of the International Health Regulations specifically references the SPS Agreement in draft Article 48, (January 1998), which states: "The provisions of these Regulations do not prejudice the rights and obligations of the parties bound by the World Trade Organization Agreement on Sanitary and Phytosanitary Measures which came into force on 1 January 1995 or any subsequent amendment to that Agreement". The SPS Agreement, however, does not reference the International Health Regulations, nor does it recognize the capacity of the World Health Organization to provide dispute resolution for public health matters between Member States of the WHO (draft IHR Article 56). The recognition of this capacity as a reference in the SPS Agreement would provide a natural and useful linkage between these documents and provide a credible and consistent focus for health risk assessment for Member State disputes.

#### Progress on the IHR Revision

5. A group of international consultants met in December 1995 and considered methods to improve the utility and effectiveness of the Regulations in view of the public health and economic consequences

of recent outbreaks of infectious diseases of international importance. They determined that the principles upon which the Regulations are based remain valid but that significant revisions would be required to meet current and future challenges posed by infectious disease threats. The consultation proposed that the Regulations should provide for the immediate reporting of a number of defined clinical syndromes. This would facilitate the rapid recognition and reporting of outbreaks of new or unusual infectious diseases. Immediate notification of syndromes would normally be followed later by a report on the specific disease involved after confirmation of the diagnosis. By expediting the notification of syndromes, international awareness of rapidly evolving infectious disease threats would be improved. Another major recommendation was that the Regulations should be revised to include provisions designed to limit or prevent the introduction of inappropriate or unnecessary control measures that could affect international trade and transportation.

- 6. The governments of all Member States were invited to designate an official focal point for liaison with WHO on the IHR revision. Over 80 Member States have now done so. All potentially interested IGOs and NGOs were also invited to designate focal points for this purpose and several have done so.
- 7. To assist the Committee in preparing the revised IHR, a small working group was set up to advise on the provisions to be included in the revised IHR, in the light of the principal recommendations of the consultation in December 1995. The composition of the working group was based on the need for expertise in public health and quarantine matters, disease surveillance, international cooperation in public health, communicable diseases including food borne diseases and vector control, as well as legal expertise and experience in the application and administration of the existing IHR.
- 8. The informal working group of experts met twice in 1996 and 3 times in 1997 and formulated the concepts on which the revised IHR will be based and on the structure of the IHR document. In renewing the IHR, the original fundamental principle to ensure maximum security against the international spread of diseases with minimum interference with world traffic and trade will be retained. Furthermore, many of the public health provisions of the current IHR which remain valid at the present time, will be included in the revised IHR. However, important changes are proposed under the revised IHR, involving a new approach to mandatory notification as well as a major alteration in the structure of the IHR, as follows:

#### (a) Notification

In accordance with recommendations from the consultation in December 1995, the revised IHR will require immediate reporting of a number of defined clinical syndromes that are of international importance. This will facilitate timely notification, which would normally be followed by specific disease reporting once the diagnosis has been confirmed. It will also provide for reporting of disease outbreaks of unknown origin where a potential hazard to international travel or trade is observed. The syndromes, which will be notifiable only where an international public health threat is involved, include acute haemorrhagic fever, acute respiratory, acute diarrhoeal, acute jaundice and acute neurological syndromes as well as a category covering other undefined syndromes of presumed infectious origin. The precise definition of the syndromes, to ensure appropriate levels of sensitivity and specificity for reporting purposes, is the subject of international consultation at the present time.

## (b) Structure of the revised IHR

The proposed structure for the revised IHR will take the form of:

- a framework document containing (i) general principles and obligations on appropriate public health measures and (ii) legal provisions relating to the operation and amendment of IHR and incorporating by reference the technical annexes (see below); and
- a series of annexes describing technical provisions and specific requirements, which because of the reference in the framework part to the annexes will form an integral part of IHR.
- 9. In addition, there will be operational guidelines to accompany IHR and assist in their application. Thus, the IHR framework will stipulate appropriate measures that should be taken, for example, for the management and control of syndromes or diseases subject to the Regulations; to eliminate or reduce animal hosts or vectors of disease near airports, ports and container terminals; to disinsect aircraft leaving an airport in an area where mosquito-borne disease occurs using internationally approved procedures. In all such instances, the technical details of the measures to be taken will be described in full in the annexes. The annexes will be subject to regular review and will be updated as necessary. This new structure for the IHR will provide basic regulations of a generic nature which should remain valid for many years. At the same time, the specific public health measures contained in the annexes could be modified rapidly according to changing needs and new knowledge. The intention is to ensure longevity of the IHR together with adaptability of the specific technical provisions. It is envisaged that, if the World Health Assembly agrees to delegate to the Executive Board of the World Health Organization the necessary authority, the annexes could be revised upon approval of the Executive Board after having been considered by the Committee on International Surveillance of Communicable Diseases or other appropriate expert committee.
- 10. An important parallel to the revised text will be a move to a more collaborative response to significant outbreaks, where all key partners will be linked to a decision and recommendation process.
- 11. The provisional draft text of the revised IHR was distributed in February 1998 to Member States, other IGOs and NGOs and to the members of the Committee on International Surveillance of Communicable Diseases. The syndromic approach to notification is being evaluated in a pilot study in a limited number of selected countries in each WHO region. Information seminars were held in each region for the participating countries in October-November 1997 and several country visits by WHO staff were also arranged. The draft IHR will be revised in light of the experience gained during the pilot study. Information from this study will be complemented by a retrospective evaluation of outbreak reports received by WHO (EMC).
- 12. The Committee on International Surveillance of Communicable Diseases will be convened to finalize the text after completion of the pilot study and any necessary revision of the draft IHR. A meeting of the Committee is planned to take place in 1998 and its recommendations submitted to the World Health Assembly in 1999. Progress reports are published every six months in the *Weekly Epidemiological Record*.
- 13. Further information on the revision of the IHR can be obtained by writing to WHO-EMC, attention Dr. L.J. Martinez, Room 6022, Avenue Appia 20, Geneva 27, Switzerland, or by E-mail: Martinezli@who.ch.