Second Regional Consultation on the Proposed Revised

International Health Regulations,

WHO-SEARO, 29 June – 1 July 2004

Project: ICP CSR 002
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<td>Rapid Response Team</td>
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Executive Summary

A Second Regional Consultation on the Proposed Revised International Health Regulations (IHR) was conducted in New Delhi, India, from 29 June to 1 July 2004. The meeting was convened by the HO Regional Office for South-East Asia.

The general objective of the consultation was to review the revised IHR working paper in preparation for the meeting of the global Intergovernmental Working Group (IGWG), scheduled to be held in WHO headquarters in November 2004. The specific objectives were:

1. To review the revised IHR based on the deliberations and observations made at the country-level workshops and to identify important issues of concern to Member States;
2. To review national capacity in implementing the revised IHR, and
3. To facilitate country preparedness for the meeting of the Intergovernmental Working Group.

The meeting was attended by 35 participants from 9 Member States plus an observer from the U.S. Department of Health and Human Services. There were 14 WHO staff members on the secretariat. One consultant was engaged to assist with the meeting.

The meeting was in two main parts. Days one and two focused on the proposed draft IHR, its strengths and weaknesses, and potential improvements. These discussions also considered the draft IHR, article by article. Day three focused on strengthening communicable diseases surveillance and response capacity to support implementation of the revised IHR. The format consisted of technical presentations and discussions that were reported back by rapporteurs appointed by the groups. There was a final plenary session to review key IHR issues and recommendations.
Key issues and concerns from the meeting:

General

- **Support for revised IHR** – There was consensus that the revised IHR will contribute to strengthening national surveillance systems and ensuring global health security.

- **Need for complete public health definitions** – The definitions section (Article 1) needs to be expanded to include all key terms. Wherever possible, these terms should be defined in a way that is consistent with standard public health terminology.

- **Need to strengthen core capacity in Member States** – There was general agreement that Member States currently have insufficient core capacity (Annex 1) to fully implement the revised IHR. There are important questions about how and when this core capacity can be built.

- **Need to ensure that WHO has sufficient capacity to support the operation of IHR** – The revised IHR requires WHO to provide assistance that goes beyond technical support. WHO will need sufficient resources to allow it to work with national health authorities to ensure smooth implementation of IHR.

- **Need to clarify the role of National IHR Focal Points (NFP)** – There is a need to clarify the role of NFP, particularly as this function relates to the role of the health administration (Article 3 and Annex 1). For example, the authority of NFP to report events where this might be in conflict with the health administration in a particular country.

- **Need to clarify the scope of IHR** – There is complete agreement that IHR should cover diseases and hazards with a biological or unknown etiology. However, the meeting could not reach a consensus on the inclusion of chemical and radionuclear events, or whether to include diseases and hazards caused by deliberate releases.

- **Need for a list to supplement the decision instrument** – Participants supported having the decision algorithm (Annex 2) as the core mechanism for identifying events that need to be notified (Article 5). However, the majority thought that this should be supplemented by a list of diseases and other events that should be routinely notified. Such a list should be in a form that can be easily amended i.e. annex or guideline.

- **Need to include mechanisms to incorporate regional and local health threats** - It is not clear how much emphasis the revised IHR will place on disease conditions that have special importance for specific countries or groups of countries e.g. the threat of
importation of yellow fever into the SEA Region. Member States hope that IHR can support continuous surveillance and preventive action to manage such local threats.

- **Need to recognize the importance of animal diseases** – The reporting of animal disease of human health significance should be incorporated into the IHR process. This could be done in several ways. Annex 1 could include a capacity to receive and assess reports of diseases in animals that create a potential for disease in humans. Annex 2 could specifically mention diseases in animals in the list of events with potential high public health impact.

- **Need for clearer description of response measures** - Considering the importance of responding effectively to PHEIC, Article 10 and annexes contain little on how such responses are organized and what they may contain. An example is the role of quarantine in the containment of PHEIC. Given that this measure has recently demonstrated its effectiveness in supporting the response to SARS, it deserves to be defined and recognized in IHR.

- **Need for a clear and acceptable process for sending investigation teams** – Participants endorsed the value of Member States collaborating with WHO teams in on-the-spot studies to assess risk and the adequacy of control measures (Article 10). However, the mechanism for initiating such responses needs further discussion.

- **Need for IHR to override trade and economic interests in a PHEIC** - The IHR seems to lack articles indicating how public health actions may need to take precedence over trade agreements and short-term economic considerations in responding to PHEIC.

- **Need for technical guidelines** – Technical guidelines are needed to expand on many of the requirements outlined in the articles and annexes.

- **Need for further development of provisions for ground crossings** - There was some discussion about the status of ground crossing (Article 15) and “dry ports” as these are the main points of entry for many Member States in the Region. The term “ground crossing” should be defined (Article 1). There are issues around when to “designate” ground crossings and how to give them similar recognition to ports and airports generally.

- **Need to clarify the rights of persons to refuse public health measures** – There is a need to clarify the rights of persons to refuse public health measures in PHEIC and
how these rights will be balanced against public health needs in such situations (Article 36).

- **Need to ensure that Review Committee is effective** - Participants thought it important that the Review Committee (Article 45, Annex 10) be multi-disciplinary. The Committee should review and report on the operation of IHR at least annually for the first five years of operation. A number of specific suggestions were made about the operation of this committee; these are included in the body of this report.

- **Need a process for resolving disputes between Member States and WHO** - It is not clear how disputes between WHO and Member States will be resolved by the current articles dealing with disputes (Article 47).

- **Possible need to delay entry into force** - Entry into force on 1 January 2006 (Article 52) may be too soon if countries are expected to have all measures in place by then. Other options include delayed or phased implementation.

**Key issues and concerns from the meeting regarding Capacity Strengthening**

**IHR capacities needing the most strengthening i.e. main gaps**

- **Community level** – Need to establish simple, sustainable systems for identifying and reporting events of importance. Common reported gaps include: having clear technical guidelines on what to report (including rumours, syndromes); sufficiently trained workforce; simple, effective reporting mechanisms.

- **Intermediate level** – Need core resources for receiving and responding to reports from the community level. Common reported gaps include: having identified focal persons and rapid response teams (RRTs) at this level; appropriate reporting tools; sufficient laboratory facilities and personnel; emergency stocks of drugs and other resources for emergency responses.

- **Central/National level** – Need to have organizational structure(s) to provide IHR functions, backed up by political commitment and resources. Common gaps include: early warning alert and response system (EWARS); public health emergency preparedness and response plans; national laboratory capacity, including established collaborations with reference laboratories; sufficient trained epidemiologists and other public health professionals.
None of the participants reported having sufficient intersectoral capacity to ensure effective operation of IHR. Such a capacity is needed to achieve the following: communication and coordination within and between authorities; support for the National Focal Point; establishment of integrated surveillance across sectors; obtaining a wide mandate and resources for IHR function; establishing a consistent and supportive policy and legal framework; coordinating activities at points of entry; assessing and building capacity.

- **Designated points of entry** – All capacities described in Annex 1B require strengthening. Particular gaps include: access to organized medical services; facilities for transport of ill travellers; inspection of conveyances; safe environments for travellers; trained personnel for control of vectors; legal provisions and standards; contingency plans, especially with respect to bio-hazardous and radionuclear material; trained personnel for ports at entry and exit; appropriate medical equipment; quarantine and isolation facilities; agreements with local medical facilities for isolation and treatment; coordination between agencies; referral mechanism to medical examination; facilities for screening for bio-hazardous, chemical and radionuclear substances; equipment for disinfection.

**External support needed by Member States**

- **Financial support** – For all areas of capacity strengthening. Particular needs are for laboratory facilities; communication infrastructure; resources for emergency preparedness and response (EPR), including drugs, vaccines and storage facilities.

- **Training and workforce development** – Particularly for intermediate level and national level staff on all aspects of IHR and associated capacities. This includes: in-service orientation/training programmes; incorporation of surveillance/epidemiology into established training programmes; specific courses on topics such as data analysis and outbreak investigation; more intensive workforce development to increase essential public health skills.

- **Guidelines and standards** – These need to include guidelines that are specific to the needs of all surveillance levels and all workforce groups. Specific guidelines are needed for public health emergency response plans.
- **Surveillance and reporting tools** – A range of tools are needed to facilitate reporting and analysis processes required by IHR. These include appropriate electronic reporting software, forms, and documentation. Specific tools are needed to support the early warning alert and response system (EWARS).

- **Advice and advocacy for establishing effective IHR processes** – To ensure the development of an effective multisectoral response to IHR, it may be useful to encourage Member States to establish IHR intersectoral groups. Relevant sectors, include: public health and health services; customs/civil aviation/shipping; livestock and agriculture; trade and commerce; home/internal affairs; immigration.

- **Specific support for designated points of entry** – Support is needed to develop core capacities of designated points of entry, as described in the previous section. This includes financial, technical, and training resources. WHO has the mandate to work with relevant international partners on developing these capabilities.

- **Regional and global infrastructure expected from WHO** – This meeting identified several critical components of IHR capacity building that WHO, particularly the Regional Office, needs to provide. These capacities include:
  
  - **Receiving and responding to notifications** – WHO needs to provide an accessible contact point equivalent to NFP of Member States. There should be sufficient capacity in the Regional Office to manage regional problems, and in WHO headquarters to manage global problems.
  
  - **Regional communication** – WHO is responsible for managing regional information sharing networks and providing timely reporting to Member States on PHEIC.
  
  - **Regional planning and coordination** – WHO needs a regional strategy to support development of IHR capacities in Member States. Elements include systematic assessment of gaps in capacity; strategic planning; coordination and networking of existing providers (e.g. laboratories, training centres; specialized expertise); and coordinating approaches to donors.
  
  - **Regional and global advocacy** – WHO can use its unique mandate to advocate for adoption of IHR and associated measures by Member States.
Recommendations

(1) The WHO IHR Revision Team should consider input from this consultation in the continuing revision process.

(2) The revised IHR should give adequate emphasis to improving coordination with agencies dealing with surveillance and control of animal diseases of public health importance.

(3) WHO should provide the revised version of IHR to Member States before the IGWG meeting in November 2004.

(4) WHO should support the implementation of the revised IHR by:
   • Translation into local languages, as required;
   • Provision of technical support to build capacity at the Member State level, especially in the areas of strengthening surveillance, early warning and response for PHEIC;
   • Providing regional infrastructure and support to facilitate the operation of IHR, including through networking, laboratory support, and technical capacity at country and regional levels.

(5) Member States should actively prepare for the IGWG meeting and successful adoption of a revised IHR by continuing to promote dialogue on this subject with all relevant stakeholders. This process could include:
   • Briefing stakeholders on the outcome of the Second Regional Consultation on the proposed revised IHR;
   • Formation of an intersectoral group to facilitate implementation of the revised IHR across all relevant sectors.

(6) Member States should continue to support the development of capacities to implement IHR. Recommended steps include:
   • Conducting an inventory of capacity to support IHR and provision of results to the Regional Office SEARO to enable development of a regional IHR capacity strengthening plan
   • Considering a national surveillance and response strengthening strategy of the type presented at this meeting.

(7) The WHO Regional Office should review its core capacity for facilitating IHR implementation in the Region.
1. INTRODUCTION

The second Regional Consultation on Revision of the International Health Regulations (IHR) was held in New Delhi from 29 June to 1 July 2004. It was convened by the WHO Regional Office for South East Asian Regional Office. This meeting was part of the consultation process that will lead to a final draft of the revised International Health Regulations to be presented to the Fifty-eighth World Health Assembly in 2005.

There is a strong consensus that IHR needs to be revised to provide an effective basis for preventing international spread of infectious diseases. The present regulations were issued 35 years ago, in 1969. Increasing globalization and the emergence of new diseases such as severe acute respiratory syndrome (SARS) have highlighted the importance of establishing a more effective basis for coordinating the response to international threats to human health.

To help refine the draft IHR, WHO regional offices have convened meetings to consult Member States on the proposed revision of IHR and associated documents. These meetings have also provided an opportunity to review the core requirements for public health surveillance and response that countries and areas need to support the introduction of IHR.

This meeting followed the First Regional Consultation of National IHR Focal Points on Revision of the International Health Regulations, held in New Delhi on 13-14 April 2004.

2. OBJECTIVES AND EXPECTED OUTPUTS OF WORKSHOP

The general objective of the Consultation was to review the revised IHR working paper in preparation for the meeting of the global Intergovernmental Working Group, to be held at WHO headquarters in November 2004.

The specific objectives were:
To review the revised IHR based on the deliberations and observations made at the country-level workshops and to identify issues of important concern to Member States;

(2) To review national capacity in implementing the revised IHR, and

(3) To facilitate country preparedness for the meeting of the Intergovernmental Working Group.

The specific outcomes were:

(1) The revised IHR document was reviewed including major areas of concern, reservations etc. as identified and listed in the sections below.
(2) A comprehensive list of all concerns raised by Members States on the content of the proposal and the process planned to address those issues and concerns to facilitate the preparation of a final draft for the Intergovernmental Working Group.

3. PROCESS OF WORKSHOP

The programme of the meeting is attached at Annex 1, and a list of documents distributed during the workshop at Annex 2. The documents included the IHR working paper (the proposed draft) and initial comments from countries.

The meeting was in two main parts. Days 1 and 2 focused on the proposed IHR, its strengths and weaknesses, and potential improvements. Day 3 focused on strengthening communicable diseases surveillance and response capacity to support implementation of IHR. The format for the meeting consisted of brief presentations followed by discussion groups that were reported back by rapporteurs appointed by the groups. There was a final plenary session to review key IHR issues and recommendations.

The meeting commenced with the inaugural address given by Dr Poonam Khetrapal Singh, Deputy Regional Director, where she explained the importance of this workshop.
There were 35 participants (Annex 3) from 9 countries as well as a representative from the US Department of Health and Human Resources. The secretariat included 14 WHO staff, including from CSR/HQ, SEARO and WPRO. A consultant was also engaged to help facilitate the consultation and prepare the meeting report.

Dr Shiv Lal (India) was elected Chairman and Dr Selina Ahsan (Bangladesh) as Co-Chairperson. Dr H.M. Fernando (Sri Lanka) was appointed Rapporteur.

In Technical Session I, presentations were made on the following agenda items: Global health security and IHR – Dr Guenael Rodier; Overview of IHR revision process and consultation – Dr Max Hardiman; and IHR revision process in the Western Pacific Region: Major issues and recommendations – Dr Tee, Dato Ah Sian. This was followed by a general discussion of the IHR revision process.

In Technical Session II, Dr A.S. Abdullah made a presentation on the IHR revision process in the SEA Region, followed by presentations by the participant countries on their national IHR workshops with emphasis on process, outcomes, issues and recommendations. The presentations were followed by a general discussion.

In the first Working Group session, four working groups were set up, with representation of each country in each group. This was to review the context and need for IHR, strengths and potential weaknesses, and key issues. A plenary was held, followed by a discussion.

Working Group session II provided an opportunity to review in detail the proposed IHR articles and annexes and to identify and discuss key issues. The groups were requested to concentrate only on certain sets of articles: Articles 1 – 12 (Group 1), Articles 13 – 32 (Group 2), Articles 33 – 43 (Group 3), Articles 44 – 55 (Group 4). The four groups made their presentations at the plenary session, followed by detailed discussion.

Technical Session III commenced with a presentation by Dr Stella Chungong on Strengthening Communicable Disease Surveillance and Response Capacities. This was followed by a useful discussion. Dr K.K. Datta made a presentation on Regional Capacity for CSR – Assessment Report. Participants had a number of observations on this issue.
In Working Group Session III, the four groups then discussed the main communicable disease surveillance response capacity strengthening needs of the Region, the external support needed to build these and the infrastructure needed from WHO. The groups were requested to focus on specific aspects of capacity strengthening: Community and Intermediate Level (Group 1), Central/National Level – Health Sector Focus (Group 2), Central/National Level – Intersectoral Focus (Group 3), Designations Points of Entry (Group 4). After discussion the groups reported back at a plenary session. There was a brief presentation from Dr Michael Baker on the potential use of an Inventory of Capacity in Member States of WHO SEA Region to support implementation of IHR.

The meeting concluded with a plenary session where the rapporteur presented a summary of the meeting process, outcomes and recommendations. This was followed by concluding remarks from Dr Guenael Rodier, Dr A.S. Abullah and Dr Poonam Khetrapal Singh.

**4. PRESENTATIONS ON REVIEW OF IHR**

The following presentations were made during the consultation meeting. The full text of the inaugural speech made by the Deputy Regional Director is at Annex 4. Copies of the other presentations are available on request.

**4.1 Inaugural address by the Deputy Regional Director**

Dr Poonam Khetrapal Singh, Deputy Regional Director, WHO-SEARO, welcomed the participants to the Second Regional Consultation on the Proposed Revised International Health Regulations. She highlighted the need for revision of the current IHR which were issued in 1969. This has assumed greater urgency because of the increasing globalization of infectious diseases, as demonstrated during the recent outbreaks of SARS and avian influenza. She summarized the important milestones in the IHR revision process thus far and the regional consultation process undertaken in the SEA Region, notably the First Regional Consultation of IHR National Focal Points in April 2004 and the subsequent national consultations on the proposed IHR. There was a bi-regional consultation with the Western Pacific Regional Office. Significant issues identified at these consultations have included: the need for clearly defining the role of national IHR focal points and the support they
need; the scope of IHR with regard to non-biological hazards (chemical and radiological); refining the decision instrument to determine public health emergencies of international concern (PHEIC) by including lists of disease conditions; clarifying some of the definitions used in the legal document; and outlining clear mechanisms for notification of PHEIC by concerned national authorities. She also highlighted the need to review existing core capacities and facilities in relation to those required to implement the revised IHR.

4.2 Global health security and the International Health Regulations

Dr Guenael Rodier, (WHO/HQ) presented an overview of communicable disease surveillance and response. This began with an outline of the dynamic nature of microbial threats. Micro-organisms evolve and spread resulting in the emergence and re-emergence of infectious diseases across the globe. These natural processes are exacerbated by ‘man-made’ threats from accidental and deliberate releases of infectious agents. He outlined the three strategic directions for responding to these threats: containing known risks; responding to the unexpected; and improving preparedness. Containing known risks includes influenza pandemic preparedness and measures aimed at containing meningitis, yellow fever and cholera. Responding to the unexpected includes continuous screening of events of potential international importance and outbreak responses coordinated through the Global Outbreak Alert and Response Network (GOARN). Improving preparedness includes efficient early warning systems, integrated diseases surveillance, strengthening national referral laboratories, strengthening bio-safety programmes, and preparedness for deliberate epidemics. The new IHR will support all of these broad strategies.

4.3 An overview of IHR revision process and consultations

Dr Max Hardiman, (WHO/HQ) presented an overview of the IHR process. This began with an outline of the purpose and nature of IHR. Serious and unusual disease events are inevitable and globalization means the effects are felt everywhere. An agreed code of conduct protects against both the risks to public health from international spread of disease and the risk from unnecessary or excessive use of restrictions. Dr Hardiman described the legal basis for IHR and the limitations of the 1969 version that is currently in force. He discussed the aims of the revision and the benefits that will flow from this. He pointed out that IHR is not specifically concerned with protecting the health of
travellers, or establishing surveillance for particularly diseases, though there are synergies with these processes. He explained how IHR provides for routine measure to deal with certain known risks, and the capability to detect and respond to sudden heightening of risk. He reminded participants that international disease control is based on early detection and control of emerging hazards by national systems before such events become PHEIC. WHO is committed to supporting the development of national capacity. The Global Outbreak Alert and Response Network (GOARN) provides international back-up for these capacities. Dr Hardiman described the hierarchy of the IHR document, notably the core text, annexes, and referenced guidelines. He highlighted the key changes in the revised IHR and the benefits that are expected from these revisions. He described the revision process and the many opportunities for input by Member States, notably the role of the regional consultation meeting leading up to the IGWG meeting on 1-12 November 2004. He described the key issues and concerns that have arisen so far: scope in terms of public health emergencies and chemical and radionuclear event; possible need for disease lists; notification process; use of unofficial information from credible sources; national sovereignty vs. international responsibilities; incentives and compliance; mandatory timelines; role of IHR focal points; rapid response vs. transparent/inclusive processes; consistency with other international obligations and treaties; operational coordination; feasibility of implementation. He concluded by summarising the important opportunity provided by the IHR revision process.

### 4.4 IHR revision process in the Western Pacific Region

Dr Tee, Dato Ah Sian, (WHO-WPRO) made a presentation on the IHR revision process in the Western Pacific Region, including major issues and recommendations that came out of this. She summarised the key issues and controversies identified in the Western Pacific Region (WPR) consultation in April 2004. Dr Tee described the Inventory of Capacity in Member States that is being used to assess the capacity in relation to core requirements for IHR implementation. She summarised the main recommendations from the IHR consultation in WPR. These include acknowledging and affirming existing regional surveillance and response arrangements; clarifying the role of IHR National Focal Points (NFPs) and periodically updating the list of NFP; and developing an IHR implementation plan for the Region.
4.5 Regional IHR revision process in SEAR

Dr A.S. Abdullah, (WHO-SEARO), described the IHR revision process in the SEA Region. An important part of this process was the First Regional Consultation of National Focal Points on revision of IHR, held in New Delhi on 13-14 April 2004. That meeting reviewed key issues for further discussion and prepared draft country action plans for arriving at a national consensus. Subsequent consultations in Member States have continued the advocacy process and sensitized key stakeholders such as trade, external relations, travel and tourism, agriculture and transport, shipping, civil aviation, attorney general. National-level IHR workshops were then held in most Member States. These aimed to make stakeholders aware of the importance of the IHR review process, review the draft IHR and key issues, and identify core capacity requirements. The IHR revision process links to the integrated disease surveillance and response (IDSR) regional strategic plan (2002-2010). Assessment workshops being carried out in SEAR countries will contribute needed information for implementation of both IDSR and IHR.

4.6 Strengthening communicable disease surveillance and response capacity

Dr Stella Chungong, (WHO/HQ) presented an overview on strengthening communicable disease surveillance and response capacities. This presentation began by outlining the communicable disease surveillance and response challenges faced by many countries, notably gaps and poor coordination. She outlined the steps involved in a structured approach to national surveillance and response strengthening: (1) Risk assessment of communicable disease; (2) Prioritization of communicable diseases for surveillance; (3) Assessment of national capacities for surveillance, early warning and response; (4) Development of a national surveillance plan of action; (5) Implementation of this strengthening plan; (6) Monitoring and evaluation of progress, outcomes and impact; and (7) Research to improve key elements of the strategy. Core capacities for such systems include: event (rumour) verification; early warning and response; appropriate tools for surveillance; adequately trained human resources; laboratory capacity, and appropriate norms, standards and guidelines. WHO has approaches to support the development of these core capacities. She concluded by pointing out how the revised IHR provides a framework that can guide and support capacity strengthening.
4.7 Assessing regional capacity for CSR in the South East Asian Region

Dr K.K. Datta, (WHO-SEARO) presented a report on regional capacity for communicable disease surveillance and response. The purpose of this process has been to review the existing surveillance and response systems in Member States to identify strengths, weaknesses, opportunities and threats (SWOT). The tool used is a regional protocol for comprehensive assessment of national disease surveillance systems (adapted from AFRO). It has been applied to Sri Lanka, Myanmar and Maldives. This assessment showed that all countries had established infrastructure for generating surveillance data, notification and response. It also identified a number of important gaps, which in summary included:

- While legal tools existed in all countries, they were usually out of date and requirements were not well understood by clinicians.
- Standard guidelines were not widely available. Not all the diseases under surveillance had case definitions, and where they were available, were often not used. Composite surveillance manuals were not available. Case management protocols were available only for a few diseases.
- Case detection, registration and confirmation were incomplete, particularly for cases diagnosed outside hospitals.
- Reporting was primarily by mail, with no electronic reporting.
- Data analysis was largely confined to the central level and even here there was little skill at detecting early warning of potential outbreaks.
- Reported outbreaks were usually investigated though this was primarily descriptive.
- Epidemic preparedness was very limited though essential drugs and supplies were usually available.
- Routine feedback on surveillance system operation was generally poor.
- Coordination of surveillance systems was largely lacking, particularly at province/division/district level.
- Personnel generally had some training but needed more in-service training in epidemic investigation and surveillance, particularly data analysis.
- Resources were inadequate for most surveillance and response processes.
- Laboratory involvement in surveillance was absent, except in outbreaks, and quality assurance mechanisms were lacking.
5. OUTCOMES FROM WORKSHOP

Main strengths, weakness, issues and concerns

5.1 Main Strengths of Proposed IHR
Groups were asked to summarise the main strengths of the proposed IHR revision and the ways in which they saw it assisting member states in managing important public health threats in the region.

- **Strengthens surveillance** - The proposed IHR will help strengthen disease surveillance systems within countries, build a more transparent process for notification internationally, and improve communication channels and networks generally.

- **Broadens scope of concerns** – The broader scope of the proposed IHR is more relevant to current and future public health threats than the previous narrowly-focused IHR.

- **Clarifies reporting and communications processes** – The IHR provides a clearly-defined notification process, and also allows WHO to utilize information about diseases from other sources. It generally supports appropriate risk communication. It provides information sharing mechanisms within the Region, and globally.

- **Provides a common framework for responding to PHEIC**- The IHR delineates responsibilities more clearly. The defined role of the National Focal Point for IHR and clear linkage with the global outbreak and response mechanism are important advances. The revised IHR will generally increase the importance given to public health threats and the responsiveness of countries to them. It will strengthen early warning systems and facilitate better preparedness, timely action and collaboration.

- **Provides for more effective, flexible and appropriate responses** – This revision is essential to ensure that IHR is responsive to evolving needs and emerging challenges.
It will provide common procedures for assessed risk and linking public health measures to these assessed risks. Responses will be appropriate and time-bound. The IHR provides procedures for obtaining technical input that can shape a response that is flexible and linked to specific events.

- **Helps in building a commitment to developing core capacities** - The IHR sets out a broad set of core capacity requirements, including those for points of entry, that countries must develop.

- **Clarifies role of WHO in supporting global collaboration** – The IHR increases the scope for collaboration among Member States and with WHO. It sets out a clear leadership role for WHO in supplying technical expertise to implement IHR. WHO will help in coordination between countries, particularly those which are not on good terms. The IHR established a coordination mechanism for different stakeholders and agencies and a basis for technical collaboration and partnership.

### 5.2 Main Potential Weaknesses

Groups were asked to summarise the main potential weaknesses of the proposed IHR revision and the ways in which they saw it potentially interfering with Member States in managing important public health threats in the Region.

- **Inadequate core capacity in Member States** – There was general agreement that Member States currently have insufficient core capacity to fully implement the revised IHR.

- **Limited resources of WHO** – The revised IHR requires WHO to provide assistance that goes beyond technical support. WHO will need to work with national health authorities to ensure smooth implementation of IHR.

- **Lack of emphasis on regional and local health threats** - It is not clear how much emphasis the revised IHR will place on disease conditions that have special importance for specific countries or groups of countries, e.g. the threat of yellow
fever importation into the SEA Region. Member States hope that IHR can provide leverage for countries to undertake continuous surveillance and preventive action to manage such local threats. This was one of the few areas where they could see IHR potentially interfering with Member States in managing important public health threats, e.g. by limiting the application of specific routine measures at ports of entry.

- **Lack of measures to override trade and economic interests** - The IHR seems to lack articles indicating how public health actions may need to take precedence over trade agreements and short-term economic considerations in responding to PHEIC. There needs to be some protection against IHR being surpassed by trade-related instruments.

5.3 Main Issues and Concerns

Groups were asked to summarise issues and concerns they thought needed further discussion during the meeting.

- **Core capacity** - Capacity needs to be emphasized as the basis for the implementation of IHR. It is necessary to outline minimum core capacities in the areas of early warning, notification, and response required at different levels of implementation. Resources to this end can be mobilized using the legal framework as a common tool for advocacy. However, there are major questions about how and when this core capacity can be built.

- **Animal diseases** – The reporting of animal disease of significance to human health should be incorporated into the IHR process. This could be done in several ways. Annex 1 could include a capacity to receive and assess reports of diseases in animals that create a potential for disease in humans. Annex 2 could specifically mention diseases in animals in the list of events with potential high public health impact.

- **Technical guidelines** – Technical guidelines are needed to expand on many of the requirements outlined in IHR.
• **Role of NFP** - The role of the National Focal Points is not clear. For example, their capacity to report where this might be in conflict with the health authority in their own country.

• **Investigation teams** – The IHR does not identify the mechanism that WHO will use to launch its assistance teams.

• **Resolving disputes** - It is not clear how disputes between WHO and Member States will be resolved.

• **Directive nature of document** – There was discussion about how directive IHR needed to be. Some of the wording in the document (e.g. “shall” and “can”) has an imposing, top-down feel. A question was also raised as to whether IHR could be a guideline rather than a legal document. However, there was strong support for a common legal framework and procedures for Member States to follow in times of public health emergencies of international concern.

• **Sanctions** – The IHR does not outline what measures will be taken against countries that do not comply with the Regulations.

• **Scope** – There were divided views about the inclusion of chemical and radionuclear events and deliberate releases.

• **Use of other sources of information** - Issues around the use of unofficial information from credible sources.

### 6. REVIEW OF ARTICLES AND ANNEXES

This section lists articles and annexes where participants identified important issues and concerns that need to be resolved during the final revision of IHR. A full list of the articles and annexes, along with comments, is included in Annex 5.

**Article 1 Definitions**
These need to be expanded to include all key terms in IHR. Wherever possible, these terms should be defined in a way that is consistent with standard public health, risk assessment and epidemiological terminology.

**Article 3 Communications**

Need to clarify the role of National Focal Points for IHR, particularly as this relates to the role of the health administration.

**Articles 4 and 5, Annexes 1 and 2 Surveillance and Notification**

Some infections in animal populations are clearly events that create a potential for disease in humans, as has recently been demonstrated by avian influenza. There are several points in IHR where the importance of zoonotic disease could be given greater recognition. These points include:

- Annex 1 – A capacity to receive and assess reports of disease in animals that create the potential for disease in humans.
- Annex 2 – Disease in animals could be specifically mentioned in the list of examples of events with the potential to have a high public health impact.

**Article 5 Notification and Annex 2 Decision Instrument**

The majority favoured having the decision instrument as the core mechanism for deciding what should be notified, supplemented by a list that can be easily amended (e.g. annex or guideline).

The scope of IHR remains unresolved in terms of whether it should include:

- Diseases and hazards with a biological or unknown etiology vs. also including hazards and diseases caused by chemical and radionuclear agents.
- Diseases and hazards that are accidental vs. those also caused by deliberate release.

**Article 10 Response**

Considering the importance of responding effectively to PHEIC, the articles and annexes contain few details about how such responses are organized and what they may contain. An example is the role of quarantine in the containment of PHEIC caused by microbiological agents. Given that this measure has recently demonstrated its
effectiveness in supporting the response to SARS, it deserves to be defined and recognised in IHR.

**Article 10 On-site assistance**
Participants endorsed the value of Member States collaborating with WHO teams in on-the-spot studies to assess the threat posed by PHEIC and the adequacy of control measures. However, the mechanism for initiating such responses needs further discussion.

**Article 15 Ground crossings**
There was some discussion about the status of ground crossing and “dry ports” as these are the main points of entry for many Member States in the Region. This term should be defined in the definitions section (Article 1). There are issues around when to “designate” them and how to give them similar recognition to ports and airports generally.

**Article 36 Rights of persons**
The rights of persons to refuse public health measures in emergency situations need further discussion and clarification.

**Article 45 Review**
Participants thought it important that the Review Committee be multi-disciplinary. The committee should review and report on the operation of IHR, at least annually for the first years of operation. There were a number of specific suggestions about the operation of this committee that are included in the annex to this report.

**Article 46 Amendments and additional annexes**
There was some discussion as to whether the Executive Board (EB) should be able to adopt amendments to annexes without their having to go to the full World Health Assembly (WHA). There was some support for this approach as it helped to make a distinction between the articles, which can only be amended by the full WHA, compared with the Annexes which can be amended by the EB on its own.

**Article 52 Entry into force**
Entry into force on 1 January 2006 may be too soon if countries are expected to have all measures in place by then. Other options include:

- Delay to June 2006
- Phased implementation

**Annexe 1 Core capacity requirements for surveillance and response**
The ability of Member States to meet core capacity needs resulted in considerable discussion.

**7. IMPLICATIONS FOR CAPACITY BUILDING**

**7.1 IHR Capacities needing the most strengthening i.e. main gaps**

Groups were asked to identify the IHR capacities (those specified in Annex 1) that need the most strengthening. They commented according to the three levels described in Annex 1A, and those listed in Annex 1B.

**Community level**

- Listing of informers (focal persons) in the community (village health guides, community leaders, village volunteers, CBOs, private medical practitioners, sub-centres, health posts, family health section)
- Guidelines/standards of reporting events/rumours from community to HCWs
- Sensitization/training of key informers at the community level – syndromic reporting
- Mechanism for communicating information to the intermediate level – direct, phone, fax, post cards etc

**Intermediate level**

- Rapid response teams (RRTs) – Focal persons
- Training of RRTs on outbreak investigations, rumour verification
- Reporting tools – Reporting guidelines/standards
• Mechanism for communicating information

• Laboratory – specimen collection, transport, testing, referral

• Data analysis skills

• Case management guidelines

• Emergency stocks – supplies and drugs, storage

• Resources for emergency preparedness and response (EPR), and EPR plan

• Mechanism for reporting to the national level

Central/National level – health sector focus

• National assessment capacity: clear communication channels and mechanism for early warning (procedure/protocol); competent personnel and focal point; capacity for real time data analysis; intersectoral support

• National notification capacity: political commitment; IHR focal point empowered with full authority - clear roles and responsibility in the country and to WHO. Even if it is a body, one person should be identified for contacting WHO; clear communication channels and means

• National response management capacity: national multi-sectoral committee for epidemic and emergency preparedness and rapid response teams (should be at all levels); epidemic preparedness plan; emergency fund/financing mechanism - for equipment, supplies, transport; media risk communication strategy /public information management strategy

• National laboratory capacity: skilled laboratory staff- need for training; SOPs; Quality assurance programme; National Public Health Laboratory; Laboratory networking- collaboration with reference laboratories; Biosafety/biosecurity; logistic support

• National onsite assistance capacity: Rapid response team; advice team-build capacity; logistic support

• National operational response capacity: Clear lines of communication and identified focal persons at all levels; logistic support; training
Priorities

- Public health emergency preparedness and response plan
- Political commitment-
- Empowered IHR focal point
- Resource allocation
- National laboratory strengthening - all aspects and collaboration with reference labs
- Skill development
- Early warning and alert response system

Central/National level – intersectoral focus

- Poor communication/coordination within and between authorities
- Lack of coordinated surveillance (and also plan)
- Lack of resources – financial, infrastructure, human resources, technical
- Inadequacy of legal framework (at national level and within agencies)
- Inadequate understanding of stakeholders about IHR
- Inadequate policy advocacy

The Way Forward is to build a coordinated and effective intersectoral response to PHEIC. It was suggested to form a core Technical Group (TG) and a wider Support Group (SG) of key stakeholders.

- Technical Group (TG) could include public health and health services; customs / civil aviation / shipping; livestock and agriculture; trade and commerce; home affairs; immigration
- Support Group (SG) could include information; environment; tourism; law and justice; finance; foreign affairs; non-Govt/private/

Mandate of TG/SG

- To support the National Focal Point in intersectoral activities on IHR
- To coordinate establishment of integrated surveillance across sectors
To coordinate activities at the points of entry

To build and coordinate an effective intersectoral response to PHEIC

To facilitate review of existing legal frameworks and also development of appropriate legal system in relation to IHR

To assess and build capacity, i.e. training, technical assistance, etc.

**Designated points of entry**

- Access to organized medical services
- Access to equipment for transport of ill travellers
- Inspection of conveyances
- Safe environment for travellers
- Trained personnel for the control of vectors
- Legal provisions and standards need to be developed to adapt the new regulations—emphasis on emergencies
- Contingency plan, especially for bio-hazards and radionuclear material
- Trained personnel for ports at entry and exit
- Appropriate medical equipment and gear
- Quarantine, isolation and facilities
- Necessary transport
- Agreements with local medical facilities for isolation and treatment coordination with other agencies
- Referral mechanism to medical examination
- Facilities for screening for bio-hazards, chemical and radionuclear substances
- Equipment and capacity for disinfection

**7.2 External support needed by Member States**

Groups were asked to identify the external support their countries need to help them strengthen core-capacities required at various levels for implementation of IHR.
Community and intermediate levels

- Technical support - guidelines/standards/tools
- Financial support - Laboratories, surveillance systems, EWARS, communication, training
- Training institutions – incorporation of surveillance/epidemiology in the training programmes, and in-service orientation/training programmes
- Information sharing network
- Monitoring and evaluation

Central/National level – health sector focus

- Network/collaboration with reference laboratories
- Training – links with academic institutions
- Information exchange mechanisms including early warning
- Regional/sub-regional requirements
- Advocate for political commitment, especially for resource allocation
- Guideline on emergency preparedness and response in public health emergency, (e.g. EWARS)
- Facilitate collaboration with reference labs
- Assist development of national emergency public health preparedness plan and guidelines
- Develop country capacity for public health emergency preparedness and response through training

Central/National level – intersectoral focus

- Training
- Technical assistance
• Financial resources

**Designated points of entry**

• Financial and technical support for personnel and equipment
• Assistance with development of a public health emergency contingency plan
• Financial and technical support and arrangements for affected travellers
• Similarly for those persons who are not ill but suspected
• Mandate and processes for disinfecting aircraft

**7.3 Regional infrastructure expected from WHO**
Groups were asked to identify the regional and sub-regional infrastructure they expect WHO to provide to ensure successful operation of the IHR.

**Community and intermediate level**

• Linkage of national training centres with regional training centres
• Networking of national labs with regional labs
• Information sharing network

**Central/National level – health sector focus**

• See under external support

**Central/National level – intersectoral focus**

• Regional strategy

• Regional support
  o Inventory of facilities and expertise
  o Policies and procedures for collaboration
  o Lab-based resources
- Epidemiology-based resources
- Data management and communication resources
- Funds and Logistics
- Training and Technical

- Capacity for responding to regional problems to be built at WHO regional level
- Capacity for responding to extra-regional problems to be built at WHO HQ

**Designated points of entry**

- See under external support
8. CONCLUSION AND RECOMMENDATIONS

In conclusion, the meeting reached consensus that the revised IHR will contribute to strengthening of national surveillance systems and ensuring global health security. The following recommendations were made for consideration by WHO:

1. The WHO IHR Revision Team should consider input from this workshop in the continuing revision process.

2. The revised IHR should give adequate emphasis to improving coordination with agencies dealing with the surveillance and control of animal diseases of public health importance.

3. WHO should provide the revised version of IHR to Member States before the meeting of IGWG in November 2004.

4. WHO should support the implementation of the revised IHR by:
   • Translation into local languages, as required;
   • Provision of technical support to build capacity at the Member State level, especially in the areas of strengthening surveillance, early warning and response for PHEIC,
   • Providing regional infrastructure and support to facilitate operation of IHR, including through networking, laboratory support, and technical capacity at country and regional levels.

5. Member states should actively prepare for IGWG and successful adoption of a revised IHR by continuing to promote dialogue on this subject with all relevant stakeholders. This process could include:
   • Briefing stakeholders on the outcome of this Second Regional Consultation on the proposed revised IHR;
   • Formation of an intersectoral group to facilitate implementation of the revised IHR across all relevant sectors.
6. Member states should continue to support development of capacities to support the operation of IHR. Recommended steps include:
   - Conducting an inventory of capacity to support IHR and provision of results to SEARO to enable development of a regional IHR capacity strengthening plan;
   - Considering a national surveillance and response strengthening strategy of the type presented at this meeting.

7. WHO/SEARO should review its core capacity for facilitating IHR implementation in the Region.

The meeting expressed its appreciation for the effort of WHO in revising the existing IHR, and its support for the comprehensive consultation process at national and regional levels. The invaluable contribution of the workshop participants was also acknowledged.
# Programme

**Tuesday – 29 June 2004**

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<tr>
<th>Time</th>
<th>Activity</th>
<th>Presenter/Notes</th>
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<tr>
<td>0800 – 0900</td>
<td>Registration</td>
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<tr>
<td>0900 – 0930</td>
<td><strong>Inauguration</strong>&lt;br&gt;• Inaugural Address&lt;br&gt;• Introduction to participants&lt;br&gt;• Election of office bearers&lt;br&gt;• Announcements</td>
<td>Dr Samlee Plianbangchang, Regional Director, WHO-SEARO&lt;br&gt;Dr A.S. Abdullah, Coordinator, CDC, WHO-SEARO&lt;br&gt;Dr Samlee Plianbangchang, Regional Director WHO-SEA&lt;br&gt;Dr A.S. Abdullah Coordinator, CDC, WHO-SEARO</td>
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<tr>
<td>1000 – 1015</td>
<td>Objectives and Expected Outcomes</td>
<td>Dr A.S. Abdullah, Coordinator, CDC, WHO-SEARO</td>
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<tr>
<td>1015 – 1030</td>
<td>Global Health Security &amp; International Health Regulations</td>
<td>Dr Guenael Rodier, Director, CDS, WHO-Geneva</td>
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<tr>
<td>1030 – 1100</td>
<td>An overview of IHR revision process and consultations</td>
<td>Dr Max Hardiman, Project Leader, IHR Revision Team, WHO-Geneva</td>
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<tr>
<td>1100 – 1115</td>
<td>Experience of WPRO in IHR revision process and major observations / recommendations</td>
<td>Dr Tee, Dato Ah Sian, Director Combating Communicable Diseases, WHO-WPRO</td>
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<tr>
<td>1115-1130</td>
<td>Discussion of IHR revision process</td>
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<td></td>
<td><strong>Technical Session II</strong></td>
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<tr>
<td>1130 -1140</td>
<td>Regional IHR revision process in SEAR</td>
<td>Dr A.S. Abdullah, Coordinator, CDC, WHO-SEARO</td>
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<tr>
<td>1140- 1300</td>
<td>Country Presentations including process, outcomes, issues, and recommendations</td>
<td>National IHR Focal Points</td>
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<tr>
<td>1400 – 1430</td>
<td>Country Presentations (continued)</td>
<td>National IHR Focal Points</td>
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<tr>
<td>1430 – 1450</td>
<td>Discussion of Country Presentations</td>
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<tr>
<td>1450 – 1500</td>
<td>Setting up Working Groups (1, 2, 3 &amp; 4) and Terms of Reference</td>
<td>Dr Ayana Yeneabat STP, CSR WHO-SEARO</td>
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<tr>
<td>1530 – 1700</td>
<td><strong>Working Group Session I</strong>&lt;br&gt;<strong>Overview of IHR</strong>&lt;br&gt;To review context and need for IHR, strengths and potential weaknesses, and key issues for further discussion</td>
<td>Group 1&lt;br&gt;Group 2&lt;br&gt;Group 3&lt;br&gt;Group 4</td>
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### Wednesday – 30 June 2004

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Description</th>
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| 0830 – 0930| **Plenary Session**  
Presentation of group reports, and identification of issues for further discussion on day 2 |
| 0930 – 1030| **Working Group Session II**  
**Review of articles, annexes and issues**  
Detailed review of the proposed IHR, article by article, annexes and key issues  
Articles 1-12  
Articles 13-32  
Articles 33-43  
Articles 44-55  
Group 1  
Group 2  
Group 3  
Group 4 |
| 1100 – 1300| **Working Group Session II (contd.)**  
Articles 1-12  
Articles 13-32  
Articles 33-43  
Articles 44-55  
Group 1  
Group 2  
Group 3  
Group 4 |
| 1400 – 1500| **Working Group Session II (contd.)**  
Articles 1-12  
Articles 13-32  
Articles 33-43  
Articles 44-55  
Group 1  
Group 2  
Group 3  
Group 4 |
| 1530 – 1700| **Plenary Session**  
Presentation of group reports, discussions and consolidation of observations and recommendations  
All groups |

### Thursday – 1 July 2004

<table>
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<tr>
<th>Time</th>
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| 0830 – 0900| **Technical Session III**  
**Strengthening CD Surveillance and Response Capacity in SEAR**  
Dr Stella Chungong, Medical Officer, Epidemiology & Training, WHO-Geneva |
| 0900 – 0930| **Core capacity – Observation from comprehensive assessment of National Surveillance Systems in SEAR**  
Dr KK Datta STP, CSR, WHO-SEARO |
| 0930 – 1030| **Working Group Session III**  
**Capacity strengthening**  
Strengthening communicable disease surveillance and response capacity to support introduction and |

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<table>
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<tr>
<th>Time</th>
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| Operation of the IHR                        | Community and Intermediate level  
|             | Central/National level (Health sector focus)  
|             | Central/National level (Intersectoral focus)  
|             | Designated points of entry                                                           |
| 1100 – 1200 | **Working Group Session III (continued)**  
|             | Community and Intermediate level  
|             | Central/National level (Health sector focus)  
|             | Central/National level (Intersectoral focus)  
|             | Designated points of entry                                                           |
|             | **Group 1**  
|             | **Group 2**  
|             | **Group 3**  
|             | **Group 4**  
| 1200 – 1300 | **Plenary Session**  
|             | Presentation by working groups on capacity strengthening  
|             | **All groups**  
| 1400 – 1500 | **Plenary Session**  
|             | Presentation of conclusions from group work  
|             | Recommendations from the meeting  
|             | **Group Rapporteurs**  
|             | **Overall meeting Rapporteur**  
| 1500        | **Closing Session**  
|             | **36**
Annex 2

List of Documents

1. Objectives
2. Tentative Programme
3. List of Participants
5. International Health Regulations (1969)
7. Regional Strategic Plan for Integrated Disease Surveillance 2002-2010, SEA-CD-131
8. Summary of outcomes from Consultation Meetings on the International Health Regulations Proposals, May 2004
10. Frequently Asked Questions (FAQ) on the Proposed Revision of the International Health Regulations
11. Global Crises – Global Solutions: Managing public health emergencies of international concern through the revised International Health Regulations, WHO/CDS/GAR/2002.4
12. Terms of Reference for the Working Groups
13. Report of national workshop on IHR – Bangladesh
15. Report of national workshop on IHR – India
17. Report of national workshop on IHR – Maldives
18. Report of national workshop on IHR – Myanmar
22. Report of national workshop on IHR – Timor
Annex 4 - Opening speech by Dr Poonam Khetrapal Singh.

Inaugural Address by Dr Poonam Khetrapal Singh at the Second Regional Consultation on the Proposed Revised International Health Regulations
WHO-SEARO, New Delhi 29 June – 01 July 2004

Distinguished participants, colleagues, ladies and gentlemen, It is with great pleasure that I welcome you all to the Second Regional Consultation on the Proposed Revised International Health Regulations.

I am glad to see some of the distinguished participants who also attended the First Regional Consultation on the Proposed Revision of IHR. There are others from ministries and departments of the respective countries whose role in the revision and implementation of the revised IHR would be vital.

For the benefit of these participants, I would like to highlight some milestones in the IHR revision process thus far.

As you are all aware, the International Health Regulations adopted in 1969 and currently in force, provide the only legal framework for security against the international spread of diseases while avoiding unnecessary interference with international traffic. This legal framework is restricted to only three diseases; namely cholera, plague and yellow fever.

Since the adoption of IHR in 1969, however, there have been several developments worldwide, including changes in disease patterns, and epidemiological changes.

While the globalization of infectious diseases is not a new phenomenon, increased population movements, growth in international trade in food and biological products; social and environmental changes linked with urbanization, deforestation and alterations in climate, have reaffirmed that infectious disease events in one country are potentially a concern for the entire world. This was clearly demonstrated during the recent outbreaks of SARS and Avian influenza.

Therefore, the need to revise the existing International Health Regulations took on an urgent dimension. This would provide a broader framework for protecting populations against the spread of infectious diseases across national boundaries and to respond adequately to public health emergencies of international concern.

Recognizing this need, the World Health Assembly adopted resolution WHA48.13 on new, emerging and re-emerging infectious diseases and WHA48.7 on the revision and updating of the International Health Regulations in 1995. The Health Assembly, among other things, requested the WHO Director-General to take measures to review the International Health Regulations.
Subsequently, between 1995 and 1997, a number of global consultations and working group meetings were held to secure agreement on the direction of the revision process.

To facilitate the revision process, the International Health Regulations Revision Project was established at WHO/HQ in Geneva.

Recognizing the need for participation of Member States in the Revision Process, the Health Assembly adopted Resolution WHA56.28 in 2003 urging Member States to give high priority to the work on the revision of the International Health Regulations and to provide resources and extend the necessary cooperation to facilitate the process.

Since then, a revised draft of the International Health Regulations has been developed and shared with all WHO Member States.

In February 2004, the WHO Director-General requested all Regional Offices to inform Member States on the progress made and requested Member States to critically review the revised IHR document.

Accordingly, the First Regional Consultation on the Revision of the International Health Regulations with the National IHR Focal Points was held in the WHO Regional Office from 13 to 14 April 2004. This meeting reviewed the draft revised IHR document and identified key issues, concepts and definitions that need further clarifications, which were forwarded to the IHR Revision Project Team in WHO/HQ. Moreover, it recommended conducting national level consultations on the proposed IHR document in each Member Country, with the involvement of other concerned sectors of the government.

Distinguished participants, based on the recommendations of the First Regional Consultation Meeting, all Member Countries in this Region have conducted national consultations on the proposed IHR. I believe these were conducted with the full and active participation of all national stakeholders.

Similar consultations on the proposed revision of the IHR were also held in all other WHO Regions. SEARO had the opportunity to participate at the regional consultation in WPRO, and learn from their experience.

Likewise, WPRO had participated in our own First Regional Consultation on the proposed revision of IHR.

Such bi-regional cooperation is important due to the proximity of the Member States of both the regions, geographically, culturally, and socio-politically.

We have also been working closely with our colleagues in WHO headquarters in this regard.

These regional and national consultation meetings, while appreciating the importance of the revised regulations, have identified a number of important issues, concepts and terminologies that need further clarification and discussions. This is necessary to
ensure that the Regulations are not only revised on schedule with as much consensus as possible, but are also implemented effectively.

Some of the significant issues identified at the various regional and national consultations on the proposed IHR document include:

1. The need for clearly defining the strategic level, authority, and allocation of functions of national IHR Focal Points and the support they need.

2. The scope of the International Health Regulations, with regard to public health emergencies of international concern, as spelt out in the revised IHR also raised considerable debate. The issue was whether non-biological hazards (chemical and radiological) should be included or whether the IHR should be limited to infectious diseases and diseases of unknown aetiology. This may need to be further discussed.

3. Refining the decision instrument to determine public health emergencies of international concern (PHEIC), with suggestions to include lists of disease conditions.

4. Clarifying some of the definitions used in the legal document such as “excessive measures”; “affected areas”, and “public health measures”.

5. Outlining clear mechanisms for notification of public health emergencies of international concern by concerned national authorities to the World Health Organization.

I am sure many more issues would have been raised at various national workshops. These may require further clarification / deliberation, in terms of reservations or concerns you may have from your own national perspectives.

Members of the secretariat as well as the resource persons from the Regional Office, WPRO and WHO Headquarters will be happy to provide you with the required technical support in this regard.

Distinguished participants, while it is clear that the International Health Regulations need to be revised, we need also to review existing core capacities and facilities vis-à-vis those required to implement the revised IHR.

Keeping this in mind, we have set aside a session to review existing core capacities in our Member States and to identify areas that require strengthening and support. In this session, we will critically assess and discuss existing strengths, gaps and needs with regard to core capacities for disease surveillance, early warning on outbreaks, epidemic preparedness, notification and response at national, sub-national, district and community levels. The discussions should also identify the required capacities to undertake public health measures at ports of entry and exit as per the revised Regulations.
Distinguished participants, colleagues, I look forward to your deliberations in terms of reviewing issues and concerns on the proposed IHR document, such as definition of a specific term in the articles, possible legal implications, perceived sovereignty issues or scope and the role of various agencies. In addition, your suggestions to strengthen the core capacities required for effective implementation of the revised IHR, would be most appreciated.

I wish you all fruitful deliberations and a pleasant stay in New Delhi.

Thank you.
Annex 5 – Detailed list of IHR articles and annexes with specific comments

This annex lists detailed comments and suggestions from discussion groups.

Article 1 Definitions

- **Affected area** – Should refer to the smallest geographical area for recommended measures
- **Affected** – Definition should include “animals” also
- **Baggage** – Should clarify whether this includes both accompanied and unaccompanied baggage. Also review whether the term “Personal effects” is widely understood or a better definition might be used
- **Contamination** – Definitions seems incomplete. Should it refer to “biological, chemical or radionuclear substances”. There was discussion as to whether “public health risk” needed to be included as part of this definition
- **Disease** – Should include “health condition” as well as illness
- **Event** – Should include “health condition” as well as disease unless definition of disease is expanded as suggested
- **Health authority** – The term “local” seems unnecessary in this definition
- **Isolation** – Definition should include “animals”. This definition should also refer to “quarantine” if this is taken to be a specific form of “isolation” for the purpose of these regulations.
- **Medical examination** – Definition should include “by authorised personnel” or similar phrase to make it clear that this examination does not necessarily need to be performed by a medical doctor.
- **National IHR focal point** – Review what term should be used when referring to the “centre”, “body” or “entity” that takes this role.
- **Point of entry** - This definition should perhaps include the terms “legal” or “designated”
- **Port** - Term could be extended to include “Dry Port” or “Land Port” to cover land crossings that function as ports. Alternatively, a separate definition of Ground crossing could be included in this article.
- **Suspect** – Include “animals” in this definition
- **Traveller** – Should specifically include “Crew members”
- **Public Health Emergency of International Concern** – Should be included in the definitions section

Article 2 Purpose

- There was discussion as to whether the term “traffic” should be replaced with “travel and trade”

Article 3 Communications
Article 4 Surveillance
• No comment

Annex 1 A. Core capacity requirements for surveillance and response
• Section 3(a) - The time limits for assessment and notification were discussed – 24 hours seems too little time, 48 hours would be more realistic
• Section 3(d)(e)(f) - Rapid communication links need to be established or developed. As with all of the capacities listed here, some countries will need assistance with this work.

Article 5 Notification
• There was discussion regarding the need for a disease list to supplement the decision instrument (see under list of major issues)
• Section (2) the words “such times” seem unnecessary and could be deleted
• Section (2) need to add “or” after sub-sections a,b,c,d,e
• The ability to comply with this article will depend on the country’s core capacity

Annex 2 Decision Instrument
• No comment

Article 6 Consultation
• No comment

Article 7 Information
• Section (2) – This needs an additional subsection (c) to cover goods that may be contaminated by chemical and radionuclear contaminants
• Section (4)- Should probably specify the time delay for informing WHO of the health measures being implemented.

Article 8 Verification
• Should this process also refer to “clearing” false rumours as well as verifying those that are true?
• It seems inconsistent that this article refers to the “health administration” “ rather than the national IHR focal point.

Annex 3 Processes for determining a PHEIC and issuing temporary recommendations
• There should be representation from the affected country or region on the emergency committee
• There should be provision for the affected country to request an end to temporary recommendation

Article 9 Determination of PHEIC
• No comment

Article 10 Response
• Section (3) - On-site assistance should be at the request of the member state. It was recognised that in reality WHO needs to carry out on-site investigations in collaboration with member states. The wording of this section needs to be amended to reflect that reality.

Article 11 Temporary recommendations
• Section (1) – There need to be sufficient mechanisms for consultation with member states and affected organisations built into this article and/or Annex 3.

Article 12 Standing recommendations
• No comment

Article 13 Health administration
• Section (a) - It will be difficult to develop and maintain all of the capacities described in annex 1 for all land crossings

Article 14 Airports and Ports
• Section (1), (2), (3) - Appear reasonably but it is not clear how these minimum standards will be verified.
• Section (5) – Since it is not mandatory to have WHO certify airports and port, it is not clear why this paragraph is included.

Annex 1 B Core capacity for designated entry points
• Section 2(b), (c) – Need to clarify the terminology relating to the isolation of suspect travellers (quarantine). Quarantine is a necessary tool for diseases such as SARS and yellow fever, so it should be clearly defined and its role recognised.

Annex 4 Technical requirements for conveyances and operators
• Ship Sanitation Control Exemption Certificate - Suggest adding the following information requirements: name of the ship and its registration/IMO number; type and tonnage of ship; name of the port and authority’s name; and type and condition of animals.

Article 15 Ground crossings
• It will be necessary to develop a clear approach to defining what is meant by “sufficiently important” in this context.

Article 16 Health authority
• Section (3), (6) - Suggest adding “animals” to the list of people and things that are included in these lists.
• Section (5) - It is suggested to include consideration of other existing international regulations in this section.

Article 17 General provisions for information, examination & inspection
• Agreeable

Article 18 General provisions for conveyances and conveyance operators
• Agreeable

Annex 5 Specific measures for vector-borne diseases
• Agreeable

**Article 19 Ships in transit**
• Agreeable

**Article 20 Affected conveyances**
• Agreeable

**Article 21 Conveyances at points of entry**
• Section (5) – This currently refers only to the aircraft. Suggest include its application to ships as well

**Article 22 Surveillance of travellers**
• Agreeable

**Article 23 Medical examination, vaccination or other prophylaxis**
• The terms “Vaccination” and “Prophylaxis” should be defined as has been done for the term “Medical examination”.
• Section (1) – In situation where WHO recommendations are inadequate or not available, (e.g. newly emerged infections) the country should have flexibility to implement necessary precautions

**Article 24 Goods in transit**
• Agreeable

**Article 25 Container and container loading areas**
• Additional guidelines are probably needed to provide more detailed information on keeping container loading areas free from infection

**Article 26 General provisions for health documents**
• Agreeable

**Article 27 Certificates of vaccination or other prophylaxis**
• There was some discussion about whether this article should include reference to animals or whether this area was adequately covered by provisions in animal health law

**Annex 6 Vaccination, prophylaxis, and related certificates**
• The certificate must be completed in English. There should not be an option of completing it in French.

**Annex 7 Requirements concerning vaccination or prophylaxis for specific diseases**
• Agreeable

**Articles 28 Maritime declaration of health**
• Agreeable

**Annex 8 Model of maritime declaration of health**
• The following additional questions are suggested: Are there any animals on board as cargo or pets? Are there any stowaways on board?
Article 29 Health part of the aircraft general declaration

• Agreeable

Annex 9 Health part of the aircraft general declaration

• The words “if required” should be deleted from the section “Signature, if required”

Article 30 Bills of health

• The term “bills of health” needs to be defined

Article 31 Charges for medical examination, vaccination or other prophylaxis

• These charges should be left to individual countries to decide

Article 32 Certificates on measures applied to travellers and their baggage

• Agreeable

Article 33 General provisions (initiation and facilitation of measures)

• Section (1) Suggestion was made that the words “within their capacity” be added so that this provision reads: “Health Administration shall facilitate the efficient and effective implementation within their capacity of WHO’s verification and response activities under these regulations.”

Article 34 Excessive measures

• Discussed and endorsed the article.

Article 35 Cessation of full implementation of measures

• Discussed at length and have endorsed it. The group felt that while it is not easy to define what constitutes an excessive measure, it is important to have consultations and WHO advice on public health measures. In situations where such measures taken by a member state are “excessive”, WHO should provide advice on the recommended measures.

Article 36 Rights of persons

• This article is related to the rights of persons regarding public health measures. The group discussed experiences from yellow fever, SARS, avian influenza, and how this article relates to measures that may be required and the need for informed consent.

• The groups suggested a provision should be included for alternative measures when there is no consent of the individual.

Article 37 Migrants, nomads, seasonal workers or persons taking part in periodic mass congregations

• The group endorsed the article with some suggestions. While there may be operational difficulties in some instances it is mainly applicable in mass congregations like pilgrimages.

• Section (1) - Suggest include “refugees” to the list of categories

• Section (2) - Hygiene on conveyances, i.e. ships, aircraft, buses, needs to be standardised for other circumstances as well those that apply under this article.
• Section (3) – There was comment that the wording did not make clear whether it refers to the category of people listed above or to the required health measures. Suggestion: rephrasing was “WHO may make temporary and standing public health recommendations appropriate to the circumstances in consultation with the relevant institutions”

Article 38 Persons enjoying diplomatic status

• While the group endorsed this article, there was some concern about its consistency with provisions of the Vienna convention. This point needs further investigation by the IHR revision team.

Article 39 Transport of biological materials

• This article was endorsed. The group suggested that this article make reference to guidelines on handling specimens and bio-safety procedures.

Article 40 Infection control

• The intent of this article was supported. It was suggested that the term “health care settings” needs to be broadened to include other high-risk settings such as laboratories and points of entry and exit.

Article 41 Information sharing during a suspected intentional release

• The group endorsed the article. Concerns were raised about the difficulty of implementation and getting immediate information.

• “Accident releases” of harmful biological, chemical and radionuclear agents are likely to be more common than “intentional releases” and potentially just as likely to constitute PHEIC. Reporting of such events should also be covered by the IHR in this or another article.

Article 42 Arrangements between states

• The group endorsed the article as a whole as it benefits all the member states and builds upon existing arrangements. However, there is a need for clarification of the legal implications of this article for other arrangements such as bilateral memoranda of understanding.

Article 43 Armed forces

• The group endorsed this article with a suggestion of possibly including “police” as in “armed forces and police”

• It was also suggested that this phrase be amended to require these measures during public health emergencies because such measures are sensitive and difficult to apply on a routine basis. The wording would then have the following phrase added to the end “…during public health emergencies”.

Article 44 Reporting

• Acceptable as drafted

Article 45 Review

• Acceptable as drafted

Annex 10 The Review Committee

• Section (1) - The functions of the Review Committee were supported
• Sections (2)-(6) - There was some concern regarding composition of the committee. It should include experts from other related fields, as well as public health experts, and regional representation. It should operate in a transparent manner (section (2) provisions should cover this concern)

• The frequency of meetings of the review committee should be explicit. To carry out its review function (Article 45 (a) and Section 1(a) of Annex 10) it should probably meet at least one a year for the first 5 years to produce an annual review of the functioning of the regulations and annexes.

• Section (14) – There should be a specified time limit for the review committee to provide advice on disputes

• Suggest inserting a clause in annex 10 providing for expedited proceedings depending on the urgency of the circumstances

Article 46 Amendments and additional annexes

• Sections (1) – Presumably the Review Committee may also recommend amendments of both articles and annexes to the Director General. This point should perhaps be stated explicitly.

• Section (2) - There was discussion as to whether the executive board (EB) should be able to adopt amendments to the annexes on its own without referral to the WHA (unlike changes to articles which must be submitted to the entire WHA)

Article 47 Settlement of disputes

• The provisions of this article do not appear suitable to cover disputes member countries have with WHO

• The group wondered whether there were any other mechanisms for making binding settlements other than by asking for this option at the time of requesting arbitration (Section (3)).

• Section (2)(3) - There should be a time limit for advice on settlement of disputes by the Review Committee in clause 2 and arbitration in clause 3

• Section (4) – Does this section need to make explicit reference to disputes resolved in accordance with clause (2) and (3)?

Article 48 Existing conventions, regulations and similar agreements

• Generally acceptable as drafted

• Section (1) – Should make explicit that if a country does not sign the new IHR, the 1969 IHR still apply

• Section (2) - Add explanatory footnote to indicate it’s applicable only to those who signed it. WHO should make the Pan American Sanitary Code provisions which remain in force available to all member states

Articles 49- 51 Period for rejection or reservations; reservations; withdrawal of rejection or reservation

• Generally acceptable. WHO should ensure reservation is addressed in the earliest WHA.

Article 52 Entry into force
Member States may not be ready to implement the full IHR by January 2006 due to capacity limitations. The group would like the following options considered:

- Changing the implementation date to June 2006, and/or
- Adding a provision allowing phased implementation of specific components of the revised IHR. This option could allow delayed implementation of limited parts of the IHR, notably the sections on core capacity.

**Article 53 States not members of WHO**
- Acceptable as drafted

**Articles 54 Notification by the Director-General**
- Acceptable as drafted

**Article 55 Original texts**
- WHO should assist Member States by translation of IHR documents into their own languages.