July 9, 2004

Japan's comments on the first draft of the proposed revision of the International Health Regulations (IHR)

I General comments

1. Principles of the IHR and urgent need for a new IHR

Asian countries including Japan experienced the SARS outbreak last year. Fortunately, we did not have any cases in Japan, but we strongly felt the need for a revised IHR.

Japan therefore fully endorses the fundamental principle of the IHR, which is to provide maximum security against the international spread of disease while avoiding unnecessary interference with international traffic.

The avian influenza outbreak early this year also reminded us of the urgent need for the IHR to be in complete form as soon as practicable, which will require revision of domestic laws concerning quarantine.

2. Scope of the IHR

Japan has difficulties in supporting the inclusion of diseases caused by chemical or radionuclear material as the main scope of the IHR.

We fully agree with the argument that when an event is initially detected, there will be some cases that we cannot distinguish as intentional or unintentional. Therefore, we suggest that the IHR should be ready to detect "unknown" diseases that might possibly be chemical, nuclear or the intentional spread of pathogen. But we do not think it is practical to design the IHR to detect and respond to known chemical and radionuclear incidents. We believe this is in line with the resolution adopted in the 56th WHA.

Response to emergencies associated with biological, chemical and radionuclear materials is closely related to the domestic and international management of these materials, which commonly international organizations as well as domestic ministries other than the health sector -
such as police, military forces, economy, transportation, science and technology industries – are in charge. Thus, if the IHR made response to chemical and nuclear incidents its objective, a health ministry may no longer remain the responsible agency and will be forced into time-consuming consultations, since the current IHR draft seems insufficient to handle a chemical or nuclear event.

We would like to make it clear that it is not that we are neglecting the need for an international response to emergencies, but we support the idea of putting the IHR in practice as soon as possible, prior to broadening the notion of the IHR, now that we are facing present threats of emerging and reemerging infectious diseases such as SARS, highly pathogenic avian influenza, and viral hemorrhagic fever.

We believe it is necessary to make further comments if it would be decided that diseases caused by chemical or radionuclear material were included into the scope of IHR, and in such case, we would like to make reservation to make such comments on the article related to the diseases.

3. Addition of diseases list

The revised draft IHR uses an algorithm to determine what constitutes a PHEIC, which is subject to interpretation and might not in all instances result in the notification of all diseases we believe should be subject to notification. There are diseases we want to detect even single cases such as SARS. Japan studied this issue intensively when we revised our national law, and developed the current surveillance system which is a hybrid system.

In addition, since our domestic law concerning quarantine is based on the current IHR with a disease-specific list, it would be more desirable in terms of policy continuity to have one, and to make it subject to periodic review for relevance and currency.

4. National sovereignty

We understand that the IHR does not supercede national sovereignty; therefore the IHR cannot allow any entity, including the WHO, into a
country for disease investigation if that country does not accept it. We consider the current IHR to be clear on this point. If such a case arises, the IHR needs some mechanism that will not undermine the principle of sovereignty but still ensure the principle of the IHR.

II Specific comments

1. The reference to events associated with chemicals and radionuclear materials should be removed from the definition of ‘public health emergencies of international concern (PHEIC).’

【Contents】
Page 2, Foreword
In the fourth line of the seventh paragraph, delete the phrases ‘chemical or radionuclear materials’.

Page 4, Article 1
In the second line of the second paragraph, delete the phrase ‘contamination’

Page 5, Article 1
In the second paragraph, the definition of ‘disease’ should be revised to remove the reference to an illness caused by chemical or radionuclear sources and should be limited to ‘an illness caused by or suspected to be caused by a biological source’

Page 7, Article 5-2(d)(6)
In the second line, delete the phrase ‘contamination’

Page 8, Article 5-2(e)
In the second line, delete the phrase ‘contamination’

Page 10, Article 13(c)
In the second line, delete the phrase ‘contamination’

Page 11, Article 14-3(a)
In the second line, delete the phrase ‘decontamination’

Page 11, Article 16-1
In the third line, delete the phrase ‘contamination’

Page 11, Article 16-3
In the second line, delete the phrase ‘decontamination’

Page 12, Article 18-3
In the third line, delete the phrase ‘contamination’

Page 14, Article 21-2
In the sixth line, delete the phrase 'decontamination'.
In the seventh line, delete the phrase 'contamination'.
Page 15, Article 25-2
Delete the phrase 'contamination'.
Page 16, Article 28-4(b)
In the second line, delete the phrase 'contamination'.
Page 17, Article 29-3(b)
In the second line, delete the phrase 'contamination'.
Page 18, Article 41
In the first line, delete the phrases 'chemical or radionuclear'.
Page 19, Article 42-1(f)
In the first line, delete the phrase 'decontamination'.
Page 27, Annex 1-B-2(g)
In the third line, delete the phrase 'contamination'.
Page 29, Annex 2-1-2
Delete the tenth paragraph 'Release into the environment of a chemical or radiological agent that has contaminated or has the potential to contaminate a population and/or a large geographical area.'
Page 30, Annex 2-2-4
In the first line of the third paragraph, delete the phrases 'chemical or nuclear'.
Page 30, Annex 2-3-7
In the second line of the fifth paragraph, delete the phrase 'decontamination'.
Page 35, Annex 4 Section 5
In the seventh line, delete the phrase 'contamination'.
Page 36, Annex 4 Section 5
In the ninth line, delete the phrase 'contamination'.
Page 36, Annex 4 Section 5
In the tenth line, delete the phrase 'decontamination'.
Page 36, Annex 4 Section 5
In the eleventh line, delete the phrase 'contaminated'.
Page 37, Annex 4 Footnote 1
In the first line, delete the phrase 'contamination' and the phrase 'chemical' in the second line.
Page 37, Annex 4 Note
In the second line, delete the phrase 'contamination'.

As stated in the general comments above, including regulations concerning response to emergencies associated with chemical or radionuclear materials seems to exceed the fundamental principle of the IHR. The point is that although we fully understand the significance of international response to public health emergencies regardless of causes, broadening the notion of PHEIC to include emergencies associated with chemical and radionuclear materials is likely to require too many changes, both domestically and internationally, which we fear will hinder the prompt enforcement of the revised IHR. Another point we would like to stress is that our proposal is not to exclude protection from new and future public health emergencies. Notification of all the events potentially constituting a public health emergency (see Article 5) will serve the purpose of protection from new and future public health emergencies all the same.

A diseases-specific list is needed in addition to an algorithm. We propose the following list be added to Annex 2 to complement the algorithm.

Cholera
Plague
SARS
Smallpox
Viral hemorrhagic fevers (Crimean-Congo, Ebola, Lassa, Marburg)
Yellow fever

The revised draft IHRs uses an algorithm to determine what constitutes a PHEIC, which is subject to interpretation and might not in all instances result in the notification of all diseases we believe should be subject to notification. Japan studied this issue intensively when we revised
our national law, and developed the current surveillance system, which is a hybrid system. In addition, since our domestic law concerning quarantine is based on current IHRs with a disease-specific list, it would be more desirable in terms of policy continuity to have one, and to make it subject to periodic review for relevance and currency.

The pathogens on the list are designated in our domestic quarantine law in terms of seriousness, capacity for widespread outbreak, and need for international restrictions. For that reason, we are confident that the list will also serve the purpose of the revised IHRs.

3. The role expected of the National IHR Focal Point needs further clarification. In addition to the main role of enjoying the responsibility and authority of communicating directly with the WHO in the process of national policy-making, it needs to be made clear that it is not necessarily within the role of the National IHR Focal Point to deal with technical information on IHR.

[Contents]
Page 5, Article 1
Add the sentence ‘The National IHR Focal Point may or may not serve as an information centre on the technical aspects of IHR’ to the definition of ‘National IHR Focal Point.’

[Rationale] The scope of the role of a national IHR focal point is subject to interpretation. Countries may find it difficult to distinguish information that is essential to national policy-making from rumors which lack evidence in a situation where any information, regardless of credibility, gathers at the health administration.

4. When the WHO detects evidence of a possible public health emergency of international concern and requests information thereon, it should be the right of the State concerned to ask for due information supporting the request.
[Contents]
Page 9, Article 8.3(a)
Add the sentence 'which the WHO shall provide the information thereon or its source at the request of the State concerned' at the end.

[Rationale] Since this article entitles the WHO to request information from a State based on reports from sources other than notifications, sharing information that gives grounds to the WHO's request and mutual understanding thereon should be essential. Also, excessive requests for information can be quite a burden to a State, which needs certain consideration.

In determining that a certain event constitutes a public health emergency of international concern, the WHO should verify the certainty of the determination by providing the information that it is grounded on.

[Contents]
Page 9, Article 9.2(a)
Add the sentence 'providing due information that gives ground to the determination'

[Rationale] It is of great benefit to the State within whose territory, as determined by the WHO, PHEIC is occurring to share information with the WHO in order to take measures to avoid confusion resulting from not being informed of the process and grounds of the WHO determination.

6 The term of validity needs to be specified as to temporary and standing recommendations.

[Contents]
Page 33, Annex 3 Section II 11
Specify a term of validity of a temporary recommendation.
Page 48, Annex 3 Section V 16(0)
Specify a term of validity of a standing recommendation.

[Rationale] Temporary and standing recommendations need periodic reviews to ensure that they are still scientifically valid and meet operational
requirements. Therefore it may be desirable to set up a standard as to the term of validity.

7 The general provisions on departure inspection require further discussion.

[Rationale] While we fully recognize the importance of inspection on departure, there seems to be a need for further discussion as to details such as causes, areas and a commencing date. In addition, considering the need for various preparations concerning legal problems, infrastructure and manpower, it seems unlikely to expect a discussion of such details on the same day of the IHR's enforcement.

8 Other points which need further discussion
   - "Reservoir" needs to be defined in Article 1 and should be differentiated from "vector" in usage. (Art. 1)
   - Consideration should be given to phased implementation for some of the new systems such as departure inspection and container surveillance, considering the need for changing national legislation and the time needed for capacity building. (Art. 17 & 25)
   - WHO needs to explain specific figures on information, materials and samples, which WHO requires to be provided. For example, if materials contain original substances which caused diseases, it is necessary to deal with them very carefully. In addition, if materials are obtained from human body, like blood, we should have problems of confidentiality, intellectual property and ethics. (Art. 41)