



WORLD HEALTH ORGANIZATION

INTERGOVERNMENTAL WORKING
GROUP ON REVISION OF THE
INTERNATIONAL HEALTH REGULATIONS
Provisional agenda item 3

A/IHR/IGWG/4
7 October 2004

Review and approval of proposed amendments to the International Health Regulations: explanatory notes

1. This document has been prepared in response to requests by several Member States during the consultations on revision of the International Health Regulations. It provides an explanation to the main changes made to the working paper issued in January 2004,¹ which resulted in the draft revision.²

MAIN ISSUES AND KEY AMENDMENTS

2. This section explains the changes made in response to major concerns of a large number of Member States or which are, by their nature, cross-cutting and not tied to a single article.

Scope

3. The scope of the current International Health Regulations, adopted in 1969, is limited to three “notifiable diseases” (see paragraphs 7 and 8, below). Extending the scope to cover unknown or unforeseeable public health threats was one of the main reasons for revising the Regulations. The draft revision defines “disease” as an illness “caused by biological, chemical or radionuclear sources”, thereby expanding the scope of the Regulations to other infectious diseases and to events and public health threats deriving from chemical and radionuclear sources. This extension beyond the range of the existing Regulations is justified on the grounds that the release of chemical or radionuclear agents often manifests itself at the outset through symptoms or signs, sometimes even before their cause is known. The ability of the international community, in particular through WHO’s coordination, to obtain a reliable assessment of, and to respond to, potentially grave health threats would be impaired if the scope of the Regulations were limited to diseases that were already identified as being caused by infectious agents only. For these reasons, the same definition of “disease” has been retained in the draft revision as in the January 2004 working paper. Several Member States have expressed two concerns at this extension of scope. The first is because it represents a qualitative change from the historical focus of the Regulations and the international sanitary conventions before them. The second, and main, concern is the presence, in the chemical and radionuclear fields, of several international instruments and organizations dealing with accidents and other forms of pollution that result in the

¹ Document IGWG/IHR/Working paper/12.2003.

² Document A/IHR/IGWG/3.

release of chemical or radionuclear agents into the environment. An unqualified extension of the Regulations' scope and of the authority of WHO to act in those two areas could lead to conflicts with or duplication of other international instruments and the activities of other competent international organizations. Member States cited in particular the activities of IMO and IAEA in marine pollution and radionuclear emergencies, respectively.

4. In revising the January 2004 working paper, the Secretariat has sought to meet these concerns while preserving a sufficient breadth of scope to ensure that the revised Regulations are an effective tool, particularly for the notification of and the response to various threats to global public health. Analysis of existing international instruments, supported by the outcome of consultations with the relevant international organizations, led to the conclusion that it would be difficult to draw a sharp line between events caused by infectious agents and those caused by other agents. For example, accidents leading to chemical marine pollution fall under several international agreements and the competence of IMO, which has the authority to coordinate the international response thereto. However, the same cannot be said with regard to land-based chemical accidents, for which there is no comparable legal framework. Moreover, in both the chemical and radionuclear fields, the existing instruments are not necessarily comprehensive and do not always adequately address the health dimension of accidental or other forms of release.

5. In view of the foregoing considerations, it was decided not to respond to questions about the broader scope of the draft revised Regulations through a dedicated Article that used as a dividing line the nature of the agent causing the health threat or the existence in principle of other relevant international instruments. Rather, the draft revision tackles the issue of competence and respective roles flexibly by taking into account the variety of possible circumstances. Specifically, Article 12 requires WHO to coordinate its activities with other international organizations or bodies, in particular when the notification or verification of, or response to, an event falls within their competence. This generally worded requirement reflects what happens in practice in cases of overlapping mandates over the same event; the agencies concerned coordinate their respective activities on the basis of specific arrangements or on a case-by-case basis. For WHO, the overriding concern governing such coordination should be to ensure adequate protection of public health. Article 15 of the draft revision requires the Director-General also to consider relevant international standards and instruments, and activities undertaken by other relevant international organizations and bodies, when deciding upon recommendations. Furthermore, Article 58, paragraph 1 introduces criteria for the interpretation of the Regulations that would assist States Parties and WHO in reducing the possibility of conflicts with other international instruments.

6. Finally, many Member States asked the Secretariat to review the possible interaction between the Regulations and other international agreements, and to furnish a list of such agreements. An analysis of these relations and listings of the agreements reviewed are available separately.¹

¹ Document A/IHR/IGWG/INF.DOC./1.

List of diseases to supplement the decision instrument for the assessment and notification of events that may constitute a public health emergency of international concern¹

7. Member States expressed different views regarding lists of diseases, ranging from a strong desire to retain a fixed list of diseases for mandatory international notification to not wanting any such list in the text. Given these divergent views, a compromise has been introduced that maintains the centrality of the decision instrument set out in Annex 2 of the draft revision, while indicating those diseases that, by virtue of their epidemiological characteristics and severity, present particular concern globally. A list of three diseases for mandatory notification is proposed, based on the judgement that a single confirmed case of any of the three, anywhere in the world, would always meet the criteria in Annex 2 and require notification; these have been termed “notifiable diseases”. A second list of diseases that should always trigger an assessment of the event using the decision instrument and, where indicated by that assessment, notified to WHO has been introduced in the draft revision (Annex 2, Part B); this list is based on comments made by Member States.

8. It is important to note that many other events involving the occurrence of diseases also require notification to WHO as events that may constitute a public health emergency of international concern. The lists of diseases are provided to support Member States and aid the use of the decision instrument mandated in Article 5 and Annex 2.

WHO recommendations

9. The issuance by the Director-General of public health advice and guidance in the form of recommendations is seen as a crucial means of coordinating and orientating the international response to events and public health threats. The recent precedents of WHO’s recommendations in response to the outbreaks of severe acute respiratory syndrome and avian influenza (due to the H5N1 strain of Influenzavirus A) have confirmed and validated the effectiveness of this approach.

10. Several provisions in the January 2004 working paper prohibited States Parties from taking certain actions in the absence of a WHO recommendation (see, for example, Articles 19, 21, 23 and 24 in that text). However, many Member States felt that these references to WHO recommendations, and their interplay with binding prohibitions, created considerable confusion and could lead to undesirable ambiguities in the legal status of measures introduced by States Parties which exceeded or differed from those recommended by WHO. Concerns were also expressed that limiting the authority of States Parties to introduce additional health-related measures through dependence on WHO’s issuing recommendations concerning a particular event unduly restricted the sovereignty of States Parties. In response to these concerns, in particular to avoid creating confusion or ambiguity that could weaken the practical effectiveness of recommendations, these references have been eliminated, with the sole exception of a bracketed reference in Article 31 in the draft revision, whose justification is clarified in the explanation to that article below.

11. Concerns were also expressed that the process to be followed by WHO in issuing, modifying or terminating temporary or standing recommendations was not sufficiently transparent and accountable, and that the procedure foreseen in the January 2004 working paper did not allow States Parties that could be affected by those recommendations to participate adequately in the process. That text has,

¹ See document A/IHR/IGWG/3, Annex 2.

therefore, been modified in various respects, which are also explained below under the specific articles concerned. The most important change is the introduction of new Article 15, which specifies the principles and criteria to be considered by the Director-General when issuing, modifying or terminating recommendations. Some of the criteria are similar to those used in other relevant international instruments, concerning measures that may have an impact on international traffic, thus facilitating synergy between corresponding processes.

12. The procedures for the issuance, modification and termination of recommendations have also been revised, in order to respond to Member States' requests for more clarity, transparency and interaction. At the same time, it has been deemed important to preserve the basic approach used in the January 2004 working paper, namely, that the committees providing scientific advice to the Director-General should remain technical bodies composed of individual experts rather than political bodies of an intergovernmental nature.

Additional measures

13. Several Member States requested the flexibility to implement additional health measures. New Article 39 allows States Parties to take necessary measures otherwise precluded by various articles (e.g. Articles 23, 25, 27 and 29). Article 39 includes basic requirements to ensure consistency of such measures with the purpose of the Regulations. At WHO's request, a State Party would need to provide the scientific justification for the measure. Finally, the above flexibility is additional to the possibility of undertaking actions permitted by the clause on "applicable international agreements" (see paragraph 16 below).

On-site visits by WHO teams

14. Many Member States commented that the provisions in the January 2004 working paper obliging them to collaborate with WHO, for example, in conducting on-the-spot studies, were neither acceptable nor feasible. These provisions (Article 8, paragraph 3, and Article 10, paragraph 3) have been redrafted to emphasize the supportive role of WHO in investigating and responding to events that may constitute a public health emergency of international concern. Thus, WHO is obliged to offer assistance and justify its concerns. States are not obliged to accept WHO's offer but, when declining an offer is judged to increase any risk that the event will spread to other States, WHO may share information with States Parties about the situation and the nature of the assistance that has been offered. The sending of teams of experts to affected areas is not the only type of support that WHO can offer in such situations. For example, it can be crucial that diagnostic specimens are sent rapidly to WHO collaborating centres in order to characterize adequately the nature of potentially serious health events.

Core capacities of the Member States

15. Member States expressed concern over their ability to provide in time the core capacities required for the entry into force of the revised Regulations. New language in the draft revision introduces a grace period and highlights the need for increased cooperation between WHO and States and among all States Parties to assess existing capacities and mobilize financial and technical resources to strengthen them.

Applicable international agreements

16. Member States have requested clarification of the “applicable international agreements” referred to in various articles. The phrase would apply to agreements to which the States concerned are Parties in circumstances where both the agreement and the Regulations apply. The purpose of the reference is to enable State action in a manner permitted by those agreements even if not otherwise permitted by the Regulations.

REMARKS BY PROVISION

17. This section summarizes the specific changes introduced in the draft revision compared with the January 2004 working paper. For reasons of brevity, only the main revisions are discussed. Corresponding articles in the working paper are indicated in parenthesis in the titles. Articles without any changes, or without changes requiring explanations, are not commented on.

Article 1 Definitions

“competent authority”. This term replaces “health authority” in response to the concern raised by several Member States that the latter was not necessarily the responsible entity with regard to the application of certain measures.

“contamination”. Some Member States considered the original definition circular in nature. The definition has been revised based on the generally understood meaning of the word among public health professionals.

“disease”. In response to Member States’ comments requesting recognition in the text of the threat of animal disease to human beings, the original definition has been revised accordingly. With regard to the scope of “disease”, see paragraphs 7 and 8 above.

“infection”. The definition has been revised to avoid circularity and to bring it into line with its plain meaning in public health practice.

“inspection”. This definition has been modified to provide for situations where the “competent authority” does not itself carry out the inspection but nonetheless plays a supervisory role as the ultimate responsible party.

“medical examination”. The definition of this term has been revised in order to clarify the full extent of the examination and to specify that such examinations may be either invasive (a definition of which has also been included) or non-invasive.

“public health emergency of international concern”. There was a broad consensus that, given the importance and cross-cutting nature of this expression and its cardinal role with regard to the functioning of the Regulations, it was essential to include a definition of the term in the text. The definition of this term was based on various proposals submitted by Member States.

“public health threat”. In order to avoid any potential confusion with the term “risk”, which has been interpreted in different ways by Member States, the word “threat” has been substituted for purposes of clarification.

“quarantine”. Member States expressed support for a definition of this term that, in their view, better distinguishes the isolation of “suspect persons” from that of “affected” persons.

Article 2 Purpose

Based on new language proposed by a number of Member States, the purpose has been revised to further specify the objectives sought by the Regulations.

Article 3 Responsible authorities

The revision of this article (previously entitled “Communication”) endeavours to clarify the functions of the National IHR Focal Points and their relationship with WHO IHR Contact Points. In addition, the draft revision refers (with few exceptions) mainly to “States Parties” as the subject of obligations and rights under the Regulations in order to avoid references to a number of different national authorities. Consequently, additional text has been introduced in this article dealing with the designation by States Parties of the authorities responsible for the implementation of the Regulations, which were referred to as health administration(s) in the January 2004 working paper.

References to “competent authorities” have been retained in other articles where it was felt that referring to “States Parties” could be confusing, in particular when dealing with the implementation of health measures in a specific situation.

Article 4 Surveillance

Member States expressed support for the insertion of a grace period during which to build surveillance and response capacities and for express language stating WHO’s obligation to provide technical assistance and training to countries in these capacity-strengthening activities. Some Member States requested that their role in “assessing” information be recognized in the text.

Article 5 Notification

A new sentence has been added to the provision to link it more clearly with the assessment of events introduced in the preceding article. A 24-hour time frame is now specified in paragraph 1. For clarity, paragraph 2 in the January 2004 working paper has been moved to a separate article (Article 9) providing for WHO’s use of the information it receives from notifications and other sources.

Article 7 Other reports

Paragraph 1 has been revised on the basis of comments received to clarify that WHO shall attempt to obtain verification from the State Party concerned before taking action on reports from sources other than notifications or consultations. Paragraph 2 now specifies that reporting must be done within 24 hours of receipt of evidence of a public health threat, and it focuses on the reporting of exported or imported cases of disease and vectors, but not “suspects”. Furthermore, in light of the existing reference to public health threats that may cause international spread of disease, which is applicable to all reporting under the paragraph, the additional reference to a possible public health emergency of international concern was deleted. In paragraph 3 (formerly paragraph 4) the number of travellers who must be delayed or refused entry or departure in order to constitute “significant interference” has been left unspecified, in brackets, for consideration by Member States. Finally, former paragraph 3 has been moved to Article 9 and consolidated with other provisions on WHO communications.

Article 8 Verification

The fact that verification is done by the States instead of WHO has been clarified in paragraph 1. Paragraph 2 includes a 24-hour period in which States Parties are obliged to acknowledge WHO requests for verification. Paragraph 3 has been simplified and amended in accordance with the comments reviewed above in paragraph 14. Subparagraph 3(a) in the January 2004 working paper has been omitted, as its substantive content is now included in paragraphs 1 and 2 of this Article.

Article 9 Provision of information by WHO

Paragraph 3 of former Article 7 and paragraph 2 of former Article 5 received numerous requests from Member States for clarification and further detail, particularly with regard to confidentiality and related issues, and have been consolidated in this Article.

Article 10 Determination of a public health emergency of international concern (formerly Article 9)

The provision has been revised in response to comments requesting a clear and transparent procedure and appropriate information to, and consultations with, the State affected by the event. Consequently, paragraphs 2 and 3 regarding the procedure to be followed to determine the occurrence of a public health emergency of international concern have been transferred here from Annex 3 in the January 2004 working paper. New paragraph 4 clarifies the factors and considerations which the Director-General has to take into account in determining the occurrence of a public health emergency of international concern.

Article 11 Response (formerly Article 10)

The grace period for Member States to meet the response capacity requirements (see Annex 1) has been included in paragraph 1. Paragraph 2 has been redrafted to reflect WHO's obligation to support Member States in responding to all public health threats at their request, and not only to public health emergencies of international concern. Paragraph 3 has been amended in accordance with the comments analysed in paragraph 14 above. Paragraph 4 has been inserted in response to comments by Member States and paragraph 6 has been moved to this Article and adapted from paragraph 2 of former Article 33.

Article 12 Cooperation of WHO with international organizations and bodies

Article 12 has been introduced in response to comments from Member States requesting WHO to coordinate its activities under the Regulations with international organizations and bodies that may be competent to deal with specific aspects of certain events. (See paragraphs 9-12 above.)

Article 13 Temporary recommendations (formerly Article 11)

Paragraph 3 has been introduced in response to Member States' concerns about the duration of temporary recommendations and the need for a periodic assessment of their appropriateness.

Article 15 Criteria for recommendations

See paragraphs 9-12 above.

Article 16 Recommendations with respect to conveyances, containers, goods, cargo and persons

This Article has been introduced in response to proposals made by several Member States for the inclusion in the body of the Regulations of a non-exhaustive list of health measures that could be recommended by WHO with regard to conveyances, containers, goods and cargo on the one hand, and to persons on the other. This Article now lists measures that appeared in Annex 4 of the January 2004 working paper, or that are based on standard public health measures that may be necessary in certain circumstances.

Article 17 General obligations (formerly Article 13)

Changes were made in accordance with the comments related to Article 3 to clarify the responsibility of States Parties in the implementation of the Regulations through a body with authority for the management of the public health issues at national ports or airports. Such a body may be governmental (whether federal, provincial or local), a private agency or another body depending on national administrative structures. Subparagraph (c) has been reworded to indicate that the requests for data referred to are non-routine.

Article 18 Airports and ports (formerly Article 14)

A reference to Article 35 has been included in paragraph 2 as the certification requirements have been moved from Annex 4 of the January 2004 working paper into the main body of the text at the request of Member States. Paragraph 4 of Article 14 of the working paper has been incorporated into paragraph 3 of this Article. A new paragraph 5 further specifies certification requirements.

Article 19 Ground crossings (formerly Article 15)

Concerns were raised by Member States regarding ground crossings. The text, however, has not been substantively modified, because the significance of the role played by ground transport in the international spread of disease is not clear. The risk associated with ground transport is normally considered to be much lower than that associated with air and sea transport.

In addition to the risk being lower, it is also much more difficult to implement appropriate measures, owing to the usually high volume of “local” and lower-risk cross-border traffic; long land borders that can be crossed at hundreds of points; and the numerous points on either side of any international border at which ground-based conveyances stop for the loading and unloading of passengers and goods.

Most traffic at ground crossings is between two States only. Consequently, bilateral agreements on any necessary health measures may be more efficient than general prescriptions in the Regulations. However, in the circumstances where Member States can identify specific crossings at which it is feasible and justified to augment public health capacities, this Article provides a legal framework to do so.

Article 20 Competent authorities (formerly Article 16)

Several Member States expressed the need to move crucial obligations previously included in the annexes to the main body of the text, and the Article reflects this. The requirement incumbent on

authorities to be prudent when applying or requiring the application of sanitary procedures is also stated in this Article, highlighting the supervisory role played by the “competent authorities”.

Article 21 Health measures on arrival and departure (formerly Article 17)

Paragraph 1 provides for examinations, inspections and information requirements that Member States may choose to impose and also refers to new Article 28 on humane treatment of travellers. Paragraph 2 expressly provides for application of additional health measures based on evidence of a public health threat. Such evidence can be used as a basis for implementation of health measures under various other articles (e.g. Articles 24, 25, 27 and 39). Article 27 describes potential responses by State Parties if a traveller does not comply with requirements for various health measures.

Article 22 Conveyance operators (formerly Article 18)

Changes have been made in order to maintain consistency and clarity over whom the obligations are directed to. Paragraphs 1 to 3 of Article 18 of the January 2004 working paper have been included in paragraph 1 of this Article. In response to comments received, some of the technical material referred to in paragraph 2 of former Article 18 has been moved from the previous draft of Annex 4 to this Article.

Article 23 Ships and aircraft in transit (formerly Article 19)

This Article has been expanded to extend its applicability to aircraft in transit.

Article 24 Affected conveyances (formerly Article 20)

In response to Member States’ comments, the draft revision clarifies that the competent authorities determine both whether a conveyance is affected, on the basis of evidence found on board during an inspection, and when the conveyance is no longer affected. The requirement that evidence must be found on board during an inspection in order to authorize health measures appears in other provisions (e.g. Articles 17, 21 and 25 and Annex 5). The revised text provides guidance for the implementation of health measures, including isolation. Paragraph 2 now clarifies the procedures to be followed where measures cannot be applied.

Article 25 Ships or aircraft at points of entry (formerly Article 21)

The revised Article deals specifically with ships and aircraft rather than conveyances generally. Based on comments received, paragraph 3 incorporates text from Article 35 of the current Regulations, which explicitly allows States Parties to determine whether arrival of the ship or aircraft would result in the spread of a disease.

Article 27 Health measures relating to admission (formerly Article 23)

Member States requested that the Regulations should indicate options for them when travellers do not consent to health measures required under this Article. Paragraph 1 replaces the reference to WHO recommendations and the Regulations generally with specific references to Article 39 and Annexes 6 and 7, pursuant to which States Parties may require in certain cases medical examinations, vaccination or other prophylaxis as conditions of admission for travellers. Paragraph 2, on informed consent, was moved here from former Article 36. New paragraph 4 allows a State Party, subject to certain protections, either to refuse admission to travellers, or alternatively, in certain limited

circumstances, to apply the aforementioned measures in the absence of consent by a traveller. Given the broadened scope of the Regulations and the options for additional health measures, the Article now also provides that medical measures must minimize risks of disease transmission.

Article 28 Humane treatment of travellers

This Article was introduced in response to comments pointing out that States Parties, when applying health measures that may affect individuals, should exercise appropriate care and minimize any discomfort or distress that may arise from measures adopted for public health purposes.

Article 29 Goods in transit (formerly Article 24)

This provision has been revised to permit greater flexibility in applying health measures pursuant to Article 39 and by deletion of the reference to WHO recommendations.

Former Article 30 Bills of health

Several Member States asked about the meaning of the term “Bills of health” or requested the introduction of a broad exception to the rule. Given the questionable usefulness of the provision, it was deleted.

Article 30 Container and container loading areas (formerly Article 25)

The redrafting has sought, first, to clarify to whom the obligations provided in this Article are addressed, and secondly, to respond to concerns over their feasibility. In addition to vectors, reservoirs have been included in this and other relevant articles in response to comments received. Paragraphs 4 and 5 have been moved here from paragraphs 14 and 15 of Annex 4 of the January 2004 working paper.

Article 31 General rule (formerly Article 26)

The issue of applying Article 39 to this Article is bracketed because of a divergence of views expressed on the appropriate degree of flexibility that should be granted to States Parties. The text concerning WHO recommendations has been retained in case the reference to Article 39 is deleted. If the reference to Article 39 is maintained, the text on WHO recommendations might be deleted as it is already reflected in Article 39. In order to minimize the possibility of conflicts with other relevant international agreements, the word “routine” has been eliminated.

Article 35 Ship sanitation certificates (formerly in Annex 4)

In line with the concerns expressed by Member States, crucial obligations resulting from the issuance of Ship Sanitation Control and Ship Sanitation Control Exemption Certificates have been moved from section 2 of Annex 4 to this provision.

Article 36 Charges for health measures (formerly Article 31)

Divergent comments were received with respect to Article 31 of the January 2004 working paper. A request was made to reintroduce paragraph 2 of Article 82 of the current Regulations in case charges were allowed. Paragraph 1 has, therefore, been placed in brackets to reflect the difference of

opinion among Member States and an adapted version of paragraph 2 of Article 82 of the existing Regulations has been added.

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

This Article was deleted in light of comments received and new articles in the draft revision, such as Article 39, which provide the necessary flexibility required by Member States wanting to tackle the issues previously dealt with in this provision.

Article 37 Charges for certificates (formerly Article 32)

Divergent views were expressed by Member States about whether certificates should be issued free of charge or on a cost-recovery basis. For this reason, the expression “free of charge” has been placed in brackets.

Article 38 Implementation of health measures (formerly Article 33)

The changes introduced in this Article as compared with Article 33 of the January 2004 working paper include transferring former paragraph 2 to Article 11 and making the title more specific. The Article has been retained in view of the importance of the principles it embodies for the pursuit of the purpose of the Regulations.

Article 39 Additional health measures

See paragraph 13 above.

Former Article 40 Infection control

The provision was deleted following comments that it was too general to provide States Parties with guidance and too potentially far-reaching to be feasible to implement. The subject matter was also considered to go beyond the generally accepted scope of the Regulations.

Article 40 Cessation or full implementation of health measures (formerly Article 35)

Based on comments received, paragraph 1 now requires States Parties, on request, to provide scientific justification for health measures they implement that vary from recommendations.

Article 41 Collaboration and assistance

Paragraph 1 of this Article has been introduced in response to several comments requesting that the draft revision should clearly provide the possibility for States Parties to collaborate with each other in a number of areas related to the implementation of the Regulations. Paragraph 2 has been introduced to specify WHO’s commitment to collaborate with States Parties in the implementation of the Regulations.

Article 42 Rights of persons (formerly Article 36)

Comments received concerning the human rights implications of the draft revision are reflected in paragraph 1 by reference to “international human rights law” as opposed to the narrower

“applicable international agreements which provide for, or protect, the rights of persons”. Paragraph 2 of the January 2004 working paper has been moved to Article 27 as it deals specifically with certain measures applicable to travellers, which are now consolidated in that provision. A new paragraph has been introduced in its place, in response to requests from several Member States for a specific provision requiring the respect of confidentiality of personal data.

Article 43 Persons enjoying immunities under international law (formerly Article 38)

This Article now ensures the implementation of appropriate health measures under the Regulations without prejudice to the enjoyment of immunities under international law. The scope of the Article has been enlarged to cover also persons other than diplomatic agents, such as senior government officials, who also enjoy such immunities.

Article 45 Information sharing during a suspected intentional release (formerly Article 41)

In response to comments from Member States, this Article now clearly states that the obligation for States Parties to provide to WHO all relevant information, materials and samples is subject to their security and law enforcement requirements.

Article 46 Armed forces (formerly Article 43)

This Article has been revised in response to requests from several Member States that States Parties should be required to ensure the compliance of their armed forces with the Regulations.

PART IX – THE IHR ADVISORY PANEL, EMERGENCY COMMITTEE AND THE REVIEW COMMITTEE

This new Part contains provisions that were included in Annexes 3 and 10 of the January 2004 working paper. Many comments received requested that the terms of reference, composition and procedure of the Emergency Committee and Review Committee should be incorporated into the main body of the Regulations. The former Annexes 3 and 10 have consequently been deleted and their contents transferred to this Part, which has been organized into three chapters dealing separately with each of the various organs.

Chapter I – The IHR Advisory Panel

Article 47 Composition

The IHR Advisory Panel was referred to in both Annex 3 and Annex 10 of the January 2004 working paper, giving the impression that each annex dealt with a different panel, and thereby creating confusion. Consequently, a new provision has been introduced expressly to regulate the establishment and composition of the Panel. Paragraph 2 has been included in direct response to requests for a more significant role for Member States in its composition.

Chapter II – The Emergency Committee

Articles 48 Terms of reference and composition; Article 49 Procedure

Articles 48 and 49 deal with the institutional and procedural aspects, respectively, of the Emergency Committee, with the text being taken largely from section II of Annex 3 of the January 2004 working paper. Article 48, paragraph 2 clarifies the duration of the tenure of Committee members and the criteria the Director-General shall follow in appointing them. Following requests by Member States, Article 49, paragraph 6 now grants the State Party concerned the right to present its views to the Committee.

Chapter III – The Review Committee

Article 50 Terms of reference and composition; Article 51 Conduct of business; Article 52 Reports; Article 53 Consideration of disputes; and Article 54 Standing recommendations

The text in this Chapter formed part of Annex 10 of the January 2004 working paper, with the Articles being based on the sections of that Annex. As a consequence, Article 45 of the working paper has been deleted. In response to comments from Member States, a new subparagraph (f) in paragraph 1 of Article 50 has been introduced in order to entrust the Review Committee with the function of considering reservations to the Regulations; and there is now a clear reference, in paragraph 5 of Article 50, to the criteria that the Director-General shall follow in appointing Committee members.

PART X – FINAL PROVISIONS

Article 55 Reporting (formerly Article 44)

Comments from Member States focused on the need for clearly established parameters and procedure for reporting by States Parties and how they would contribute to the regular review of the Regulations. Consequently, paragraph 1 now provides for periodic reports, and under paragraph 2 the Review Committee will have the responsibility for reviewing the reports, consistent with its general functions under the Regulations.

Article 56 Amendments (formerly Article 46)

Taking account of the comment made by many Member States that the Executive Board should not have the authority to amend the annexes, as suggested in the January 2004 working paper, Article 56 provides that any amendment shall be submitted to the Health Assembly for adoption. Furthermore, paragraph 2 requires that proposed amendments be communicated to States Parties four months before the Health Assembly at which they are to be considered.

Article 57 Settlement of disputes (formerly Article 47)

New paragraph 5 concerns the relationship between the dispute settlement mechanism under the Regulations and those of other international organizations or established under international agreements, and was included to address the concerns of certain Member States over possible conflicts.

Article 58 Relationship with other international agreements (formerly Article 42)

This Article, which broadens Article 42 of the January 2004 working paper, reflects requests by several Member States that the Regulations should not conflict with other international agreements whose scope may overlap with that of the revised Regulations. The approach followed in proposing paragraph 1 of this Article is explained in a separate document on relations with other international instruments.¹

Article 59 International sanitary agreements and regulations (formerly Article 48)

In light of comments received, the list of international sanitary agreements and regulations in paragraph 1 has been revised by deletion of the first three conventions cited in the January 2004 working paper, which have been replaced by subsequent and widely accepted international agreements and regulations.

Article 60 Entry into force; period for rejection or reservations (formerly Articles 49 and 52)

In response to comments received, a period of 12 months for notifying rejection of, or reservation to, the Regulations or an amendment thereto has been introduced, replacing the period of six months set in Article 49 of the January 2004 working paper. Paragraph 2 clarifies the relationship between the general entry into force of the Regulations and their status in respect of States that have rejected or made reservations to them, become Members of WHO after their adoption, or non-Member States that have accepted the Regulations. The following articles deal separately with each of those particular situations.

Article 61 Rejection

The provision, based on paragraphs 1 and 3 of Article 49 of the January 2004 working paper, was introduced in order to state clearly the legal effects of a rejection of the Regulations.

Article 62 Reservations (formerly Article 50)

The text of this Article has been subdivided so as to make it easier to comprehend the various situations contemplated. Moreover, in order to align the regime of reservations under the Regulations with international treaty practice, paragraph 5 clarifies the effects of the acceptance by the Health Assembly of a reservation.

Article 64 New Member States of WHO (formerly Article 52)

For the sake of clarity and consistency, paragraph 2 of Article 52 of the January 2004 working paper is reproduced as a separate provision. The period for notifying the rejection of, or any reservation to, these Regulations or any amendment thereto, is prolonged from six to 12 months in accordance with the period provided for current Member States under paragraph 1 of Article 60.

¹ Document A/IHR/IGWG/INF.DOC./1

ANNEX 1

Paragraphs 1 to 3 have been introduced in order to satisfy Member States' concerns that further guidance was needed on the process to be followed to meet core capacity requirements. In the response to public health emergencies of international concern at points of entry (section B, paragraph 2(b)), several Member States requested a specific reference to "affected animals" inasmuch as they pose a risk to travellers.

ANNEX 2

PART A DECISION INSTRUMENT FOR THE ASSESSMENT AND NOTIFICATION OF EVENTS THAT MAY CONSTITUTE A PUBLIC HEALTH EMERGENCY OF INTERNATIONAL CONCERN

Article 5, paragraph 1 obliges States Parties to notify WHO of all events that may constitute a public health emergency of international concern in accordance with the decision instrument contained in this Annex. This algorithm is designed for assessing the need to notify different types of events that may include:

- disease outbreaks;
- laboratory confirmation of important pathogens, where even a single case of disease may be of international concern (e.g. yellow fever in an Asian context);
- intentional release of biological agents; and
- biological, chemical or radionuclear contamination resulting in a risk to public health.

The instrument consists of a decision tree and a series of supplemental questions that will direct the assessing State in determining whether the event is serious, unusual or likely to spread internationally or to have a serious effect on travel or trade. This approach allows States Parties to take into account the context of an event when notifying WHO. Lists of diseases do not allow context to be taken into account and therefore, when used alone, are less valid as criteria for international reporting. There is, however, a small number of diseases for which a single case occurring anywhere in the world would, when subject to assessment under the decision instrument, always result in a notification to WHO, making them, in effect, notifiable diseases; in response to requests from Member States, these diseases have been identified and listed after the instrument.

The decision tree has been amended in the draft revision by the addition of a question about notifiable diseases, thereby creating two starting points for assessing whether to notify WHO: the first being about whether an event involves a notifiable disease and the second about whether an event meets two of the four criteria detailed in the subsequent sections I to IV.

PART B PARTICULAR DISEASES REQUIRING UTILIZATION OF THE DECISION INSTRUMENT

In response to other comments from, and as a further aid to, States Parties, this Part lists some diseases that do not automatically require notification but which, because of their potential rapidly to spread internationally, should always result in a State using the decision instrument to assess the need to notify WHO. This list is *not* exhaustive and there will be occasions when events associated with other diseases will also require notification; most importantly, there will be events to which no disease label can be attached that must also be notified because the nature of the event meets the criteria described in the instrument.

The instrument guides the State Party in the identification of events that may constitute a public health emergency of international concern. The determination that an event actually constitutes such an emergency is made by the Director-General in consultation with the notifying State Party (see Article 10).

When there is insufficient information available to assess an event using the instrument in this Annex, States Parties may confidentially consult with WHO, as provided for by Article 6.

ANNEX 3

MODEL SHIP SANITATION CONTROL EXEMPTION CERTIFICATE/SHIP SANITATION CONTROL CERTIFICATE

The model Ship Sanitation Control Exemption Certificate/Ship Sanitation Control Certificate has been modified to bring it in line with the model Deratting Certificate and the model of the Maritime Declaration of Health in the current Regulations. Specific changes include adding the name and nationality of the ship. This model is currently undergoing review by an expert group.

ANNEX 4

TECHNICAL REQUIREMENTS PERTAINING TO CONVEYANCES AND CONVEYANCE OPERATORS

This Annex reflects comments of Member States on the need to incorporate substantive provisions in the annexes of the January 2004 working paper into the main body of the text. For example, the provisions on ship sanitation certificates have been moved to Article 35 and those relating to health measures for conveyances, containers, goods and cargo are now in Article 16. The model sanitation certificate appears in Annex 3.

ANNEX 5

SPECIFIC MEASURES FOR VECTOR-BORNE DISEASES

This Annex maintains the existing rights and obligations for the control of vectors of yellow fever, which primarily relate to the disinsection of aircraft coming from areas where there is a risk of transmission. The revised text allows the extension of vector-control measures to other disease situations, as necessary. In response to comments received, the earlier obligation to keep container

loading areas free of vectors has been modified in paragraph 4 to the more feasible establishment of vector-control programmes. Paragraph 8 has been simplified.

ANNEX 6

VACCINATION, PROPHYLAXIS AND RELATED CERTIFICATES

Paragraph 1, as redrafted, refers only to vaccines or prophylaxis designated by WHO (through Annex 7 or a recommendation under the Regulations). Paragraph 4 now indicates that the supervising clinician can be any “authorized health worker”. Paragraph 9 has been expanded to provide additional details on contraindications and exemptions for vaccination or prophylaxis.

MODEL INTERNATIONAL CERTIFICATE OF VACCINATION OR PROPHYLAXIS

The dates required on the model certificate have been clarified: the box indicating the period of validity of a specific vaccination or prophylaxis has been modified to allow the period between vaccination and the development of protection to be taken into account when documenting the date from which the certificate becomes valid. The text has been revised in line with the changes made to paragraph 4 of the Annex.

ANNEX 7

REQUIREMENTS CONCERNING VACCINATION OR PROPHYLAXIS FOR SPECIFIC DISEASES

Paragraph 2 has been reformatted with additional information. Member States have expressed divergent views on the current requirement for designation of yellow fever vaccination centres: some believe this practice to be out-dated and unnecessarily bureaucratic, while others consider it an essential requirement to ensure the quality of vaccination and certification. Consequently, new subparagraph (f) has been introduced as a suggested compromise. An additional sentence in the final paragraph provides for health measures as an alternative to quarantine for persons exempted from vaccination.

= = =