I. GENERAL COMMENTS

It was noted that the Spanish translation is inadequate.

The Central American experience with existing bilateral and multilateral agreements was stressed and the need to consider their implications when implementing the IHR.

It was suggested that the financial and normative implications be considered in the implementation of the IHR with regard to the strengthening of core capacities as set out in the Regulations. The need for a grace period in which to attain this level of capacity was also highlighted.

The text mentions biological, chemical, and radio-nuclear agents in some instances. Nevertheless, it is suggested that the text be more explicit and state that the scope of the IHR is not limited to biological agents.

Regarding the Spanish translation, it was suggested that the text of the IHR be written using accepted legislative techniques, which establishes that all legal instruments prohibit or permit and that the (Spanish) text be written in the present indicative tense. Member States requested that PAHO/WHO ensure that the (second) IHR draft be jointly reviewed by (Spanish-speaking) legal and technical personnel. Such a review would not only guarantee the clarity of the translation of the IHR, but also the spirit and proper use of universally accepted technical language.
II. KEY ISSUES

1. **Core Capacity.** Commitment from States must be secured to guarantee necessary funds to comply and/or develop core capacities required under the IHR.

2. **Entry into force.** Regarding the implementation of IHR provisions, the roles and responsibilities of the interested parties within States need to be specified. These functions include strengthening the legal framework of the IHR. It is recommended that the IHR be incorporated into (national) legal order so that in spite of eventual amendments to the Regulations, the overall legal framework would remain. Member States proposed the creation of a multi-sectoral and multi-disciplinary group, including the armed forces, to assist in the implementation of the IHR.

3. **Committees.** The affected country must be part of the Emergency Committee. The functions of the Review Committee must be expanded so that it includes a close monitoring and control of the Regulations' provisions and should be included in Annex 10. This annex can also include sanctions against persons, organizations or companies that do not comply with the IHR.

4. **Notification/Information/Verification.** During a Public Health Emergency of International Concern (PHEIC), in addition to notification to WHO, a formal network or communication mechanisms must be activated between the countries regarding the evolution of such event within stipulated timeframes.

5. **Communications.** A clear definition of the National Focal Point (Center/Person) as well as their roles and functions is needed.

6. **Decision Instrument.** Clarify that the criteria to answer the four main questions are independent (Spanish translation inconsistent).

7. **Ground Crossings.** Member States emphasized the significance of the weak active surveillance and the vulnerability at non-designated ground crossings.

8. **Measures.** It is suggested that a non-exhaustive template of possible public health measures that may be adopted during a PHEIC (for example, quarantine and isolation) appear in the text. It was also suggested that the health administration should inform travelers about health risks and recommendations about their destinations.

9. **Charges.** Member State delegations felt that they be should be allowed to charge for services rendered and medical supplies.

10. **Definitions.** Definitions overall were found to be circular and ambiguous. It was suggested that they be revised and the Article be named "Glossary of Terms" to reflect that these are for the purpose of the Regulations.
11. **Commitment WHO.** WHO should take responsibility for communications with other relevant international organizations while maintaining affected States informed, and a WHA resolution should set forth the commitments of these organizations. WHO must avoid overlaps of the IHR with existing agreements between Member States and other agencies so that they are compatible and integrated within the countries.

12. **References.** The importance of having references in footnotes and available was emphasized and it was suggested that an Annex 11 be included listing relevant technical guidelines and guides.

### III. SPECIFIC COMMENTS

#### PART I - DEFINITIONS, PURPOSE AND COMMUNICATIONS

**Article 1 - Definitions**

The Spanish translation of “ship” was made so that it translates to “boat”. It is suggested that the definition of ‘boats’ is expanded from a technical and legal standpoint so that it includes ships and vessels.

It is suggested that there be a definition of WHO in order to clarify that communications are with the country office, regional office and headquarters.

It is not advisable to include the term to be defined within its definition since this produces circular definitions (e.g. infection, port, disinfection, point of entry, contamination).

It is requested that a definition for “bill of health”, stated in Article 30, be included in the Definitions article. It was also considered that the Spanish translation to “patent of health” is inadequate and it was recommended that it be changed to “certificate of health” in order to ensure a single understanding of the term.

It is suggested that the definition of “significant interference” as stated in Article 7, be moved to the Definitions article. The Spanish translation of this term is vague and it is recommended that it be replaced with “unnecessary obstacles”.

It is suggested that the definition of the National IHR Focal Point be modified, since direct communication of this body with WHO might sideline high-level State authorities.

It is suggested that the Definitions article be replaced with a Glossary of Terms, since these terms already have established definitions, indicating that the said definitions are for the purpose of the Regulations.

No point of contact is defined for the focal point.

**Quarantine** should be defined in the text.
It is suggested that widely accepted definitions be employed for commonly used terms in the field of public health.

There is a typographical error in the definition of “means of transportation” which appears in the text as “means of communication.”

The Definitions article should be divided into two sections: one of universally accepted definitions and another of definitions specifically pertaining to the IHR.

It is suggested that the definition of “contamination” include physical, chemical, and biological aspects.

In the definition of “goods”, clarification was requested on what was meant by “tangible products”.

The word “preliminary” should be deleted from the definition of medical examination, it is as there is a universal understanding as to what is meant by this term. Perhaps a preliminary examination should be distinguished from a medical examination per se. This would allow for a pre-determined standardized preliminary examination without requiring the presence of a physician. Another alternative would be to replace “preliminary” with “initial”. It was also noted that the Regulations mention ‘preliminary examination, medical examination, and physical examination’. These terms should be defined more specifically.

It is suggested that definitions of the certificates found in the Annexes be defined.

It is suggested that definitions of the certificates in the annexes are included.

In the definition of “event” the following underlined addition is suggested: “...manifestation of disease or an occurrence that creates a potential for disease or public health risk.”

**Article 2 - Purpose**

It was suggested that “unnecessary interference” be more clearly defined. It was recommended that this term be replaced with “unnecessary obstacles”.

As currently drafted, the purpose of the Regulations is to "provide[s] security against the international spread of disease”, but (Member State) delegations felt that it should read “is an instrument that facilitates security.”

It was suggested, once again, that the Regulations ‘facilitates security’ against not only the spread of diseases, but also against "biological, chemical and radio-nuclear agents.”

It is suggested that the text be changed as follows: “The purpose of the International Health Regulations is to provide a legal basis for the assessment, management and communication of biological, chemical, and physical risks for the protection and promotion of public health while avoiding or minimizing unnecessary obstacles to international traffic.”
Article 3 - Communications

Member State delegations noted confusion in the use of the term Focal Point: it is not clear whether it refers to a person or to a center. It was suggested that a clear differentiation be made between the National Center and persons who act as focal points or their alternates.

The makeup of the National Center was discussed as well as the need for involving other relevant ministries in this center. The word 'center' is confusing and gives the idea that one must be created. It the term "responsible national institution" was put forward instead, since a minimal national infrastructure is needed in order to achieve the states purpose of the IHR.

PART II - SURVEILLANCE, NOTIFICATION, INFORMATION, VERIFICATION AND RESPONSE

Article 4 - Surveillance

In item 2, it was proposed that in addition to disease, health risks and injuries be included.

Article 5 - Notification

With regard to notification time, it was felt that a timeframe was required for retaining information regarding events that may constitute a PHEIC and that the Regulations should establish time limits for notifying other Member States.

Paragraph b) should be deleted to allow the remaining items to be exclusive by adding "or" between them.

Article 7 - Information

It was suggested that a provision in the Regulations explicitly allow for the notification of neighboring States amongst themselves which would be simultaneous to WHO notification.

Item 2 should be modified to read as follows: "The health administration shall immediately inform WHO and the affected States of evidence of a public health risk in another State that may cause international disease spread ..."

'Reservoirs' are not contemplated in item 2 a). Paragraph b) would read better if the term “carrier” was replaced.

Article 8 - Verification

It is necessary to emphasize that if a State does not have the resources for the verification of an event, PAHO/WHO will provide assistance as soon as possible.
It is suggested that the term ‘rumor’ be changed since the text will be used by people without a background in epidemiology and, thus, may underestimate its importance.

**Article 9 - Determination of a public health emergency of international concern**

It was recommended that in item 2, the text "In addition WHO may make such information and recommendations available to the general public", is moved to Article 5–Communications.

It is suggested that the IHR provide that reporting within the affected State be undertaken by the health administration of said State.

Explicit mechanisms are recommended for resolving differences of opinion between WHO and a State as to the existence of a PHEIC.

**Article 10 - Response**

In item 3, an amendment was suggested to the phrase "WHO may offer assistance" as follows: "**WHO shall offer assistance...**"

**PART III - RECOMMENDATIONS**

**Article 11 - Temporary recommendations**

Item 2 should be revised so that it is clear that WHO will communicate any temporary recommendations to States in addition to conveyance operators. It is also proposed that this item state that reporting be done through the Health Authority to the international agencies responsible (for conveyance operators).

**Article 12 - Standing recommendations**

It was suggested that a heading is included recommending that States inform persons traveling to affected areas of health measures recommended by WHO.

**PART IV - POINTS OF ENTRY**

**Article 13 - Health Administration**

In paragraph a) of the Spanish text, the word “velarán” should be replaced with “aseguraráñ” which captures the meaning of the English word 'ensure' more accurately.

Paragraphs a), b) and c) should clearly indicate that these conditions should exist as a matter of routine and not only during a PHEIC.
Article 16 - Health Authority

It should be clear that there is no need for the health authority to be physically present when monitoring compliance with the standards set out in the articles. The health authority simply ensures that the standards are met.

To avoid unnecessary confusion, it is recommended that the term 'health authority' always be used in the singular form.

PART V - PUBLIC HEALTH MEASURES

Chapter I - General provisions

Article 17

It is suggested that the text be modified as follows:

"Subject to applicable international agreements and Articles 33 and 36 of these Regulations, if a public health risk is suspected, the health authority may..."

Chapter II - Special provisions for conveyances and conveyance operators

Article 18 - General provisions

There is an error in the Spanish version and item 4 should be corrected so that "communication" is replaced by "transport".

Article 19 - Ships in transit

It was suggested that the title of the article be changed to “Ships and aircraft in transit”

Article 20 - Affected conveyances

In item 1 paragraph b), it was suggested that the text be changed to: "In order to obtain an adequate level of control of public health risks, methods or procedures recommended by the WHO shall be used. Where these are not available, the health authority may decide the technique to be applied of a case-by-case basis."

It was proposed to add a paragraph providing for the protection of the State against legal action should fumigation or the application of other health measures result in harm or injury to people or companies.
Article 21 - Conveyances at point of entry

The draft should be modified to provide that points of entry designated as such must have the basic capacities to guarantee access to conveyances even during a public health emergency (of international concern). It is proposed to delete the text after and including “If the point of entry is not equipped...” so that the full text of the item reads as follows: “Unless otherwise recommended by WHO, or authorized pursuant to applicable international agreements, a conveyance shall not be prevented for public health reasons from calling at any designated point of entry.”

In item 4, ground transportation of passengers is not taken into consideration and should be included. In addition to officers in command of ships and aircrafts..., the following should be added: "collective means of ground transportation".

In item 5, it is proposed that the article includes “ships”.

Chapter III - Special provisions for persons

Article 22 - Surveillance of travelers

The term “suspect traveler” was found to be ambiguous and should be changed to "suspect case."

PART VII - CHARGES

Article 31 - Charges for Medical Examination, vaccination or other prophylaxis

Member State delegations felt that a minimal charge should be levied for vaccines and services they provide. It is suggested that the Regulations set appropriate rates—an established amount that covers the cost of the service or (medical) supplies.

PART VIII - GENERAL PROVISIONS

Article 36 - Rights of persons

In item 2, the delegation of Panama requested that it be made clear that vaccination did not only refer to yellow fever and that it be specified that the Regulations refer to international travelers upon their arrival.

It was noted that the article needs a third item establishing actions for which compliance is required and providing for situations where a person refuses vaccination. The following text was proposed: “In the event of a PHEIC, the health administration may carry out medical examinations, vaccination, and other prophylactic measures. Should the traveler refuse to under go
these measures, the health administration may take special measures (isolation, quarantine, and in extreme cases denying entry into the country) to protect public health.”

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

It was suggested that “refugees” be added to this article.

**Article 38 - Persons enjoying diplomatic status**

There was issue with the Spanish translation of “diplomatic status”.

**Article 39 - Transport of Biological Materials**

It was suggested that both the entry and exit of biological materials be included.

An item should be included that emphasizes the supporting role of the WHO in facilitating and expediting the international shipment of samples.

**Article 40 - Infection control**

The translation into Spanish was made so that the title and contents of the article translates to “fight against infection”. It was suggested that this be changed so that instead of “fight” that “prevention and control” are used. The suitability/relevance of including an article on infection control in the IHR was questioned.

**Article 41 - Information sharing during a suspected intentional release**

The title and contents of this article should be changed so that it includes the “…suspected intentional or accidental release”.

**Article 43 - Armed forces**

The text should be changed so that the Spanish translation conveys the same meaning as in the English version with “States should ensure that military conveyances, containers, cargo, and personnel meet the requirements of the Regulations”, rather than as it read now which conveys that “States should monitor…”

**PART IX - FINAL PROVISIONS**

**Article 45 - Review**

It was felt that the functions set out in this article overlap with those in Annex 10, which was considered redundant.
Article 47 - Settlement of disputes

In item 1, there are problems with the translation of the word “resolved”.

Article 48 - Existing conventions, regulations and similar agreements

The text should be changed so that the Spanish translation reflects the English version which provides that these Regulations “replace” the provisions other agreements listed in the article.

Article 50 - Reservations

In item 2, the Spanish translation should be changed so that instead of “A refusal in part of the Regulations” be changed to “A rejection”, as it reads in the English version.
ANNEXES

Annex 1

B. Necessary Core Capacity in the Airports, Ports and Terrestrial Border Posts Designated

In item 1, paragraph a) the Spanish translation should read as the English version where it states that "To provide access to an organized medical service..."

In item 1, paragraph c) the text should be edited to reflect that training programs as well as trained personnel will be provided for the inspections of conveyances.

In item 1, in paragraph d) cargo compartments should also be added to the list of potential risk areas that should be inspected.

In item 2, a reference should be included to environment health guidelines within ports and airports.

It was found that using the term vectors alone was insufficient and it was suggested that reservoirs be added.

In item 2, paragraph c), the term "suspect travellers that are not ill" was questioned and ot should be clarified. It was considered a suspicious person that is not ill is considered a contact. The term might be replaced by simply 'suspect traveller' or 'suspect case'.

It is suggested to change the order of the paragraphs of the item 2, leaving the current paragraph d) before paragraph c) since it is considered that the interview should precede isolation. Clarification is required as to whether the appropriate space for interviews mentioned in paragraph d) is different from the place of isolation mentioned in paragraph c). It was also suggested that "isolation" be replaced by 'quarantine'

Annex 2

An error was observed in the translation into Spanish, where the “or” was translated as “and” in the criteria to answer questions 1 and 3.

It was suggested to take two recent situations in the subregion were analyzed using the decision instrument and that these results be circulated through the subregional networks of communication and to PAHO/WHO.

Annex 4

It was found necessary to clarify that the measures stipulated in Annex 4 are routine and permanent and not only during a PHEIC.
In item 1, paragraph 1, it should be redrafted to make it clear that the operator is not the person responsible for carrying out the inspection.

In Section 5, in the last phrase, it is recommended adding the role of the State changing the phrase thus: "The States will establish the measures that agree with previous assessment of public health risk taking into account the recommendations of the WHO"

Change the error from the Spanish word “derrota”, meaning defeat and change it to “de ruta”, meaning routing as it is in the English draft

**Annex 6**

Item 4 should be changed so that it includes the official stamp of the center administrating the vaccine as well as the name and signature of the professional that supervising the application of the vaccine.

In item 5 it should be clearly stated that the language of the State administering the certificate may be used in addition to the English or French.

**Annex 7**

Vaccination requirements should be stipulated not only for travelers coming from affected areas, but also for those who will be traveling to affected areas.

In the item 2, paragraph b), with regard to vaccination against yellow fever, the text should be changed to reflect that vaccination certificates “shall be required of any traveler leaving an area where the Organization has determined a risk of yellow fever transmission is present”

It was recommended that the drafting of item 2, paragraph d) so that there is no ambiguity that the vaccinated person can not be treated as a suspect if the person is asymptomatic.

It was seen that it is necessary to add that the vaccine only is effective 10 days after its application and its validity is of 10 years. The delegations propose that the States have the authority to monitor such person for 6 days.

**Annex 8**

It is proposed that more descriptive language is utilized in the diagnosis in such a way that the form can be filled by a person without medical training.

It is proposed that the table in the Annex include a title so that it reflects that said table it illustrates a list of the cases of disease observed during the trip and that the form more space the ship's crew. It is proposed that name and signature of the captain and/or of the physician on board, is available, be included.

Panama has proposed including a list of symptoms that indicate infectious diseases for the maritime health declaration (it will be attached).
Annex 9

Include the same list of symptoms that could point to infectious disease that was included in annex 8.