Considerations and points of consensus between Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, Paraguay, Peru, Uruguay, and Venezuela with regard to Document A/IHR/IGWG/2/2, of 24 January 2005
(Review and approval of proposed amendments to the IHR - Proposal by the Chair)

This document contains the considerations, consensus, and agreements reached during a Seminar to Review the International Health Regulations (IHR), held in Montevideo, Uruguay, from 26 to 28 January 2005.

I- Article 1 Definitions

Rationale
We propose that tautological definitions be revised, and that consideration be given to some of the textual proposals submitted during the Meeting in Geneva [Intergovernmental Working Group] between 1 and 12 November 2004, or other alternatives.

We propose to replace the concept of threat with risk throughout the document, especially in the definition of a public health emergency of international concern (PHEIC).

We support the definition of public health risk presented in the Proposal by the Chair and we justify the use of this broader concept which is more adequately suited to public health purposes.

We propose the inclusion of the term trade in the definition of international traffic given its importance in relations between States Parties.
We propose to add a definition of **non-invasive medical examination**, accepting the concept introduced as a footnote in the Proposal by the Chair that refers to Art. 21 paragraph 1, a) iii): “For purposes of these Regulations, the following public health procedures are covered under subparagraph (iii): temperature assessment using an ear, oral or cutaneous thermometer, or thermal imaging; auscultation of heart or abdomen; abdominal palpation; retinoscopy; visualization of the oropharynx using a tongue depressor; external collection of urine, faeces or saliva samples; external measurement of blood pressure; electrocardiography.”

We also propose to add a definition of the term **inspection** and to replace the term **abdominal palpation** with **palpation**. Furthermore, we suggest that consideration be given to the introduction of terminology that contemplates technological procedures beyond what is provided for in the text in order to take into account the contribution and development of new technologies.

In the definition of **medical examination** we suggest replacing the term **medical** with **health**.

We propose including a definition of “**Responsible Authority**”.

**Article 2 Purpose and Scope**

**Proposal**

The purpose and scope of these Regulations are to **prevent**, protect against, control, and provide public health responses to the international spread of disease in ways that are commensurate with **risks to public health**, and which avoid unnecessary interference with international traffic and **trade**.

**Article 2 b Principles**

**Rationale and proposal**

We support the text in the Proposal by the Chair because it includes as a principle that the application of the present Regulations will be with full respect for the fundamental human rights and dignity of persons.

**Article 3 Responsible Authorities**

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Rationale and proposal
We support the Proposal by the Chair because: 1) it recognizes the existence of jurisdictional authorities, 2) recognizes a National IHR Focal Point that acts with the consent of the health authority of the State Party, 3) foresees the designation of IHR Contact Points in WHO at the headquarters or at the regional level of the Organization.

There is consensus among the signatory countries that the headquarters of the Pan American Health Organization (WHO Regional Office for the Americas) in Washington, D.C. be the WHO IHR Contact Point for the Region of the Americas.

Textual Proposal:
1. Each State Party shall designate or establish a National IHR Focal Point and its responsible authorities, within their respective jurisdictions for the application of health measures under these Regulations.
2. National IHR Focal Points shall be accessible at all times to establish communication with WHO IHR Contact Points provided for in paragraph 3 of this article. The functions of the National IHR Focal Point shall include:
   a) sending to WHO IHR Contact Points, on behalf of the State Party concerned, urgent communications concerning the implementation of these Regulations, in particular under Articles 5 to 10 [and 45];

4 Surveillance
Rationale
With regard to the development of core capacities, mechanism for the assessment of such capacities in each State Party is required. The grace period for such assessment in the Regulations was two years after their entry into force. It was agreed that a reasonable period for the development of these capacities is five years after the aforementioned assessment.

Article Proposal
1- Each State Party shall develop and strengthen, as soon as possible, but no later than 5 years after an assessment of the core capacities specified in Annex IA, the capacity to detect, assess, notify, and report events in accordance with these Regulations.

5 Notification

Rationale and Proposal

We support the Proposal by the Chair and propose a period of 24 hours to notify WHO, with the understanding that receipt of information takes place once the event has met all the notification criteria defined in the decision instrument in Annex 2.

Article 7 Other reports

Rationale

With regard to unofficial sources, we propose that WHO may receive information from those sources and request confirmation of this information from the allegedly affected State Party within a limited time period to allow for verification. We request a clear justification for maintaining the confidentiality of the source. We believe that maintaining these sources confidential could have serious repercussions for a State Party, since it would hinder the confirmation or discarding of such information.

The State should have complete access to this information and only in exceptional cases, where the source of the report may be affected, should confidentiality be maintained. To this effect, we support incorporating criteria for considering these sources, to give States Parties the opportunity to gather all available facts for verification purposes and to implement any necessary measures. In such cases, the affected country shall be immediately informed of the event prior to any communications with other countries.

Article Proposal
1. WHO may take into account reports from sources other than notifications or consultations and shall assess those reports according to established epidemiological principles. Before adopting any action based on such reports, WHO shall consult with the State Party in whose territory the event is allegedly occurring in accordance with the procedures set forth in Article 8. To this end, WHO shall make the totality of the information received available to the States Parties and only in exceptional cases where it is duly justified, may WHO maintain the confidentiality of the source. This information will be used in accordance with the procedures set forth in Article 9 of these Regulations.

2. We support the Proposal by the Chair in this paragraph.

**Article 8 Verification**

**Rationale and Proposal**

We support the Proposal by the Chair in paragraphs 1, 2 and 3 and propose eliminating paragraph 4.

**Article 9 Provision of information by WHO**

**Rationale**

We agree with maintaining confidentiality as a general principle and preserving the consultation with the affected State.

**Article Proposal**

1. Subject to paragraph 2 of this article, WHO shall send to all States Parties and, as appropriate, to the relevant intergovernmental organizations, as soon as possible and by the most efficient means available, in confidence, such public health information which it has received under Articles 4 to 8 inclusive and which is necessary to enable States Parties to respond to a public health risk.
2. WHO shall use the information received under Articles 5 and 6, and of paragraph 2 of Article 7, for verification, assessment and assistance purposes under these Regulations and, unless otherwise agreed with the States Parties referred to in those provisions, shall not make this information generally available to other States Parties, unless:

a) the event is determined to constitute a public health emergency of international concern pursuant to Article 10; or

b) information evidencing the international spread of the infection or contamination has been confirmed by WHO in accordance with accepted epidemiological principles, or (Spanish negative and English positive)

c) there is evidence that:

i) available control measures will not be effective against the international spread of disease because of the nature of the contamination, the disease agent, the vector or reservoir; or

ii) the State Party lacks sufficient operational capacity to carry out the necessary measures to prevent further spread of disease; or

d) the nature and scope of the international movement of travelers, conveyances, containers, cargo, baggage, postal parcels, or goods that may be affected by the infection or contamination requires the immediate application of international control measures.

3. WHO shall consult with the State Party in whose territory the event is occurring as to its intent to make information available under this Article.

4. When information received by WHO under paragraph 2 of this Article is made available to States Parties in accordance with these Regulations, WHO may also make it available to the public if other information about the same event has already become publicly available and there is a need for the dissemination of authoritative and independent information.
Article 10 Determination of a Public Health Emergency of International Concern

Rationale and proposal
The text of this article included in the Proposal by the Chair gives the State Party a key role in the declaration of a public health emergency of international concern which resulted in a consensus in support of this proposal.

Article 11 Public health response

Rationale
We support the Proposal but request the modification of the time necessary for the development of capacities, proposing this period be similar to the one proposed in Article 4, paragraph 1, which reads “no later than 5 years after an assessment of the core capacities specified in Annex IA.”

Article Proposal
1. Each State Party shall develop and strengthen as soon as possible, but no later than 5 years after an assessment of the core capacities specified in Annex IA. for that State Party, the capacity to respond promptly and effectively to public health risks and public health emergencies of international concern as set out in Annex 1. When appropriate, WHO shall publish guidelines to support States Parties in the development of public health response capacities.

Article 19 Ground crossings

Rationale
We support the Proposal by the Chair provided the term "threat" is deleted in paragraph 2 b).

Article Proposal
2. States Parties may take into consideration the following criteria in designating ground crossings under paragraph one of this Article:
a) the volume and the frequency of the various types of international traffic, as compared to other points of entry, at a State Party’s ground crossings which might be designated; and.
b) the public health risks existing in areas in which the international traffic originates, or through which it passes, prior to arrival at a particular ground crossing.

**Article 20 Role of competent authorities**

**Rationale**

We propose modifying the Proposal by the Chair by deleting paragraphs 2 and 3, and including their content as sub-paragraphs j) and c), respectively.

**Article Proposal**

c) be responsible for the supervision of any deratting, disinfection, disinsection or decontamination of conveyances, containers, goods, cargo, postal parcels, baggage, animals or sanitary measures for persons, as appropriate under these Regulations; These sanitary procedures shall be carried out so as to avoid as far as possible injury or discomfort to persons or damage to conveyances, containers, cargo, goods or baggage or affecting the environment in a way which impacts public health.

j) Health measures recommended by WHO may be reapplied for travelers, conveyances, containers, goods, cargo, baggage or postal parcels arriving from an affected area on arrival, if there are indications that the measures applied on departure from the affected area were unsuccessful.

**Article 21 Health measures on arrival and departure**

**Rationale**

We concur that additional measures to be applied to travelers should be subject to the declaration of a PHEIC.
Article Proposal

2. On the basis of evidence of the existence of a public health risk obtained through the measures provided in paragraph 1 of this Article, or through other means, States Parties may apply additional health measures, in accordance with these Regulations, provided a PHEIC has been declared.

4. In accordance with paragraph 3 (of this Article), travelers to be vaccinated or offered prophylaxis pursuant to these Regulations, or their parents or guardians, shall be informed of any risk associated with vaccination or with non-vaccination and with the use or non-use of prophylaxis in accordance with the laws and international obligations of the State Party. States Parties shall inform medical practitioners of these requirements.

Article 22, 23, 24, 25 Special provisions for conveyances and conveyance operators

Consensus was reached to maintain the text as it appears in the Proposal by the Chair.

Article 26 Travelers under public health observation

We propose replacing the term suspect with travelers who are or have been exposed to a (public health) risk.

Article Proposal

Subject to Article 39 or, unless authorized by applicable international agreements, travelers who are or have been exposed to a (public health) risk and are placed under public health observation may continue an international voyage, if the traveler does not pose an imminent public health risk and the State Party informs the competent authority of the point of entry at destination, if known, of the traveler’s expected arrival. On arrival, the traveler shall report to that authority.
Article 27 Health measures relating to entry of travelers

Rationale
In accordance with the proposed amendment to Article 21, health measures applied to travelers should be subject to the declaration of a PHEIC.

Article Proposal
2. If a traveler for whom a State Party may require a non-invasive medical examination, vaccination or other prophylaxis under paragraph 1 of this article fails to consent to any such measure, or refuses to provide the information or the documents referred to in paragraph 1(a) of Article 21, the State Party concerned may, subject to Articles 28, 38 and 42, deny entry to that traveler. If there is evidence of an imminent public health risk and a PHEIC has been declared, the State Party, in accordance with its national legislation and to the extent necessary to control such a risk, may compel the traveler to undergo:
   a) the least invasive and intrusive medical examination that would achieve the public health objective;
   b) vaccination or prophylaxis; or
   c) additional established health measures that prevent or control the spread of disease, including isolation, quarantine, or placing the traveler under public health observation.

Article 28 Treatment of travelers

Rationale
The amendments to this article seek to further safeguard the human rights of travelers when measures are being applied to them.

Article Proposal
In implementing health measures under these Regulations, States Parties shall treat travelers with respect for their dignity and fundamental human rights and minimize any discomfort or distress associated with such measures, including by:
a) treating all travelers with courtesy and respect;
b) taking into consideration gender, socio-cultural, ethnic or religious concerns of travelers; and
c) providing or arranging for adequate food and water, appropriate accommodation and clothing, protection for baggage and other possessions, appropriate medical treatment, means of necessary communication, including alternatives to facilitate their communication in a language they can understand, and other appropriate assistance for travelers who are quarantined, isolated or subject to medical examinations or other procedures for public health purposes.

Article 29 Goods in transit
We support the Proposal by the Chair

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Chapter IV - Special provisions for goods, containers, and container loading areas

Article 30 Container and container loading areas

Rationale
We think it is necessary to include epidemiological criteria in paragraph 3 regarding inspections.

Textual proposal:
3. Whenever in the opinion of a State Party, the volume of international container traffic is sufficiently large and considering the characteristics of the cargo and the public health risks involved, the competent authorities shall take all practicable measures consistent with these Regulations, including carrying out inspections, to assess the sanitary condition of container loading areas and

1. Chile will inform its position on article 30 on 20 February at the America Group meeting in Geneva.
containers, to ensure that the obligations contained in these Regulations are implemented.

PART VI - HEALTH DOCUMENTS

Article 31 General rule

We propose the deletion of the reference in brackets to Article 39.

Text proposal:

No health documents, other than those provided for under these Regulations or in recommendations issued by WHO shall be required, provided however that this Article shall not apply to travelers seeking temporary or permanent residence, nor shall it apply document requirements concerning the public health status of goods or cargo in international trade pursuant to applicable international agreements.

Article 39 Additional health measures

Comment: We suggest a review of all instances where Article 39 is referenced to ensure that these are in line with the proposed drafting. Even if the proposed amendment is not accepted, this review should nonetheless take place.

Article Proposal

1. Within the framework of these Regulations, once WHO has declared a PHEIC, States Parties may implement additional health measures in accordance with their national health legislation and obligations under international law, provided such measures are consistent with the purpose and provisions of these Regulations.

In determining whether to implement any such measures, States Parties shall base their determination upon scientific principles and evidence and follow any guidance provided by WHO, including an assessment of the risk of international spread of the disease and of interference with

2 Chile will inform its position on article 31 on 20 February at the Group America meeting in Geneva.
international traffic and trade, applying the least restrictive measures possible.

2. States Parties shall inform WHO, within 72 hours of their application, of health measures implemented that may constitute significant interference with international traffic and trade and that are applied to an area that is not subject to a temporary or standing recommendation. Significant interference means refusal of entry or departure or delaying, for more than 24 hours, the entry or departure of conveyances or of travelers. WHO shall, in turn, [respond with]/[issue] a recommendation within 24 hours of receipt of such information.

3. Upon request by WHO, a State Party implementing such a measure shall provide to WHO the public health rationale and scientific information for it. WHO may share this information with other States Parties.

4. After assessing the information provided pursuant to paragraphs 2 and 3 of this Article, and other relevant information, WHO may request that the State Party concerned cease, modify or apply the measure in question.

5. Without prejudice to their rights under Article 57 (Settlement of disputes between States Parties), any State Party that considers itself adversely affected by a measure taken pursuant to paragraph 1 of this Article may consult with the State Party implementing such measures. The purpose of such consultations is to clarify the scientific information and the public health rationale underlying the measure with a view to arriving at a mutually acceptable solution.

Article 45 Information sharing during a suspected intentional release

Rationale and Proposal

Article 45 does not currently specify the relationship between the notification of an event of an intentional nature and an international public health risk. This broad language exceeds the scope of the IHR. If such an event were to pose an international public health risk, it would already be provided for under the IHR.
Therefore, we propose the deletion of this article as we cannot see any specific justification for its inclusion.

Article 47 Composition (The IHR Roster of experts)
We support the Proposal by the Chair.

Article 48 Terms of reference and composition (The Emergency Committee)
Rationale and proposal
We support the inclusion of the affected State Party as a member of the Emergency Committee. We support the amendment to paragraph 3 presented at the meeting in November 2004 of the Intergovernmental Working Group with the as follows 3: At least one of the members of the Committee should be an expert proposed by the affected State Party.

Article 49 Procedure (The Emergency Committee)
Rationale and proposal
In paragraph 9, we propose replacing the expression "may request" with "has the right to make a presentation before the Emergency Committee.

Article 50 Terms of reference and composition (The Review Committee)
Rationale and proposal
In paragraph 1, we propose merging subparagraphs d) and e) as follows: “Provide technical advice to the Health Assembly, the Executive Board, and the Director-General on any matter referred to it by them regarding implementation of these Regulations.”

We propose to amend paragraph 3, in furtherance of the function set out in paragraph 1 a) the Director General shall submit to the World Health Assembly for its approval, the designation of members of the Review Committee charged with reviewing the functioning of these Regulations with wide regional representation and ensure its continuity over time.
Article 53. Consideration of disputes

Rationale

We support the deletion of matters pertaining to the consideration of disputes by the Review Committee, as it appears in the Proposal by the Chair.

ANNEX 1 A – CORE CAPACITY REQUIREMENTS FOR SURVEILLANCE AND RESPONSE

Rationale:

We propose to redefine the different levels of public health response by assigning the capacities currently provided for at the local community level to the primary response levels. With regard to capacities at the national level, we propose an extension of the period for the assessment of information to 48 hours.

We also considered the need for the finalization and implementation of an instrument to assess core capacities for surveillance and response. Implementation must be carried out by States Parties with the support of WHO in accordance with Article 41 of these Regulations.

Article Proposal

1. At the local community and/or primary level.

The capacities:

a) to detect events involving disease or death above expected levels for the particular time and place, in all the areas of the territory of the State Party; and

b) to report all available essential information to other levels of public health response. At the community level, communications shall be with local community healthcare institutions or appropriate health personnel. At the primary public health response level, communications shall be with the intermediate or national response level, depending on its organizational structure. For the purposes of this Annex, essential information includes the following:
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clinical descriptions, laboratory results, sources and type of risk, numbers of human cases and deaths, conditions affecting the spread of the disease, and the health measures employed.

c) to immediately implement preliminary control measures at the primary level.

2. At the intermediate public health response level

The capacities:

a) to confirm reported events and support or implement additional control measures immediately; and

b) to assess reported events immediately, and if found urgent, to report all essential information to the national level. For the purposes of this Annex, the criteria for urgent events include serious public health impact and/or unusual or unexpected nature with high potential for spread.

3. At the national level

Assessment and notification. The capacities:

In paragraph a) of the two options in the Proposal by the Chair, we support a period of 48 hours.

Annex 2

Decision instrument for the assessment and notification and Specific diseases requiring the utilization of the instrument

Rationale and Proposal

Among the major modifications introduced by the revision of the International Health Regulations is the replacement of a list of 3 diseases with mandatory international notification by the States Parties to WHO of any event that may constitute a public health emergency of international concern (PHEIC).
A PHEIC is defined as an extraordinary event which is determined (i) to constitute a public health risk (in lieu of threat) to other States through the international spread of disease and (ii) to potentially require a coordinated international response.

The importance of a PHEIC is based on the fact that after it has been declared, WHO may issue recommendations to prevent the international spread of the disease or risk that could seriously affect international traffic and trade.

The draft revised IHR includes a decision instrument in Annex 2 that consists of an algorithm with a sequence of criteria that must be fulfilled for an event to be notified. Furthermore, the proposal includes a list of diseases complementing the decision instrument for the assessment and notification of these events.

The Delegates of the participating countries recognize that having a decision instrument for the detection of an event that may constitute a PHEIC represents an important step forwards. However, it was agreed that the current instrument, as proposed, should not be endorsed until it is improved and until a clear and precise process of validation was undertaken.

An Expert Committee established for this purpose will submit a proposal for the improvement and validation of the decision instrument with:

a) definitions of the concepts included in the instrument;

b) the development of guidelines for applying the analysis criteria in the instrument, in lieu of the examples.

c) the development of a proposal for a validation protocol.

This proposal would be submitted to the World Health Assembly in May 2005, where States Parties would be urged to carry out a process to validate the instrument, using information from their national surveillance systems as basis.
Validation proposal:

- The validation of the instrument should be carried out within 1 year from the adoption of the Regulations (by the Health Assembly).
- The following aspects should be assessed: 1) the instrument’s capacity to detect events that may constitute a PHEIC (sensitivity); 2) the proportion of the events verified among those originally detected (positive predictive value) and 3) the observed benefit based on the detection of events of international concern as compared to resources invested.
- The States Parties shall carry out the assessment in their territories in accordance with their national surveillance infrastructure capacity.
- WHO shall offer technical cooperation to the States Parties to carry out the validation process.
- The results of the assessment will be presented to the World Health Assembly, which will decide on the desirability of maintaining, enhancing, or amending the instrument.
- After the entry into force of these Regulations, the Review Committee will be charged with the process of validation and improvement of the instrument, (in accordance with the proposed amendment to Article 50), in support of States Parties.

With regard to the inclusion of a list of notifiable diseases, we do not support the proposal in document A/IHR/IGWG/3 of 30 September 2004. Pending validation of the instrument (i.e. the transition period), however, we propose to include a list of diseases which makes the utilization of the instrument mandatory in order to determine whether notification is required.

We propose criteria be defined for the inclusion of diseases in the text.

Annex 3\(^3\)

\(^3\)Chile will inform its position on Annex 3 on 20 February at the Group America meeting in Geneva
We propose a revision of the identified areas for inspection to ensure that all areas in different types of vessels are covered.

**Annexes 8\(^4\) and 9\(^5\)**

With regard to Annexes 8 and 9, we reiterate our support for the textual proposal presented by the Americas group in the IGWG in November 2004 and note that it was not included in the Proposal by the Chair.

\(^4\) Chile will inform its position on Annex 8 on 20 February at the Group America meeting in Geneva

\(^5\) Chile will inform its position on Annex 9 on 20 February at the Group America meeting in Geneva