WORLD TRADE ORGANIZATION

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Committee on Sanitary and Phytosanitary Measures

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GLOBAL CRISES – GLOBAL SOLUTIONS

MANAGING URGENT INTERNATIONAL PUBLIC HEALTH EVENTS WITH THE REVISED INTERNATIONAL HEALTH REGULATIONS

Information Paper Submitted by the World Health Organization (WHO)

Reminder: The SPS Committee agreed at its meeting of 15-16 March 2000 to hold an informal meeting with the World Health Organization on the revision of the International Health Regulations (IHR). That meeting will occur immediately following the conclusion of the Committee's regular meeting, that is, either in the afternoon of 22 June 2000 or in the morning of 23 June 2000.

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I. BACKGROUND

1. Information paper number one: "*Revision of the International Health Regulations – Public Health and Trade – comparing the roles of 3 international organizations*" was provided to the SPS Committee in June 1999. In the year since this report, the key changes proposed for the new Regulations have been further developed by the WHO Secretariat, in preparation for extensive review by WHO Member States and key stakeholders, like the World Trade Organization and the SPS Committee. We feel that it is important to gather this input during the development stage of the revision, before any actual drafting of the IHR text occurs.

2. Potentially conflicting Member requirements stemming from obligations in both the SPS Agreement and the IHR was raised as a pivotal issue in the June 1999 information paper. Of at least equal importance, however, is finding the functional synergy that could exist between the two agreements. The will to jointly investigate how we can mutually minimise conflict and investigate synergy resulted in the March 2000 request by four delegations to the SPS Committee that an informal meeting be held in June 2000, to discuss these possibilities. This paper is designed to provide background information on the key changes to the IHR, to suggest where conflict might arise, and to identify where synergy could exist. The WHO Secretariat is anxious to obtain the expert opinions of the SPS Committee regarding the health and trade issues of mutual concern, and we encourage the fullest possible participation. The WHO Member State Delegates to the May 2000 World Health Assembly were briefed by a joint WHO/WTO panel on a number of overlapping activities and issues for the WTO and WHO, including the revision of the IHR.

Which health crises concern the World Health Organization?

3. Disease events occur in every corner of the world every day, and the vast majority of these events or endemic situations remain local State or Provincial concerns only. In most cases, no traffic or trade restrictions are imposed by other countries as a result of the event. Some of these events, however, quickly become international public health problems, through cross-border transmission of disease by person-to-person spread, or through exported contaminated products. Because of extensive globalisation in travel and trade, countries are worried that diseases from even remote parts of the world could be imported. Potentially damaging traffic and trade embargoes can also be imposed, often based only on the perception of risk for disease importation. This overreaction on the part of contiguous neighbours, trading partners and other countries can sometimes take on global proportions, as happened during the plague outbreak in India in 1994. $1.7 billion was lost by India before the event could be put into proper public health focus. Such situations demand a measured and evidence-based response from a credible third party. The IHR are the only legally-binding global tool for public health, and enable WHO, in direct collaboration with WHO Member States, to address these problems.

4. The WHO Secretariat acknowledges that it can be difficult to decide what measures to take based on the sometimes limited information available during an urgent public health event, especially in the first hours and days of the crisis. To assist all concerned parties in this process, the Secretariat is preparing an algorithm which will allow both WHO Member States and the Organization to analyse the event information and determine if WHO should be alerted. In other words, what characteristics make the event both urgent *and* international? As would be expected in a health-based document, the parameters for this algorithm include a number of key medical and epidemiological criteria, like rapidity of spread and severity. The IHR, however, has a dual purpose: to "ensure the maximum security against the international spread of disease, with a minimum interference with world traffic". Since traffic and trade disruptions can be crippling to many economies, the criteria for "urgent international event related to public health" must also include the imposition of trade or travel restrictions by other Member States of WHO.

5. The WHO Member States must see value in this process, and we have suggested that both the countries suffering the disease event and other countries can benefit from this approach. As described below, all of the measures necessary to prevent importation of disease will be listed in the new IHR, and will be available to WHO Member States, under direction from WHO. Since each major international event will also have a time-limited "template" of these (maximum) measures, the WHO Member State affected by the event can be more assured that inappropriate measures will not be applied.

6. We are seeking to ensure that the new IHR will contain all of the components and authorities necessary to address these crisis management requirements, but that it also continues to provide direction for routine international disease prevention activities undertaken by international common carriers and WHO Member States.

What are the problems with the present IHR?

7. The present IHR, as a global regulatory tool for disease surveillance and response, has the following major constraints:

- *Limited coverage:* It regulates only three diseases: cholera, plague and yellow fever.
- Dependence on country notification: The IHR wholly depends on a country that has suffered an outbreak of any of the three diseases to make an official notification to WHO.
- *Lack of mechanism for collaboration:* At present little exists in the IHR to foster collaboration between WHO and an affected country.
- *Lack of incentives:* The present IHR lack effective incentives to induce compliance by WHO Member States.
- *Lack of event-specific measures*: At present WHO lacks the ability to provide specific IHR measures to prevent international disease spread. WHO directions for the application of measures cannot be tailored to the event.
- *Ineffective measures to restrict unnecessary trade embargoes during disease events*: WHO lacks powers to enforce measures that would prevent inappropriate trade embargoes by other countries against the country suffering an urgent public health event.
- *Lack of a transparent appeal process*: The present IHR does not provide for an effective and transparent appeal process that could enable affected WHO Member States to challenge WHO directions for measures during urgent international events.
- *Lack of a modern mechanism to resolve disputes between WHO Member States:* The current dispute mechanism is loosely based on a simple Director-General assisted process followed by reference to the International Court of Justice, and requires a new format with a comprehensive and transparent protocol to hear disputes. The WTO has extensive experience in this area, and could provide valuable advice.

With these major constraints in mind, key changes have been proposed to develop an IHR that would adapt to emerging trends in twenty-first century epidemiology and global traffic and trade.

II. PROPOSED CHANGES TO THE IHR

8. One of our primary objectives of the IHR revision process is to foster collaboration with WHO Member States, our partners and stakeholders. We are reviewing the gaps mentioned above in the present IHR, and we intend to transform the Regulations into an effective regulatory tool for

WHO Member States. A renewed IHR will strengthen global disease surveillance and allow the WHO to act pro-actively during urgent international public health events. Although some of the core concepts proposed for the revision of the IHR are new, many of the recommended improvements expand on areas already covered in the present IHR. The nine proposed changes in the new IHR of most interest to the SPS Committee are numbered below with lower-case Roman numerals. After each proposed change follows a short discussion on rational and impact.

Range of events to be covered

(i) The new IHR will retain the goal to "ensure the maximum security against the international spread of diseases with a minimum interference with world traffic".

9. *Rationale*: Any functioning global surveillance system must take into account the economic consequences of reporting of disease events. If the WHO notification and response system cannot guarantee that losses are kept to what is strictly required from a public health perspective, compliance with IHR reporting and notification obligations will likely be weak. Inversely, the system must be able to handle situations when barriers to trade and traffic are suddenly raised because of perceived risks of international spread of diseases, which in reality may either be small or non-existent.

10. *Impact*: WHO is committed to maintaining a dual-purpose regulation (health/traffic), and the new IHR must successfully address both aspects. Besides working directly with WHO Member States and WHO Regional Offices, consultation must include all WHO departments involved in trade, such as Food Safety, Environment, Pharmaceuticals, as well as a plethora of external stakeholders, such as the World Trade Organization, and other United Nations partner Organizations and NGOs.

(ii) The new IHR will not contain a list of notifiable diseases. Instead, it will require the reporting of all "events of urgent international importance related to public health"

11. *Rationale*: In the present world of new and re-emerging diseases, any disease list could become obsolete the day after it was printed. Also, a case of a disease in itself does not always pose any danger of international spread. The disease must be coupled to circumstances, such as place, time, extent of the disease event, closeness to an international border (or an airport), etc.

12. The key concept of the revised IHR – and one which will require substantial change in the way countries interact with WHO – is that *events of urgent international importance related to public health* should be notified to WHO. The new IHR will contain an algorithm to decide when an event would be urgent and international, and getting agreement on such an algorithm will be one of the main tasks of the IHR Revision Team. An early draft of this algorithm, which was tested during the Syndrome Pilot Study, contained the following parameters:

- high potential for spread outside the community/country;
- unexpectedly high case fatality ratio;
- unusual or unexpected event;
- occurring in a high density/urban area;
- country capacity to control and contain the event;
- significant possibility of international transport of infected persons or contaminated goods/conveyances;
- significant possibility of transport via insects, rats, or other vectors;
- event has high media profile;
- potential for imposition of trade/traffic barriers by other countries.

13. *Impact*: The concept of an *urgent event of international importance related to public health* means that countries can no longer just send off reports about diagnosed cases of cholera, plague or yellow fever in an almost automatic fashion. When there is an event with possible international consequences, several sectors of the national administration will have to quickly decide if the event fulfils the WHO criteria, and whether it should be reported to WHO.

14. A consequence of the new, wider definition of events to be notified is that the new IHR will not be restricted to outbreaks of infectious diseases, but also address other urgent events where disease may spread from one country to another. (A relevant example would be the sudden finding of some dangerous chemical contamination in exported food.)

Use of non-official information

(iii) Other information than official notifications will be used by WHO to help control urgent international events. There will be an obligation on WHO Member States to respond to requests from the WHO to verify the reliability of such information.

15. *Rationale:* In the present era of rapid electronic communication – the global information super highway – news about many urgent international events will become public before even the most efficient administration has had time to react and report. Such news, even if unverified, may quickly lead to sanctions on traffic and trade from other countries feeling threatened. It is vital that WHO makes an assessment of the situation as early as possible. In situations where apparently reliable information about a serious, and potentially international, disease event in a WHO Member State has been provided to WHO, the WHO will contact the State and ask for verification or denial within a very short time period.

16. Faced with non-notification of what appears to be an urgent international event, the WHO will need to inform other WHO Member States for their protection, and if necessary issue recommendations.

17. *Impact:* The present IHR obligation on WHO Member States to notify for three diseases is thus extended to an obligation to respond to inquiries about any potential urgent event from the WHO within a limited time. It can be foreseen that, in most such instances, the affected country will work closely with WHO to protect itself from unnecessary trade or travel embargoes. In the case of non-notification, however, the decision process must be consistent and clear.

A WHO obligation to assist

(iv) There will be an obligation on WHO to rapidly assist WHO Member States in assessing and controlling disease events.

18. *Rationale:* If the extent and potential threat of an event are initially unclear, many countries may need external assistance. WHO will then offer to send an investigating team, which will collaborate closely with the WHO Member State government.

19. In the case of an established outbreak of infectious disease, the team will not only assist in stopping the outbreak locally, but also ascertain the capability of the affected country to contain the outbreak within its borders.

20. The added benefit of granting entry to an investigation team would be to aid countries to achieve international acceptance of their capacity to prevent international spread through an independent, third-party evaluation. This should reduce unnecessary economic hardship for the affected country.

21. *Impact:* The capacity of WHO to react and assist in disease events, even when there are multiple such events occurring simultaneously, must be improved.

WHO recommendations and directions

(v) There will be a transparent process within WHO to issue recommendations or directions.

22. *Rationale:* When there is imminent risk of international spread of disease, WHO will issue either recommendations or time-limited directions. These actions could be directed either at the affected country or at all other WHO Member States, or both.

23. Since these directions will be binding and would contain the maximum measures allowed for WHO Member States, a more democratic process is proposed. Directions would be issued only at the discretion of a body constituted from all (32) members of the existing Executive Board of the WHO. This body would have to react by electronic communication due to the urgency of many events – sometimes in only hours or days, and be prepared to alter the directions for measures based on new information received from the event site.

24. The same process might apply when new barriers to traffic or trade are suddenly raised in response to events, based on uncertain or incomplete public health grounds.

25. *Impact:* This decision process requires rapid response, while at the same time building on consensus derived from the widest possible representation. Determining the most workable format remains one of the major tasks of the IHR Revision Project, but with all probability it will have to be virtual, electronic process.

(vi) The revised IHR will contain a list of all key measures that could be used in a WHO directive. In an actual event situation, the WHO will issue either specific recommendations or binding, time-limited directions from the list, depending on the potential impact of the event.

26. *Rationale:* Each urgent event is unique, and just as it is impossible to give a list of diseases (see item 2 above), there is no way to describe measures appropriate for each event in advance. The proposed model is a compromise: the list of measures that could be taken to prevent international spread of disease – at embarkation, during travel, and at point of entry – is really not very long, and should be contained in the new IHR.

27. Some of the examples of the draft measures currently under assessment in the revision process include:

> *Measures potentially applicable at point of entry into non-affected WHO Member States from an affected Member State.*
>
> *1. To travellers*
> - *no measures required*
> - *require travel history in affected country*
> - *…*
> - *…*
> - *refuse entry of persons from affected area*
>
> *2. To goods and conveyances*
> - *no measures required*
> - *require inspection of conveyance, cargo or goods*
> - *require treatment of conveyance, cargo or goods*
> - *require isolation of conveyance, cargo or goods*
> - *require destruction of cargo or goods*
> - *refuse entry of conveyance, cargo or goods*

28. During an actual urgent health event, WHO would choose the appropriate measures to be taken from the complete list, and use this as a basis for a binding directive on WHO Member States. This directive would be time-limited for the event. A protocol for ending event measures would also be included in the IHR text.

29. *Impact:* At the outset, this concept may be difficult to accept for some WHO Member States: in essence giving up some of their national sovereignty to WHO in situations of urgent international public health events. It does, however, constitute the *sine qua non* of the IHR process. If countries affected by an urgent international event cannot be guaranteed that the measures taken by other States to protect themselves will be only what is necessary and sufficient from a public health point of view, they will be extremely reluctant to report or admit the event. One could say that WHO Member States are trading some sovereignty (for a short time period) for assurance of open reporting of dangerous events from all other states. Every international agreement requires this same sort of compromise.

30. One could question the remit of WHO to make such decisions for the world, but it should be remembered that WHO is the only global organization with a United Nations-derived mandate to provide direction and co-ordination for international public health matters. WHO Member States are already looking to WHO for guidance in urgent international health situations, and if the WHO does not provide this function, who will?

(vii) The revised IHR would contain an appeal process by which WHO Member States could challenge WHO directives.

31. *Rationale:* The process described above to declare an urgent international event and issue directives needs to be rapid and consistent. There may well be instances where a country affected by an event thinks the required measures are too severe, or inversely, where other countries wanting to protect themselves think they are too lax. In both instances there must be a protocol, which creates an opportunity for a WHO directive to be challenged by WHO Member States.

32. In addition to this, there needs to be a dispute resolution protocol in the new IHR for situations when one WHO Member State complains that another State has exceeded the maximum time-limited measures given in the WHO directive.

33. *Impact:* No WHO format for an appeal process exists at present, and it needs to be developed as an important component of the Revision Project. The existing dispute resolution process in the present IHR needs to be modernised.

Other organizations

(viii) The existence of other organizations involved in matters concerning health and trade need to be acknowledged in the new IHR, with respective areas of responsibility delineated and possible synergies explored.

34. *Rationale:* When previous versions of the present IHR were accepted (in 1951 and 1969), there was little concern with other international agencies that made decisions on health, trade, sanitary issues in aviation, and maritime transactions. Since then, the World Trade Organization (WTO), and especially its Committee on Sanitary and Phytosanitary Measures (SPS Committee), has become an important player in the global health arena. The SPS Committee is now an important forum for international decisions and agreements on trade barriers linked to public health. As almost all the Members of WTO are WHO members, it follows that these countries could be bound by two international, but conflicting agreements.

35. *Impact:* The main difference between the IHR and SPS processes lies with time-lines for reaction and response. The revised IHR would deal with events in real time, whereas the SPS Committee deals retroactively with complaints about trade barriers months or years after they were first instituted. This difference should delineate the respective areas of responsibility in most instances. There are also clear possibilities for synergy between the two agreements, which should be investigated.

Oversight committee

(ix) A permanent review body needs to be established to build continuity within the IHR process

36. *Rationale:* The existing IHR became woefully out of date due to lack of a mandatory review process. The new IHR will have broad-based provisions, and will require on-going interpretation and precedence setting. For example, the similar network for reporting of urgent events between EU member States is backed by a committee that meets several times per year to clarify the application and scope of this obligation.

37. *Impact:* The WHO needs to ensure that this review process is fully supported. WHO Member States will see on-going value in the application of a sustainable, up-to-date IHR.

Summary of the vision behind the proposed changes

38. In a globalized world of the twenty-first century, the IHR build on the emergent, inexorable link between national and global surveillance for diseases. As the only international regulatory tool for global surveillance of diseases, the new IHR will contain functional and effective templates for national surveillance, as well as response systems for international disease threats and harmonisation of control measures. A thoughtful revision and modernisation could turn the IHR into a powerful tool for WHO to better fulfil its mandate "to act as the directing and co-ordinating authority on international health work".

39. The need for WHO to be given authority to issue maximum measures is founded on the following chain of reasoning, which underscores the cross-border impact of globalisation of public health:

- First, the best way to prevent international spread of diseases is to either detect disease pathogens or other public health threats early and stamp them out when they are still small.
- Second, early detection of unusual disease events requires good national surveillance.

- Third, international co-ordination is necessary since many countries may need assistance from multilateral institutions during serious disease events.
- Fourth, the need for international co-ordination presupposes the existence of an international co-ordinator to harmonise and standardise notifications, responses from other countries and the global sharing of epidemiological information.
- Fifth, effective notification of disease events to an international co-ordinator will be facilitated by an assurance of how this information will affect WHO Member States' economic interests – traffic, trade and tourism.

Building on the five-pronged dimensions of this chain of reasoning, the IHR as a legally binding regulatory mechanism for global surveillance of international disease events seeks to strike a critical balance between public health and trade. It is not an easy task to maintain this delicate balance, and it is in this context that the difficulties of the IHR revision will be understood.

40. However, it should be clear that no isolated national control strategies will work in the long run. The only certain way for countries to protect their populations from international disease threats and their consequences is to come together and agree on global solutions. These solutions can be made available to WHO Member States by including them in the new IHR.

III. CONFLICT AND SYNERGY BETWEEN THE IHR AND THE SPS AGREEMENT

41. Overlap between these agreements occurs only in the area of contaminated goods (chiefly food), that could affect human health. IHR also addresses restrictions on travellers, which are of little concern to the SPS Committee.

42. The SPS Agreement allows Members to exceed international standards when it is necessary to protect health. The IHR, on the other hand, has historically set the maximum measures that a WHO Member State can take in response to a disease event. Under the revised IHR, WHO will issue non-binding recommendations for measures in response to important international events, but there will also be instances when WHO will issue binding directions. These directions will be time-limited to the duration of the event, and may change based on new information received. In most instances, directions will not overlap with the WTO dispute process.

43. There is a possibility, however, that a Member State of both WHO and the World Trade Organization could refuse compliance with the WHO directions at the time of the event, by referring to Article 3 of the SPS Agreement. Another possibility is that an urgent event which primarily has lead to WHO directions, lingers on and still cause human cases after several months, only to finally wind up in the SPS Committee. In this scenario, there is a clear possibility for duplication of the processes in both organizations. A third situation when the processes could be duplicated would be the case when a Member State has applied measures more stringent than the recommendations or directions of WHO for this event - such a case could be appear almost simultaneously in the dispute processes of the two organizations.

44. There is, however, also considerable potential for synergy between the two international agreements. At present, the WTO does not recognise the WHO decision process in making risk assessments and statements on trade based on public health, and WHO directives cannot be referenced in the SPS process. If WTO were to acknowledge directives made by WHO at the time of an urgent international event, this could serve two purposes:

- First, in contrast to IHR, WTO has the power to enforce decisions by economic punitive measures on Member States. Knowledge that a WHO decision under the IHR may appear in the WTO dispute settlement process could act as an incentive on Member States to follow WHO directives.
- Second, in dispute situations at the WTO, the existence of a previous WHO ruling could save time and effort for the WTO by eliminating the need for each Member State to produce scientific evidence on an issue already addressed within WHO.

45. In acute events, much synergy could probably be gained if WTO Members agreed to withhold any new trade sanctions at least until recommendations (or directions) have been issued by WHO, or even until a rapid appeal process at WHO has reached a decision. With the proposed mechanisms at WHO, such a wait would not be longer than days or weeks, respectively.

APPENDIX A

SUMMARY OF PROPOSED CORE OBLIGATIONS, CAPACITIES, AND OPERATIONAL REQUIREMENTS IN THE NEW IHR

Definitions:

Core Obligations: Those unchanging and essential public health needs that establish the framework for the Regulations.

Core Capacities: The elemental level of activity needed to fulfil the core obligations.

Operational Requirements: The detailed instructional models for carrying out activities to fulfil IHR obligations.

Core Obligations for WHO Member States

- Notify WHO of potential urgent international events.
- Control national urgent public health events that threaten to transmit disease to other WHO Member States.
- Provide routine and emergent port of entry/embarkation inspection and control activities to prevent international disease transmission.
- Comply with the recommendations and directions issued from time to time by the WHO.
- Respond to requests for verification of urgent national events.
- Assist WHO investigative teams.

Core Obligations for International Conveyance Operators

- Maintain the conveyance in a manner which does not contribute to international disease transmission.
- Comply with the requirements of the Regulations as directed by WHO Member States

Core Obligations for the WHO

- Respond to WHO Member State emergent and routine needs as regards the interpretation and implementation of the Regulations.
- Provide a forum to hear WHO Member State appeals against WHO directions.
- Provide a forum to resolve IHR interpretation disputes.
- Update the Regulations as required to maintain scientific and regulatory validity.
- Provide a public health information/support role for WHO Member States regarding disputes involving other international agreements.

Core Capacities for WHO Member States

- Provide a surveillance system to quickly identify urgent national health events, analyse these events against the parameters provided to determine an urgent international event, and notify WHO.
- Provide control mechanisms that prevent the spread of national disease events to other WHO Member States.
- Provide port of entry and related are inspection and control for international travellers, conveyances, goods and cargoes.

Core Capacities for International Conveyance Operators

- Provide on-board health inspection and control measures to ensure that diseases are not carried by passengers, crews, goods, insect vectors or rodents, by the conveyance itself.

Core Capacities for WHO

- Provide a 24-hour service to respond to urgent international events that threaten WHO Member States.
- In conjunction with the affected WHO Member State(s), provide a consistent and transparent process to assess urgent international events.
- Based on this assessment, issue recommendations and directions regarding the application of selected health measures.
- Provide a collaborative notification and response process involving WHO Country Representatives, WHO Regional Offices and Headquarters, and Member State health administrations, to assist Member States in dealing with urgent international events.
- Provide a process, which allows WHO Member States to appeal the directions issued by the WHO during urgent international events.
- Provide an assisted bilateral process and a Committee of Arbitration for disputes between WHO Member States involving the interpretation of the IHR.

Operational Requirements of the new IHR

It is the practice within WHO for departments to publish operational guidelines. These guides could be adopted for reference in the new IHR after meeting an established review process. To be referenced in the IHR, a guideline would have to answer the following questions:

- Is it directly relevant to the IHR?
- Is it based on core requirements only?
- Has it completed a scientific review?
- Has it completed an operational review, by WHO Member States, operators, and other stakeholders?
- How will it maintain scientific validity?
- Will it be regularly reviewed and updated as required?

APPENDIX B

IHR REVISION PROCESS IN RETROSPECT

May 1995:	World Health Assembly passes Resolution 48.7 calling for the revision of the IHR.
December 1995:	Meeting of international experts decides to pursue syndrome notification, to try and capture all important disease events.
1996-1997:	Informal Working Group of internal and external experts established. The group concludes to develop use of disease syndromes and to continue existing public health requirements in the 1969 version of IHR
October 1997:	Initiation of Syndrome Notification Pilot Study in 21 countries selected by WHO regional offices.
January 1998:	Preliminary IHR draft distributed to WHO Member States for review and comment.
May 1998:	Progress report to the World Health Assembly.
November 1998:	Meeting of the Committee on International Surveillance of Communicable Diseases (CISCD).
January 1999:	Small working group met to analyse CISCD meeting and propose future changes.
March 1999:	Syndrome Notification Pilot Study terminated.
August 1999-Date:	- IHR Revision team strengthened - new concepts elaborated and developed - 12 meetings held with collaborating WHO Member States, - electronic Virtual Discussion Forum initiated with participants from some 40 WHO Member States - collaboration with relevant international agencies: WTO, IMO, IATA, ICAO, IAEA, EU pursued, - IHR policy paper discussed by WHO cabinet - synergy between IHR and WTO's SPS agreement explored

APPENDIX C

CONTACT ADDRESSES

Since the IHR revision process is still in the development stage, no new draft version currently exists. Information on the IHR revision can be obtained from the Secretariat at WHO Headquarters in Geneva.

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