COMMENTS from the Attorney General's Office:

Designation of Samoa's National IHR Focal Point (Article 3)

1. A principal change in the revised IHR is the introduction of a National IHR Focal Point. This is to be an institution designated by each State to act as the contact point for WHO in relation to the applicability and implementation of the IHR. The Focal Point is to notify potential public health emergencies of an international concern to the WHO. It is also proposed that it manage all communications with WHO, including on the implementation by a Member State of WHO recommendations to manage and control public health emergencies.

2. The IHR does not specify that the National IHR Focal Point is to be an organ of the Member State. My recommendation, however, is that the Samoan IHR Focal Point should be an entity that forms part of the Government, with the natural designee being the Ministry of Health.

3. An entity within the Samoan Government is best placed to fulfil the legal obligations ascribed to the IHR Focal Point under the Regulation. Moreover, such a designation would simplify channels of communication between Samoa and the WHO, since any WHO communication with the National IHR Focal Point is to be taken as a communication with a Member State and a Member State's health administration pursuant to Article 3.

Resources implications of required surveillance and response capacity (Articles 4 and 10)

4. Articles 4 and 10 require the health administration in each State to develop and maintain the capacity to detect and report public health risks and events potentially constituting public health emergencies of international concern and then to respond promptly and effectively to such risks and emergencies as specified in Annex 1.

5. The "core capacity requirements" for surveillance, reporting and response specified in Annex 1 of the IHR are admirable as longer-term objectives. However, some of these capacities appear very onerous, such as the capacity to "assess all reports of urgent events within 24 hour". Compliance with some of these Annex 1 legal requirements, including in relation to designated airports and ports, would appear to have significant resource and personnel implications for Samoa.

6. If the Ministry receives technical advice to this effect from the various Services that have been asked to comment on the IHR, I suggest that we advise the WHO Secretariat that the Annex 1 requirements should be revised so as to more realistically reflect developing country resources and levels of access to technical skills. I consider that ,the intention and spirit of these "core capacity requirements" could be maintained, whilst the details and timeframes for surveillance, assessment and response could be modified to accommodate the varying implementation capacities of WHO Members.
Clarity concerning State notification of events potentially constituting a "public health emergency of international concern" (Article 5) and WHO determination processes (Article 9)

7. A core obligation of State health administrations under Article 5 of the revised IHR to notify the WHO of all events potentially constituting a public health emergency of international concern within their territories according to the decision instrument contained in Annex 2. This procedure requires the application of an algorithm.

8. A clear and simple concept of what constitutes a "public health emergency of international concern" is of critical importance to the effectiveness of the IHR in practice. My view is that the algorithm is potentially very subjective and that it would be usefully supplemented by the inclusion of a list of serious communicable diseases that have the potential for creating a "public health emergency of international concern".

9. There are benefits in a more flexible approach to State-based determinations of events potentially constituting a "public health emergency of international concern". An obvious benefit is that it may facilitate notification of a disease the emergence of which is not known or predicted and which, accordingly, is unlisted. However, the supplementation of the Annex 2 procedure with a list would provide more certainty to States in their implementation of the revised IHR. Furthermore, there should be an agreed procedure according to which the list of diseases is regularly updated, possibly by an IHR Advisory Panel to be convened by the WHO Director General as outlined in Annex 3.

10. Article 9 of the revised IHR provides for the WHO to determine whether an event constitutes a "public health emergency of international concern in accordance with Annex 3". (Annex 3 specifies the process to be followed by the WHO in the determination of a public health emergency of international concern and the issuance of temporary recommendations). If the WHO determines that a public health emergency of international concern is occurring, Article 9 requires the WHO to inform health administrations of the occurrence and make temporary recommendations. The WHO has the discretion to "make such information and recommendations available to the general public".

11. There is nothing in Article 9 or Annex 3, however, that makes explicit that the WHO's mandatory communication to the health administration is to precede the general publication of this information. It seems possible under the text, as it is currently worded, for the WHO to inform the health administration concerned and simultaneously inform the public. This is problematic, potentially creating panic among the community that a Member State may be ill-prepared to respond to. I would recommend, accordingly, that it be explicit in the text of the IHR that the WHO is to inform health administrations (including neighbouring States) prior to any broader publication.

12. A requirement like the one proposed in paragraph 16 is especially important as Article 9(1) does not build in a requirement that the WHO shall consult with the health administration of the State in making its determination. (This is a separate issue from WHO information dissemination in relation to notification and verification processes, which is appropriately covered by Articles 7(3) and Article 8(3) of the IHR).
13. Paragraph 1 of Annex 3 provides for the WHO Director-General to "consult further" with the health administration once a preliminary determination has been made that a public health emergency of international concern is occurring on its territory. However, the nature and form of any WHO consultation before a "preliminary determination" is made is unspecified.

14. There is also no requirement in Annex 3 for the Director-General to consult with the health administration before making a final determination under paragraph 8 of Annex 3, having received the views of an Emergency Committee on whether an event constitutes a public health emergency of international concern.

15. It is recommended that there be a consultation requirement at this stage in the decision-making process, especially since the context for a final determination under paragraph 8 is that the WHO and the health administration of a territory have disagreed as to how the event should be characterised.

State sovereignty concern regarding non-requested WHO verifications and responses (Article 8(3) and Article 10(3))

16. Article 10(3) provides for the forms of assistance the WHO may offer a State experiencing a public health emergency of international concern, notwithstanding the absence of a State request for such assistance. It states, moreover, that the health administration "... shall collaborate with WHO in assessing the severity of the threat and the adequacy of control measures and, when necessary, in conducting on-the-spot studies by a team sent by WHO, with the purpose of ensuring that appropriate control measures are being employed."

17. Similarly, Article 8(3) requires a health administration in whose territory a possible public health emergency of international concern is detected to "... collaborate with WHO in assessing the potential for international disease spread... and, when necessary, in conducting on-the-spot studies by a team sent by WHO, with the purpose of ensuring that appropriate control measures are being employed". This Article does not make explicit the requirement of State consent to the entry of a WHO inspection team.

18. These Articles raise issues of State sovereignty in WHO responses to public health emergencies. I understand that this issue has also been raised by other WHO Member States who have commented on the draft IHR, including the U.S.A, Switzerland and New Zealand. I fully concur with the comments made in the Swiss Government's submission (pp.3-4):

"Some of the most difficult questions to be resolved will be those concerning national sovereignty. For epidemiological reasons, WHO needs quick and unlimited access around the world to first-hand information, preferable on-site in case of an event potentially constituting a public health emergency of international concern. For obvious political reasons, national sovereignty cannot be ignored, since WHO is not and should not become a supranational organization. One way of addressing this issue might be to fully respect national sovereignty but to define under which conditions WHO is allowed to make public a rejected offer to send an investigation team, including the justification of why the offer was made".
Review of Temporary and Standing Recommendations (Articles 11 and 12)

19. I recommend that there be a built-in periodic review of WHO Temporary Recommendations and Standing Recommendations. Even though it is likely that the WHO will frequently review these recommendations and their continued necessity, and it is clear that the WHO can amend or terminate these recommendations at any time, it could be useful to have an automatic sunset provision on recommendations if they are not explicitly renewed. For example, Temporary Recommendations could automatically expire after thirty (30) days if the WHO does not renew them. There need not be a limit on renewals, so long as the public health threat persisted, provided periodic re-assessment occurs.

Inter-relationship between the IHR and other international agreements

20. The draft IHR contain several references to "applicable international agreements", since it covers public health risks from chemical, biological and nuclear sources. The WHO should provide Member States with information concerning those agreements to facilitate Member State consideration of the nature of the obligations set forth in the IHR. Implementing the IHR will also be more difficult if the inter-relationship of its provisions with other applicable law is unclear.

21. It may be useful for the IHR to contain a general consistency clause to clarify the inter-relationship between the IHR and other "applicable international agreements". There may also be a need for modalities of co-operation between the WHO and other international organizations (such as the International Atomic Economic Agency) to be settled. There may be "public health emergencies of international concern" for which internationally agreed alert and response mechanisms already exist, e.g. international or UN Conventions dealing with the release of chemical or radio-nuclear agents. Events for which there are internationally agreed alert and response mechanisms in place should not necessarily be superseded by the IHR. Accordingly, further analysis may be required as to when the IHR will- and will not be - the prime instrument of action in relation to public health risks for which there are multiple response mechanisms.

State sovereignty regarding "excessive measures" (Article 34) and implementation of measures (Article 35)

22. Article 34 provides that State should make every effort not to impose measures exceeding those recommended by the WHO under the IHR. This, once again, raises the issue of State sovereignty. It is unclear why a State should not choose a higher level of public health protection for its population than the internationally agreed minimum standard reflected in the IHR. In this regard, I agree with the comments made by the U.S. Government in their comments to the WHO Secretariat dated 27 April 2004, citing Article 34 (among others):

"We believe these are inappropriate restrictions on a Member State's prerogative to apply additional measures to protect its nationals or others residing within its borders where such measures are consistent with international law and sound public health practice such as vaccination requirements. We are conscious of WHO's desire to strike a balance between the need to provide security against the international spread of disease, while avoiding unnecessary interference with