NATIONAL INTEREST ANALYSIS

International Health Regulations 2005

Date and nature of proposed treaty action

1. The revised International Health Regulations (IHR 2005 or revised IHR) was adopted by the World Health Assembly (WHA) on 23 May 2005 (IHR 2005 appended as **Attachment 1**). NZ is currently bound without reservation to the International Health Regulations (IHR) 1969.

2. Any rejection of or reservation(s) to the IHR 2005 by New Zealand must be made by 15 December 2006. If no rejection or reservation has been made by that date, the IHR 2005 will become binding on New Zealand; it will enter into force for New Zealand on 15 June 2007. The procedure for becoming bound by the IHR 2005 is one of tacit acceptance, provided for in the constitution of the World Health Organisation. It is proposed that New Zealand neither rejects nor lodges reservations against the revised IHR. For timing reasons, the committee is on this occasion simply asked to note the content of the IHR 2005 for their information.

Reasons for New Zealand to adopt the IHR 2005

3. The International Health Regulations 1969 are at present the principal international legal framework for preventing and controlling the international spread of disease. New Zealand has been party, without reservation, to the existing IHR since they were adopted in 1951 as the International Sanitary Regulations (which were revised and renamed in 1969). Since then, travel and trade across borders have increased while new challenges have arisen in the control of emerging and re-emerging infectious disease.

4. The IHR 1969 have been under review since 1995 and proposals were further revised following weaknesses identified during recent global outbreak alert and response activities. These outbreaks, such as SARS and Highly Pathogenic Avian Influenza (HPAI), have reinforced the need for co-ordinated international action and cooperation to prevent the spread of disease.

5. During the process of review there was widespread international support for the IHR and they were adopted without dissent by the World Health Assembly in 2005.

6. To be effective, public health action must be applied widely, consistently and in a timely and transparent manner. The revised IHR explicitly provide for these objectives.

7. The IHR 2005 aim to achieve their purpose in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.

8. As with the current IHR, there will be a requirement to notify WHO of events that may be of international public health significance. Such notifications will under the IHR 2005 apply to a wider range of potential threats because of the “all-risks’ scope and definitions of the IHR 2005. Notification of events of public health significance may cause anxiety in relation to international traffic and trade. However, timely notification assists with prompt, co-ordinated and proportionate public health responses to potential threats. This should increase the confidence of the public and trading partners in the ability of individual countries to effectively manage such threats.

Advantages and disadvantages to New Zealand of the treaty entering into force and not entering into force for New Zealand

Advantages of treaty action

9. By agreeing to be bound by the IHR 2005, New Zealand would signal its continuing support for internationally coordinated responses to public health threats. The experience with SARS in 2003, and the ongoing outbreaks of human cases of HPAI, demonstrates the globalisation of disease and the need for global responses to it.

10. The revision is an important step in strengthening the world's collective defences against infectious disease threats and risks to public health posed by other potential sources of harm (eg chemical or radiological hazards). Adoption of the revised IHR by New Zealand would help to ensure improved protection against the spread of disease internationally.

11. New Zealand will benefit from having internationally consistent surveillance and assessment of public health risks and public health emergencies of international concern and outbreak verification processes in a number of ways. These include:
    - increased public confidence in the actions being taken by New Zealand in response to public health emergencies of international concern (if and when these occur);
    - aligning processes and actions with trading partners (almost all of whom are also parties to the IHR);
    - certainty and consistency for international travellers and the travel and transport sectors.

12. By following the procedures set out in the revised IHR, New Zealand could also help guard against excessive international reactions to localised events that have low risk of international spread.

13. In addition, New Zealand will benefit from support from the WHO and groups established under the IHR 2005 in identifying and responding to public health emergencies of international concern. Specific benefits for New Zealand include continued:
    - guidance in building the core capacities necessary to quickly detect, assess, report, and respond to public health risks and public health emergencies of international concern;
    - guidance during risk assessment and verification ;
    - advice on outbreak containment, where necessary;
    - professional help to manage dissemination of information to the international media to the benefit of the country and to mitigate the effects of any restrictions;
    - access to the Global Outbreak Alert and Response Network, a "one-stop shop" of global resources to help manage a public health emergency of international concern.

14. The IHR 2005 require specific capacities for public health action including for surveillance and response, for airports, ports (and ground crossings) and other supporting capacities.

New Zealand already meets the majority of the capacities required by the revised IHR and in the remaining areas work is already underway to address identified gaps.

Potential Disadvantages of treaty action

15. No disadvantages are foreseen in New Zealand being party to the IHR 2005.

Legal obligations

16. In general terms, the framework of the IHR 2005 provides for the detection, assessment and implementation of robust and co-ordinated measures to control public health risks that are potential of international concern.

17. The IHR 2005 will set the international framework from within which member states, including New Zealand, and includes:

- ensuring the capacity to detect, assess notify and report events in line with the requirements of the revised IHR[1];
- an obligation to assess the ability of existing structures and resources to meet the minimum requirements of the IHR and to implement a plan of action to ensure these capacities are fully implemented;
- a requirement to assess events using the decision instrument in annex two of the revised IHR to determine whether they could constitute a public health emergency of international concern, and notifying WHO as appropriate[2];
- providing information to WHO on request, including information on infection and contamination at points of entry, information on health measures taken in addition to any provided for in the IHR and (as requested) information on the implementation of the revised IHR;
- responding to public health risks that threaten to transmit disease to other States, including making every effort to implement measures recommended by WHO during a public health emergency of international concern;
- providing routine inspection and control activities at international points of entry and departure to prevent international disease spread, this will include the new ship sanitation/ship sanitation exemption certification regime;
- designating:
  - ports and airports required to have capacities specified in the revised IHR
  - competent authorities at each designated point of entry
  - a national focal point;
- ensuring that ports and airports meet their obligations under the revised IHR;

[1] The capacities themselves are largely set out in Annex One of the IHR and include surveillance, assessment and response capacities at three levels: local community level, first and intermediate public health response levels and national level.

[2] Subject to further negotiation, this may include notifying WHO where there has been an intentional release of a biological, chemical or radionuclear agent within NZ as consistent with both national and international security and law enforcement requirements.

- facilitating the transportation of specimens, reagents and other diagnostic materials for verification and response purposes under the revised IHR.

18. The following features of the IHR 2005 should be noted as specifically differing from the IHR 1969. The IHR 2005 has:

    - A broader focus on a wide range of potential threats to public health including those from chemical and radiological as well as biological sources. This is wider than the existing focus of the IHR 1969 on cholera, yellow fever and plague (the quarantinable diseases).

    - The obligation of member states to notify WHO of any significant public health events reflects the wider scope of the revised IHR and is to be guided by the "Decision Instrument" contained in annex 2 of the IHR 2005

    - The concept that the WHO secretariat has the power to declare a "public health emergency of international concern" is completely new. The exercise of this power would be supported by the "Decision Instrument" (set out in the IHR 2005), as well as other considerations

    - In order to support the monitoring and management of risks to public health, the IHR 2005 specify an explicit framework of 'capacities' for detecting, assessing, managing and responding to risks to public health. These capacities to be in place locally, regionally, nationally and at the border. By June 2009 member states must complete a review of whether existing service provision meets the new requirements, and either strengthen or maintain these services as appropriate. Additionally, designated air or sea ports will have core "at all times" responsibilities/capacities and a second tier of "in emergency" capacities (see Annex One of the IHR 2005).

    - the formalisation of 'national focal points'. National focal points will have an explicit, 'whole of government' co-ordination and communication role

    - the new ship sanitation/ship sanitation exemption certification regime, which is an extension of the existing inspection and deratting/ deratting exemption certification requirements

    - fuller recognition of human rights, acknowledged and affirmed in a way that clarifies that human health protection considerations can in some circumstances impose justifiable limitations on the rights of individuals (eg, up to and including medical examinations and detention for the purposes of isolation/quarantine). Details of this principle includes provision that travellers are to be treated with respect for their dignity and fundamental human rights, not charging (or charging only for those procedures allowed under Article 40(2) and then only commensurate with the cost of the service provided) for health measures taken under the IHR, and keeping health information received under the IHR confidential, except to the extent necessary for public health purposes;

Reservations

19. Member states need to determine whether or not to lodge one (or more) reservation(s) to, or reject outright, the IHR 2005. Under Articles 21 and 22 of the Constitution of the WHO, member states must notify the Director-General of WHO of rejection or reservation(s). Like the vast majority of WHO member states, New Zealand is bound without reservation to the current IHR 1969.

New Zealand was actively involved in the review process, including associated inter-governmental negotiations and is very supportive of the final form of the IHR as adopted by the WHA in May 2005. For these reasons it is proposed that New Zealand neither reject nor seek to make any reservations.

20. If a member state does not lodge a reservation or reject the IHR 2005, they will automatically be binding on that country by virtue of that country's membership of WHO. While the IHR 2005 will not enter into force until 15 June 2007, the deadline for lodging reservations to, or rejecting the IHR, is 15 December 2006 (see Articles 59, 61 and 62).

Dispute resolution

21. Procedures for resolution of any dispute between States Parties concerning the interpretation or application of the Regulations are detailed under Article 56 (1) – (5). These procedures include in the first instance negotiations by any peaceful means. If this fails, the matter can be referred to the Director-General of WHO for arbitration so long as states freely agree to such arbitration being binding; States are not however prevented from using other forms of resolution. If there is a dispute between the WHO and any state party concerning the application or interpretation of the IHR the matter will be submitted to the World Health Assembly.

Measures the Government could or should adopt to implement the treaty action, including specific reference to implementing legislation

22. A number of specific requirements in the IHR 1969 are reflected in New Zealand legislation. Several of these legislative provisions will need amendment in order to give effect to the quite different approach of the IHR 2005. The principal changes relate to:

    - the discontinuation of the old concept of "quarantinable disease" (replaced by an all-risks framework of covering all potentially significant threats to public health);

    - termination of the deratting/deratting exemption regime for ships – currently provided for in the Health (Quarantine) Regulations 1983 (replaced by an expanded ship sanitation/ ship sanitation/ exemption certification regime), and;

    - a change in focus from examination and specific health measures for incoming craft and travellers, to a broader discretionary ability to lawfully implement a potentially wider range of health measures for both incoming and departing craft and travellers (as may be recommended by WHO on either a routine/ongoing basis or in relation to WHO-declared global public health emergency).

23. In order to give full expression to the IHR 2005, New Zealand will need to make changes to primary legislation. The policy for the proposed Public Health Bill, approved by Cabinet on 22 November 2006, will enable full compliance with the IHR obligations. This is not expected to be enacted until the end of 2007 (and implementation will be later).

24. In the meantime, and in the short term (over the next 12-18 months), the compliance with the IHR requirements which apply from June 2007 will be enabled by a combination of the following (as relevant to specific articles):

    - existing provisions in the Health Act 1956 (HA 1956) and its schedules

- ability to amend the schedule in the present HA 1956 (as was done with both Sudden Acute Respiratory Syndrome (SARS) and Highly Pathogenic Avian Influenza (HPAI) and if required the possibility of amending the Health (Quarantine) Regulations 1983)
- the Law Reform (Epidemic Preparedness) Bill, expected to be enacted in late 2006
- administrative arrangements
- voluntary compliance

Economic, social, cultural and environmental costs and effects of the treaty action

25. *Economic*: National economies are increasingly operating in regional and a broader global context. The NZ economy could be directly and indirectly affected by events (and perceptions of events) that impact on public health and on the international movement of craft, people and goods. In 2003 SARS provided a good example of the immediate and significant economic consequences of a multi-country outbreak of a novel disease. The revised IHR are intended to provide for the maximum protection of public health internationally while minimising unnecessary disruption to international traffic and consequential impacts on trade. In this sense, the IHR provide a clear context for the imposition of set what are considered to be justifiable restrictions on international traffic.

26. The IHR 2005 will also provide the transport sector and the wider international community with a measure of certainty and confidence in the measures that are implemented in response to ongoing and emerging risks to public health. For example, as with the current IHR, there will in future be a requirement to notify WHO of events that may be of international public health significance. Such notifications will apply to a wider range of potential threats and may impact adversely on international traffic and trade. However, measures such as timely notification that assist with prompt, co-ordinated and proportionate public health responses to potential threats may also increase public confidence and the confidence of trading partners in the ability of individual countries (and the international community) to effectively manage such threats.

27. The IHR also raises issues as to the inter-relationships with other intergovernmental organisations that New Zealand is a member of, such as the World Trade Organisation (WTO). These complex issues were canvassed at length during the revision process and during intergovernmental negotiations. The IHR state that they and other relevant international agreements should be interpreted "*so as to be compatible*", with an emphasis placed on collaboration.

28. The revised IHR endeavour to minimise the likelihood of such conflict by requiring the WHO to follow criteria for issuing recommendations that are similar to those used in WTO agreements. Furthermore, Article 58 specifically states that the IHR "*shall not affect the rights and obligations of any state party deriving from other international agreements*". In summary, the IHR are explicit with regard to their mandate to take measures that are least disruptive to the movement of people and goods. However, ultimately the IHR could authorise any justifiable interference in trade in order to protect public health.

29. *Social*: In specifying the core capacities required for the detection, assessment and response to public health risks within countries, the revised IHR will contribute to strengthening the generic public health infrastructure that in turn supports ongoing health protection functions. The revised IHR will also strengthen the international community's ability to prevent and control the spread of disease between countries. Both these factors will contribute to improved health outcomes, domestically and internationally.

30. *Cultural*: The revised IHR will explicitly acknowledge the importance of respecting the dignity, human rights and fundamental freedoms of all persons. This will include, as appropriate, taking account of gender, socio-cultural, ethnic and religious considerations. There will also be recognition of informed consent and privacy considerations in relation to measures implemented under the new framework.

31. *Environmental*: By virtue of its potential application to matters such as chemical spills, radiological contamination, atmospheric pollution, disease vectors and reservoirs and animal diseases of human health significance, the revised IHR may have incidental benefits to the environment.

Costs

32. The existing IHR 1969 impose a wide range of roles and responsibilities on member states, ship and aircraft operators and ports and airports. The revised IHR, in most cases, reproduces these existing obligations in an updated form.

33. The Ministry of Health estimates that the annual costs of routine surveillance and other IHR associated work (primarily by health protection officers and other statutory officers employed by district health boards) is in the order of $ 0.600 m (excluding GST). This amount does not include *ad hoc* response costs, which arise on a case by case basis. Although the costs involved in the response to an emergency are unquantifiable, such a response would not be considered a cost of IHR implementation. Implementing the IHR requirements provide the framework for such a response and the resources needed for any emergency response are separate from the implementation costs.

34. Additionally, there are approximately two-three FTEs of Ministry of Health resource (spread across at least eight employees) which also contributes to existing IHR obligations. Overall, some additional costs will accrue to the Crown and some to the transport sector as a result of the IHR 2005. These are expected to be mainly one-off costs, associated with the transition to the new regime and are expected to be relatively minor in the context of existing public health surveillance and response functions and New Zealand's' existing obligations under the IHR 1969.

Consultation with the community and parties interested in the treaty action

35. *Government:* The following departments provided comment on the NIA and/or the accompanying SDC paper: Ministry of Foreign Affairs and Trade, Ministry of Economic Development, Pacific Island Affairs, Maritime New Zealand, Department of Conservation, Civil Aviation Authority, New Zealand Food Safety Authority, Ministry of Transport, and Treasury. The following departments were provided with the opportunity to comment: Ministry of Agriculture and Forestry, Customs, Police, Ministry for the Environment, Department of Prime Minister and Cabinet, Ministry of Defence/New Zealand Defence Force, State Services Commission, Immigration, Aviation Security and Department of Justice.

36. *International transport sector:* In September 2004, the Ministry of Health consulted with a range of airport and airline operators on the proposed revisions to the IHR. There were also subsequent meetings with some port authorities and shipping operators. No significant objections were identified during this consultation. The affected shipping operators would be the foreign operators that service New Zealand's international trades, rather than New Zealand operators or ships, given that New Zealand has virtually no foreign-going ships.

37. *Public:* Public consultation on the broad proposals for the proposed Public Health Bill, the principal legal instrument for giving effect to IHR obligations, has occurred twice in the last seven years. In 1998 the recognition of relevant international obligations was discussed in a discussion document and was generally endorsed. In 2003/2004 a further discussion document outlined in more detail what was envisaged for border health protection legislation in NZ. However, the Ministry of Health has not consulted the public specifically on the subsequent drafts of the revised IHR, nor has the Ministry consulted with Mäori or Pacific peoples.

38. *International:* During the review process the WHO itself also consulted with a variety of intergovernmental and transport sector organisations, including for example, the WTO, the International Air Transport Association, the International Maritime Organisation and the International Civil Aviation Organization.

Subsequent protocols or amendments to the treaty and their likely effects

Future Protocols

39. Following the IHR 2005 entering into force, it is likely that the IHR 2005 will eventually be reviewed again in future, though the Ministry of Health is not aware of plans for any such a review at this time. However, the content and format of Annex Two (the decision instrument) is to be the subject of early and regular review as part of the implementation of the IHR 2005 - this is because of its relatively un-tested nature.

Implementation

40. The WHO has specified a clear timeframe for parties to implement the IHR. In order to give full expression to the IHR 2005 New Zealand will need to make changes to primary legislation. Work is already well underway for amending the Health Act 1956 and replacing it with the proposed public health bill.

41. In addition, the process for amending the schedule to the present Health Act is flexible enough to include new and emerging threats within a relatively short period of time. This occurred in relation to SARS and HPAI examples. The Ministry of Health has prepared an IHR 2005 implementation plan to assist with preparation for the new regime.

Withdrawal or denunciation of provisions in the treaty

42. Article 59 of the IHR 2005 provides that a State wishing to reject or make reservations to the treaty must do so within 18 months of the date of notification of adoption of the Regulations by the Director-General. Any rejection made after that date will have no effect. 15 December 2006 is the time by which notice of requested reservations or rejections are to be lodged. This treaty would be terminated if a revised version were to be adopted at a later date (refer also to articles 61 and 62 of the IHR 2005).

Prepared by: Ministry of Health

Date: December 2006