Revision of the International Health Regulations

Comments by the Swiss Government

General remarks
Switzerland attaches great importance to the global surveillance and control of infectious diseases. We are very pleased that the revision of the International Health Regulations (IHR) has been taken up and is being supported and promoted vigorously by the WHO Secretariat. We welcome the opportunity provided to comment on the Working Paper before the Regional Consultations, and to share our concerns and comments with the other Member States.

There is a need for a fundamental revision of the existing IHR to develop an effective global alert and response tool to deal with cross-border transmission of diseases. This is a challenging task, and we warmly welcome the high quality of the “Working Paper for the Regional Consultations”, particularly from an epidemiological point of view. We believe, however, that the current draft does not yet adequately address several important legal and political aspects. In addition, we are concerned that the revision and consensus-building process as currently planned may not lead to the desired result. Support by all WHO Member States and their willingness to implement the final document are crucial to ensure early detection of public health emergencies of international concern and to provide an appropriate national and international response combining maximum health protection with minimum interference with travel and trade (see comments below).

Revision process
The consensus-building process as it is currently planned might not allow for sufficient input and sense of ownership by the Member States and might therefore compromise the acceptance and implementation of the revised regulations. Our main concerns in this respect are as follows:

- The Regional Consultation is meant “to increase awareness of the IHR, to provide the opportunity to provide input and to develop a shared understanding for surveillance and response” (quote from the “Scope and Purpose” for the Consultation in the European Region). As the input by the member States is provided in writing and the Consultation is not meant to be a first round of negotiations, it is not entirely clear to us what the actual role of the Regional Consultations is meant to be. We will use it as first opportunity to exchange views and to explore possible solutions for the many challenging questions posed by the revised IHR.
- The 2nd draft of the IHR will apparently be developed by the WHO secretariat with the help of some external legal experts. We strongly suggest that WHO should consider inviting independent experts with broad experience in international public law, on the one hand, and diplomatic prowess and negotiation skills, on the other, to assist the secretariat in this important task.
The actual negotiations will take place during the Meeting of the IGWG (Intergovernmental Working Group on the Revision of the International Health Regulations) scheduled to be held in Geneva from 1 to 14 November 2004. Having only one round of negotiations might not be sufficient to arrive at a final draft to which all Member States can agree at the WHA in May 2005. We invite WHO to provide for the necessary measures in case the IGWG should decide to propose that another negotiating session be held.

Definition of the scope of the IHR
The current draft of the IHR covers diseases which “present a risk of significant harm to humans caused by biological, chemical or radio-nuclear sources” (Art. 1, Definitions). In order to avoid conflicts of competence and duplication of efforts with already existing mechanisms of alert and response, the scope of the IHR should be narrowed down. The way in which this is to be done, should be laid down in detail. We propose the following two-step approach:

Identification phase: The origin of the public health emergency is identified as having either a biological, chemical or radio-nuclear source. In this phase the mechanisms of the IHR should be applied independently of the nature of its (presumed) origin which at this stage is often unknown.

Management phase: Once the origin of a public health emergency of international concern has been determined, events for which there are internationally agreed alert and response mechanisms already in place, e.g. international or UN Conventions dealing with the release of chemical or radio-nuclear agents or the Codex Alimentarius regarding food, are followed up by the appropriate institution according to already existing procedures. In that case the IHR mechanisms should take at maximum a clearly defined subsidiary role. All other public health emergencies of international concern (mainly biological) fall within the scope of the IHR.

Algorithm and/or defined list of infectious diseases
The present draft of the revised IHR introduces the concept of "events constituting a public health emergency of international concern" instead of a defined list of diseases. Annex 2 comprises a procedure according to which events potentially constituting a public health emergency of international concern are to be assessed (algorithm). This new concept is paramount for developing an effective international system of early detection and early response. However, shifting from the aetiology-based system of the present IHR to a more comprehensive event-driven approach as proposed in the Working Draft may not be without risks. We would therefore like to suggest that both, a defined, short list of infectious diseases as well as an algorithm be included in the revised IHR. There should further be an agreed procedure according to which the list of diseases is updated on a regular basis.

With regard to the new concept provided by the proposed algorithm, there are two challenges: The concept should be designed in such a way that, on the one hand, there should not be any question of whether diseases like smallpox or SARS had to be notified
or not. On the other, however, there should also not be any danger that too much importance would be attached to the defined list of diseases so that events of unknown cause might be notified too late or not at all. Taking these two challenges into account, we have tried to slightly modify the algorithm accordingly (see attachment).

**Intentional releases (bioterrorism)**
The present draft of the IHR refers to intentional releases only in Art. 41 (Information sharing during a suspected intentional release). We propose that Art. 1 should contain definitions of what constitutes a “natural”, “accidental”, “intentional” and “suspected intentional” disease. It should furthermore be stipulated that the procedures of how to deal with an event (see two-step approach proposed above) are to be followed irrespective of whether it is presumed to be “natural”, “accidental”, “intentional” or “suspected intentional”. Any security question related to a (suspected) intentional disease should be dealt with by the appropriate institution at the national and/or international level.

**Legal questions concerning the IHR**
Several legal issues will need a thorough in depth analysis. They include:
- the specific status as regulations deducted from Art. 21
- the short time of 6 months for potential rejections and reservations
- the relationship with other international treaties
- sovereignty questions
- the role and responsibilities of WHO,
- questions relating to liability and accountability,
- compliance mechanism / incentives promoting the implementation of the IHR
- etc.

**Relationship with activities of other international organizations and with other international instruments/agreements**
The IHR raises questions which are treated by other international organizations as well and touch upon already existing agreements. The IHR should therefore contain a general consistency clause to regulate relationships with other international agreements.

Furthermore, we suggest that WHO should establish a list of relevant already existing international agreements as a working tool; it is not desirable, however, that such a list should become an Annex to the IHR since it carries the risk of not being exhaustive.

**Sovereignty questions**
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, preferably 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 organisation. 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.

Furthermore, in accordance with the WHO constitution and with the SPS agreement of WTO, the state’s sovereignty to choose a higher level of protection for its population than the internationally agreed minimal standard should be respected by the IHR.

Compliance mechanism
The IHR should contain a compliance mechanism. Similarly to those used in modern multilateral environmental agreements, this mechanism should be as non-confrontational as possible and focus on establishing incentives for the proper implementation of and compliance with the IHR.

Designation and role of the Focal Point
The current draft of the IHR requests Member States to designate a “Focal Point” which is to be accessible for WHO at all times and has in turn access to WHO at all times; any communication between WHO and the Focal Point is to be considered as a communication between WHO and the responsible health administration as well as the responsible authority (“Any information sent by WHO to the health administration shall be considered as having been sent to the State, ...”). The role of the Focal Point in the technical cooperation with WHO and other Member States following an event potentially constituting a public health emergency of international concern, and its possible role in the political decision making related to public health emergencies within the Member States has to be clarified before designating a Focal Point. These questions are particularly pertinent for Member States with a federal structure like Switzerland. One solution could be to speak of Member States instead of Focal Point and to define that WHO needs contact details of one entry point for information which is attainable 24 hours a day.

Capacity building in developing countries
The implementation of the IHR will be a very demanding task both in terms of resources (financial, personnel) as well as in terms of the necessary infrastructure to be put in place and the technical know-how to be built up. It will be a great challenge for all Member States but even more so for developing countries. It is thus important that the IHR contain provisions to facilitate the implementation of the IHR in developing countries.