Basic information

2007/2079(INI) INI - Own-initiative procedure	Procedure completed
International health regulations **Subject** 4.20 Public health 4.20.01 Medicine, diseases	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	OUZKÝ Miroslav (PPE-DE)	22/01/2007

Committee for opinion	Rapporteur for opinion	Appointed
LIBE Civil Liberties, Justice and Home Affairs	The committee decided not to give an opinion.	

European Commission

Commission DG	Commissioner
Health and Food Safety	KYPRIANOU Markos

Key events

Date	Event	Reference	Summary
26/09/2006	Non-legislative basic document published	COM(2006)0552	Summary
26/04/2007	Committee referral announced in Parliament		
26/06/2007	Vote in committee		Summary
28/06/2007	Committee report tabled for plenary	A6-0263/2007	
06/09/2007	Decision by Parliament	T6-0379/2007	Summary
06/09/2007	Results of vote in Parliament		
06/09/2007	End of procedure in Parliament		

Technical information

Procedure reference	2007/2079(INI)

Procedure type	INI - Own-initiative procedure
Procedure subtype	Initiative
Legal basis	Rules of Procedure EP 55
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/6/43037

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Amendments tabled in committee		PE390.441	29/05/2007	
Committee report tabled for plenary, single reading		A6-0263/2007	28/06/2007	
Text adopted by Parliament, single reading		T6-0379/2007	06/09/2007	Summary

European Commission

Document type	Reference	Date	Summary
Non-legislative basic document	COM(2006)0552	26/09/2006	Summary

International health regulations

2007/2079(INI) - 26/09/2006 - Non-legislative basic document

PURPOSE: to set out the Commission's views implementing the revised "International Health Regulations (2005) – the IHR.

CONTENT: the IHR is an international legal instrument the purpose of which is to prevent, protect against, and control the spread of disease. It provides a public health response that is proportionate to the risks, whilst at the same time seeking to avoid any unnecessary interference with traffic and trade. It enters into force on 15 June 2007 and is to be implemented gradually by 2016.

To make the IHR work in practice, close co-ordination between the Commission and the Member States will be necessary. The European Centre for Disease Prevention and Control (ECDC) as well as the EU Early Warning and Response System for public health threats (EWRS) will also help with the implementation of the IHR.

This Communication, in brief,:

- sets out the Commission's interpretation of the EU's legal position vis-à-vis IHR reservation and early implementation of flu-related aspects;
- clarifies the EU's role in IHR implementation, particularly through the ECDC and the EWRS;
- reminds the Member States of the restrictions the IHR places on national measures which can be taken on public health grounds; and
- encourages the Member States to develop and share their own plans for IHR implementation.

Legal competences: The IHR, an international legal instrument, involves matters of mixed responsibility between national governments and the European Community. It is not the purpose of this Communication to lists all the IHR articles that are subject to national, Community or shared responsibilities – but rather how the IHR should be implemented in a co-ordinated manner across the Community. For example, IHR Article 45 covers the processing of personal data – an exclusive Community responsibility. Article 41, on the other hand, covers charges for the application of health measures to ships and aircraft – this is not specifically dealt with under Community law and is therefore not a Community power.

Reservations: States that are party to the IHR may lodge reservations to indicate that they can not, or will not, implement particular aspects of the IHR. The Commission notes that the Member States and the Commission worked in close and effective co-operation throughout the IHR negotiations to ensure that the final IHR would be consistent with EC and national law. As a result, the Commission is satisfied that there will be no need for any EU IHR reservation. In the event that a Member State wishes to make a reservation then EU co-ordination will be necessary.

Voluntary early application of flu-related aspects: States that are party to the IHR are called upon to comply, immediately and on a voluntary basis, provisions relating to avian and potential human pandemic influenza. Within the EU context the following provisions will require early application: the designation of IHR national focal points within 90 days of adoption; follow-up mechanisms and procedures in the IHR relating to diseases which may constitute a "Public Health Emergency of International Concern" or PHEIC; notifying WHO and communicating with them any probable or confirmed case of avian influenza; the dissemination to WHO collaborating centres information and biological material related to highly pathogenic avian influenza and other novel influenza strains; developing domestic influenza vaccine production capacity or work with neighbouring states to establish regional capacity; strengthening collaboration on human and zoonotic influenza among national organisations; respecting IHR time frames for activities, particularly for reporting human cases of avian influenza; and strengthening influenza surveillance in countries affected by avian and pandemic influenza.

The Commission urges the Member States to implement the above uniformly in a co-ordinate time frame. This will require co-ordination at an EU level and as such the Commission will take any initiative which could be needed in order to facility this implementation.

Full implementation – EU role: The report states that it would be desirable to adopt an administrative memorandum of understanding between the Community and WHO in order to ensure that arrangements are clearly defined in respect of the IHR. The Commission would be responsible for drafting, negotiating and signing this memorandum.

The role of the EWRS: The scope of the EWRS is limited to communicable diseases, including those of unknown origin. It is therefore not as broad as the IHR, which includes events of unknown cause or source and the spread of toxic, infectious or otherwise hazardous materials. However, in order to maximise efficiency the Commission proposes the following working practices: nominating the same national focal point for EWRS as for IHR; simultaneously informing the EWRS and WHO about events within their territory, which are notifiable under IHR but are not potential PHEICs; informing the EU Communicable Disease network in advance of making a formal IHR notification of a potential PHEIC; and using the EWRS and or the Health Committee to help co-ordinate health risk management and response (particularly for multi-state outbreaks) prior to communicating with the WHO.

The role of the ECDC: The surveillance activities undertaken by the ECDC will be very relevant in the case of a public health threat requiring IHR notification. The ECDC can also assist the Member States with their IHR implementation. As such, the Commission proposes that the ECDC's role in the IHR should be formalised, particularly regarding the collection of data on issues within its mandate. Its role should include, for example, remaining accessible at all times, sharing information during unexpected or unusual public health events and responding to requests for WHO verification.

Roster of experts, emergency & review committees: The Commission recently wrote to the WHO proposing Commission and ECDC experts for the IHR roster. Thus, in the event of a potential PHEIC in the EU it would be appropriate for the WHO to invite the Commission and/or ECDC expert onto the IHR roster to form part of the emergency committee.

Border measures: A key objective of the IHR is to balance the need for restrictions on arbitrary border measures with the right of States to carry out necessary checks on travellers. Certain EU provisions allow the Member States to deny EU citizens entry if they are considered a threat to public health. Where Member States do intend to adopt measures for the control of communicable diseases they must inform other Member States and the Commission in advance. This is considered an important issue requiring further discussion within the Council.

Contact tracing: Under IHR provisions States may require travellers to provide information about their destination for public health purposes. There is currently no standard international approach to contact tracing. The Commission is therefore working with the aviation industry and Directors General for Civil Aviation to discuss a possible EU approach to contact tracing.

To conclude, this Communication proposes a number of working practices for EU implementation of the IHR. Taking into account the views of the European Parliament and Council, the Commission will develop these proposals further, working together with the both the Member States and the ECDC.

International health regulations

2007/2079(INI) - 06/09/2007 - Text adopted by Parliament, single reading

The European Parliament adopted by 570 votes in favour to 5 against with 4 abstentions, an own-initiative report drawn up by Miroslav **OUZKY** (EPP-ED, CZ) on International Health Regulations (IHR). The recent past had seen the emergence of new disease challenges for national and international public health and better procedures for assistance and information needed to be developed at national and regional level. Parliament acknowledged the significance of a clear and comprehensible international mechanism which aims to prevent, protect against and control the spread of disease, and to provide a public health response proportionate to the risks and accessible to all those who need it. It felt that priority should be given to ensuring maximum protection against the global spread of infectious disease and public health emergencies of international concern, but with minimum interference with world traffic. In accordance with Article 5 of the EC Treaty, the subsidiarity principle needed to be respected as the organisation of health services falls within the competences of individual Member States.

Parliament referred to the World Health Assembly Resolution of 26 May 2006 calling for voluntary early application of certain IHR aspects relating to pandemic influenza, and called on the international community to apply the WHO code of good practice on the rapid sharing of strains, published in January 2007. Parliament stressed the urgent need to implement the International Health Regulations in a coordinated manner across the Community while simultaneously strengthening existing systems and capacities. At the same time, however, on the basis of their powers and of the subsidiarity principle, it was up to the Member States alone to organise their health services, while ensuring a high level of health protection for their citizens.

In order to address better the risk, there was a need to support the development of information systems, both those meant for exchange of information between healthcare providers and those providing information for patients. Parliament emphasised the need to enhance the safety of the information systems.Furthermore, in order to achieve a high level of protection and preparedness in a highly mobile world, it was absolutely necessary to

cooperate with neighbouring and third countries. Members underlined the need for close cooperation between national as well as between national and European authorities when exchanging information in the area of public health safety in order to optimise implementation and better protect EU citizens from public health emergencies of international concern (PHEICs). Parliament recalled the role of the European Centre for Disease Prevention and Control (ECDC), and the EU Early Warning and Response System for public health threats (EWRS) in implementing the IHR and in cases of emergency, and it urged Member States to fulfil their obligations as set out in the IHR. The Commission was asked to:

- prepare guidelines for threat detection and assessment, in cooperation with the competent committee of the European Parliament;
- formalise the ECDC's role in the implementation of the IHR, particularly regarding the collection of data on issues within its mandate;
- find ways and means of supporting the establishment of adequate systems in neighbouring and third countries through financing and regional development mechanisms;
- define ways and means that will make it possible to support the WHO's policy concerning access to pandemic vaccines for developing countries;
- develop programmes to tackle European and global health threats such as healthcare associated infections and the growing resistance to antibiotic treatments. Parliament pointed out that a pan-European solution is clearly required as such health crises do not respect geographical borders.

Lastly, Parliament emphasised the need for the creation of a central EU stockpile of indisputably effective anti-viral and vaccination products to protect Union citizens against a possible influenza pandemic affecting all Member States, to complement Member State measures. EU-wide measures must be adopted by the Commission to address the possibility of an influenza pandemic such as are able to effectively halt the spread of influenza in Europe within a period of 24 hours.