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WP 121**

**Opinion 4/2006
on the Notice of proposed rule making
by the US Department of Health and Human Services
on the control of communicable disease and
the collection of passenger information of 20 November 2005
(Control of Communicable Disease Proposed 42 CFR Parts 70 and 71)**

Adopted on 14 June 2006

This Working Party was set up under Article 29 of Directive 95/46/EC. It is an independent European advisory body on data protection and privacy. Its tasks are described in Article 30 of Directive 95/46/EC and Article 15 of Directive 2002/58/EC.

The secretariat is provided by Directorate C (Civil Justice, Rights and Citizenship) of the European Commission, Directorate General Justice, Freedom and Security, B-1049 Brussels, Belgium, Office No LX-46 01/43.

Website: http://ec.europa.eu/justice_home/fsj/privacy/index_en.htm

EXECUTIVE SUMMARY

This opinion by the Article 29 Working Party is a reflection on the new US legislative proposal concerning the collection of passenger information by air carriers and shipping lines for the control of communicable diseases (Control of Communicable Disease Proposed 42 CFR Parts 70 and 71).

The US draft proposal if enacted would impose some general obligations on European air carriers and shipping lines and would in particular require them to put into practice the following:

1.) to collect and store in the EU for 60 days a number of data regarding all passengers flying to the US that are currently not included neither in the companies' passenger name record system (PNR) nor in their departure control system (DCS) such as emergency contact numbers, email addresses, travelling companions and information on the return flight in order to being able to trace them later on;

2.) to send these passenger details electronically within a 12 hour period of a request directly to the Director of the US Center for Disease Control and Prevention (CDC).

The Article 29 Working Party finds that the fight against communicable diseases is a valuable goal shared by all nations and has, therefore, to be supported in the best possible way. It is in the interest of mankind to curb the spread of diseases and to use modern techniques in the fight against scourges affecting great parts of the world.

The Article 29 Working Party is on the other hand of the opinion that the fundamental right to personal data protection has to be respected when measures are taken to fight communicable diseases and that any measures have to be proportionate. The right to personal data protection and the fight against communicable diseases are no contradictions but may work well alongside if a balanced approach is chosen.

This opinion on the new US legislative proposal examines carefully the foreseen regulations and analyses them not only in the light of the EU-Directive on Data Protection 95/46/EC, but also in the light of the WHO International Health Regulations (2005) which is non-binding in its nature but intends to support nations in their fight against communicable diseases.

The Article 29 Working Party comes to the conclusion that the US proposal if enacted in its current version would conflict with pertinent privacy provisions of the EU-Data Protection Directive 95/46/EC and the WHO International Health Regulations (2005).

* * *

THE WORKING PARTY ON THE PROTECTION OF INDIVIDUALS WITH REGARD TO THE PROCESSING OF PERSONAL DATA,

Having regard to Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data¹, and in particular Articles 29 and 30 paragraph 1 (b) thereof,

Having regard to the Rules of Procedure of the Working Party², and in particular Article 12 and 14 thereof,

HAS ADOPTED THE FOLLOWING OPINION:

1. ISSUE UNDER DISCUSSION

The Department of Health and Human Services (HHS) of the United States of America has published a Notice of proposed rule making in the US Federal Register (Vol. 70, No 229, 30 November 2005; Control of Communicable Disease Proposed 42 CFR Parts 70 and 71; hereinafter: "US proposal"). The notice is concerned with the prevention of the introduction and the spread of communicable diseases into the US.

The US proposal intends to amend the Public Health Service Act (42 U.S.C. 264-271), parts 70 and 71. The latter part concerns foreign arrivals. The intent of the proposed updates of parts 70 and 71 is to clarify and strengthen existing procedures with a view to enabling the US Centers for Disease Control and Prevention (CDC) to respond more effectively to current and potential communicable disease threats. Section 71.10 on passenger information contains provisions aimed at identifying suspects who may have been exposed to a communicable disease allowing them to provide those suspects with direct medical care while preventing further person-to-person spread of the disease.

Section 71.10 (a) requires any carrier operating flights or shipping lines operating ships on an international voyage bound for a US port to solicit from each passenger and crewmember the following information:

- (1) Full name (first, last, middle, initial, suffix);
- (2) Emergency contact information;
- (3) E-mail address;
- (4) Current home address (street, apartment, city, state/province, postal code);
- (5) Passport number or travel document number, including the issuing country or organization;
- (6) Name of travelling companions or group;
- (7) Flight information or port of call;
- (8) Returning flight (date, airline number, and flight number) or returning ports of call; and
- (9) At least one of the following current phone numbers in order of preference: mobile, home, pager, or work (Section 71.10 (e)).

¹ OJ L 281, 23.11.1995, p. 31, hereinafter: 'Directive'; available at: http://ec.europa.eu/justice_home/fsj/privacy.

² Adopted by the Working Party at its third meeting held on 11.9.1996.

In addition, further unspecified details, where necessary to prevent the introduction, transmission, or spread of communicable diseases may be required by the Director of the CDC (who has the authority for implementing part 71) if they are in the airline's or shipping line's possession (Section 71.10 (f)).

This information collected by the companies has to be retained by the company for a period of 60 days from the end of the voyage (Section 17.10 (b)). Airlines and shipping lines shall ensure that passengers are informed on the purposes for which the information is collected at the time the passengers arrange their travel (Section 71.10 (i)). The information collected under Section 71.10 may only be used for the purposes for which it is collected (Section 71.10 (h)). Within 12 hours of a request by the Director to the airline's or shipping line's agent, the airline or shipping line, pursuant to a written plan approved under Section 71.11, shall transmit in an electronic format the requested data fields specified above to the Director of CDC (Section 71.10 (d)).

In case of non-compliance, US authorities may impose sanctions on the companies concerned.

2. COMPATIBILITY OF THE PROPOSAL WITH DIRECTIVE 95/46/EC

2.1. Application of the Directive

The Directive applies as the requested information involves the processing of personal data wholly or partly by automatic means.

The exemptions of Article 3 (2) of the Directive do not apply as the US proposal is about the protection of public health, but not about processing data in the course of an activity which falls outside the scope of Community law, such as those provided for by Titles V and VI of the Treaty on European Union or to processing operations concerning public security, defence, State security (including the economic well-being of the State when the processing operation relates to State security matters) and the activities of the State in areas of criminal law.

2.2. Data collection in the EU

The proposed general obligation placed on EU based transport carriers to collect personal data from their passengers and from third parties and store this information for 60 days, breaches the provisions of the Data Protection Directive 95/46/EC, as such processing must be considered as being not required and in particular excessive (Article 6 (1) (c) and, therefore, goes against the principles of data reduction and data economy:

- The US proposal does not seem to take full account of the amount of personal data already available to other US authorities as part of existing immigration and entry controls, such as landing cards, passenger name records (PNR) or Advanced Passenger Information System (APIS) data (e.g. providing full names of passengers and other passport information) which may be exchanged under certain conditions. Nor does it take account of other internationally recognised methods regarding the direct collection of information from passengers such as public health passenger locator cards.
- The US proposal would oblige air carriers to collect specific data on air passengers without any reference to a defined and specific health threat, i.e. without being necessary for a specific purpose and without the legal foreseeability of a triggering event. This would not be in line with Article 6 of the Directive and with the definitions in Article 1 of the International Health

Regulations (2005)³, e.g. of a “public health emergency of international concern”⁴.

- The US proposal does not foresee the possibility of Article 7 (a) of the Directive – the *unambiguous consent* of the passenger (coupled with the information requirements of the Directive⁵). According to Article 2 (h) of the Directive, ‘consent’ means any freely given specific and informed indication of his wishes by which the data subject – in this case the passenger – signifies his agreement to personal data relating to him being processed.
- Article 7 (c) of the Directive does not apply to the US proposal as processing is not necessary for compliance with a *legal obligation* imposed by Community or Member State law to which the data controller (transport carrier) is subject, as this is a legal obligation imposed by the USA. An obligation imposed by a foreign legal statute or regulation, other than one created by an international instrument, may not qualify as a legal obligation by virtue of which data processing in the EU would be made legitimate. Any other interpretation would make it easy for foreign rules to circumvent the EU rules laid down in Directive 95/46/EC. A legal basis other than an international treaty or agreement could also be the commitment by a state to follow on a voluntary basis the guidelines of an international body such as the WHO, e.g. the International Health Regulations (2005).
- Article 7 (d) of the Directive does not apply to the US proposal as processing is not necessary in order to protect the *vital interests* of the data subject in the absence of a relevant public health alert where a particular individual is already suspect of a communicable disease in the meaning of Article 1 and Article 30 of the International Health Regulations (2005)⁶ or is at risk of contracting a communicable disease.
- Article 7 (e) of the Directive does in the first place not apply to the US proposal as processing is not necessary for the performance of a task carried out in the *public interest of a EU Member State*, but only in the interest of the US, unless necessary in accordance with an international instrument obligation. Such a public interest, however, could be a public health emergency of international concern which would also concern competent EU authorities. Only in such a case, in connection with Article 6 and Article 7 of the International

³ World Health Organisation (WHO), revised International Health Regulations (2005), adopted on May 23, 2005 (hereinafter: “International Health Regulations (2005)” or IHR; available at: <http://www.who.int/csr/ihr/en/>).

⁴ *IHR Article 1 Definitions*: “‘public health emergency of international concern’ means an extraordinary event which is determined, as provided in these Regulations: (i) to constitute a public health risk to other States through the international spread of disease and (ii) to potentially require a coordinated international response”.

⁵ The Directive lays down that information must be provided at least on the identity of the controller, on the purpose of the processing and, under certain circumstances, on other points (see Article 10 *et seq.*).

⁶ *IHR Article 1 Definitions*: “‘suspect’ means those persons, baggage, cargo, containers, conveyances, goods or postal parcels considered by a State Party as having been exposed, or possibly exposed, to a public health risk and that could be a possible source of spread of disease”; *IHR Article 30 Travellers under public health observation*: “Subject to Article 43 or as authorized in applicable international agreements, a suspect traveller who on arrival is placed under public health observation may continue an international voyage, if the traveller does not pose an imminent public health risk and the State Party informs the competent authority of the point of entry at destination, if known, of the traveller’s expected arrival. On arrival, the traveller shall report to that authority.”

Health Regulations (2005)⁷ a data transfer, such as via competent health authorities⁸, would be in line with Article 7 (e) of the Directive.

- Article 7 (f) might apply to the US proposal if processing were necessary for the purposes of a legitimate interest pursued by the controller i.e. the air carriers or by the third party to whom the data are disclosed. Such a reason would however only be acceptable on condition that such legitimate interests are not “*overridden by the interests for fundamental rights and freedoms of the data subject*”. Article 7 (f) requires a balance to be struck between the legitimate interest served by the processing of personal data and the fundamental rights of data subjects. This balance of interest test under Article 7 (f) should take into account issues of proportionality, subsidiarity, the seriousness of the specific public health threat that needs to be prevented and the consequences for the data subjects. In the context of the balance of interest test, adequate safeguards will also have to be put in place. In particular, Article 14 of Directive 95/46/EC provides that, when data processing is based on Article 7 (f), individuals have the right to object at any time on compelling legitimate grounds to the processing of the data relating to them.

2.2.2 Nature of data and period of conservation

- The US proposal would impose a general obligation to store personal data for 60 days irrespective of the differences between different communicable diseases with regard to incubation periods and communicability. Since this obligation has no specific disease in mind it is from a medical point of view not clear whether the storage period in its proposed form is adequate for the different types of diseases. In some cases it may be too long in other cases too brief depending on the incubation periods.
- According to the proposed amended Section 71.10 (f), additional *unspecified* passenger information could be requested by the Center for Disease Control and Prevention (CDC) which would not be in line with Article 23⁹ of the

⁷ IHR Article 6 Notification: “1. Each State Party shall assess events occurring within its territory by using the decision instrument in Annex 2. Each State Party shall notify WHO, by the most efficient means of communication available, by way of the National IHR Focal Point, and within 24 hours of assessment of public health information, of all events which may constitute a public health emergency of international concern within its territory in accordance with the decision instrument, as well as any health measure implemented in response to those events. If the notification received by WHO involves the competency of the International Atomic Energy Agency (IAEA), WHO shall immediately notify the IAEA.

2. Following a notification, a State Party shall continue to communicate to WHO timely, accurate and sufficiently detailed public health information available to it on the notified event, where possible including case definitions, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed; and report, when necessary, the difficulties faced and support needed in responding to the potential public health emergency of international concern”.

IHR Article 7 Information-sharing during unexpected or unusual public health events:” If a State Party has evidence of an unexpected or unusual public health event within its territory, irrespective of origin or source, which may constitute a public health emergency of international concern, it shall provide to WHO all relevant public health information. In such a case, the provisions of Article 6 shall apply in full.”

⁸ IHR Article 1 Definitions: “‘competent authority’ means an authority responsible for the implementation and application of health measures under these regulations.”

⁹ IHR Article 23 Health measures on arrival and departure: “1. Subject to applicable international agreements and relevant articles of these Regulations, a State Party may require for public health purposes, on arrival or departure: (a) with regard to travellers: (i) information concerning the traveller’s destination so that the traveller may be contacted; (ii) information concerning the traveller’s itinerary to ascertain if there was any travel in or near an affected area or other possible contacts with

International Health Regulations (2005) which foresees a clearly *specified* catalogue of information that can be requested by the competent health authorities.

2.3. Data transfer from the EU to the USA

The obligation on EU transport carriers to transfer the personal data to the US upon request by the Director of the Center for Disease Control and Prevention breaches the provisions of the Data Protection Directive 95/46/EC, as such transfer has no legal basis under Article 26.

- The US does not benefit from a finding that there is an adequate level for the protection of personal data as required by Article 25 (6) of the Directive.
- Considering the different purposes of the collection of passenger data, none of the existing EU-US legal schemes¹⁰ can apply: neither the PNR-Agreement which has been annulled by the European Court of Justice on May 30, 2005¹¹ nor the Safe Harbour scheme.
- By way of derogation from Article 25 of the Directive, the transfer of personal data to a third country which does not ensure an adequate level of protection within the meaning of Article 25 (2) may take place on condition that the data subject has given his consent – i.e. freely given specific and informed consent, as required by Article 2 (h) of the Directive – unambiguously to the proposed transfer. The US proposal does not foresee this possibility.
- Article 26 (d) of the Directive does not apply as the transfer is not necessary or legally required on important public interest grounds of a EU Member State, but only in the US interest, unless the transfer is based on international health agreements providing for harmonised health measures at an international or European level, e.g. within the meaning of Article 2¹² and Article 35¹³ of the International Health Regulation (2005), under specific conditions.

infection or contamination prior to arrival, as well as review of the traveller's health documents if they are required under these Regulations; and/or (iii) a non-invasive medical examination which is the least intrusive examination that would achieve the public health objective; (b) inspection of baggage, cargo, containers, conveyances, goods, postal parcels and human remains.

2. On the basis of evidence of a public health risk obtained through the measures provided in paragraph 1 of this Article, or through other means, States Parties may apply additional health measures, in accordance with these Regulations, in particular, with regard to a suspect or affected traveller, on a case-by-case basis, the least intrusive and invasive medical examination that would achieve the public health objective of preventing the international spread of disease.”

¹⁰ Cf. http://ec.europa.eu/justice_home/fsj/privacy/thridcountries/index_en.htm.

¹¹ European Court of Justice, 30 May 2006; Joint cases C-317/04 (European Parliament/Council) and C-318/04 (European Parliament/Commission).

¹² *IHR Article 2 Purpose and scope: “The purpose and scope of these Regulations are to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.”*

¹³ *IHR Article 35 General rule: “No health documents, other than those provided for under these Regulations or in recommendations issued by WHO, shall be required in international traffic, provided however that this Article shall not apply to travellers seeking temporary or permanent residence, nor shall it apply to document requirements concerning the public health status of goods or cargo in international trade pursuant to applicable international agreements. The competent authority may request travellers to complete contact information forms and questionnaires on the health of travellers, provided that they meet the requirements set out in Article 23.”*

3. OTHER ISSUES

- Information of passengers: This US proposal requires some data elements which are currently usually not collected and/or retained by the transport carriers which means that they will have to organize this collection and retention only for the purpose of satisfying US requirements. Furthermore it has to be mentioned that it is not quite clear whether the rights of the passengers are fully respected once the proposal is enacted. Although air carriers and shipping lines would be obliged to inform the persons concerned about the collection and storage of their data (Section 71.10 (d)) doubts remain on how this information is given and whether the passenger is correctly informed about his fundamental rights to access and redress in the meaning of Article 10, 11 and 12 of the Directive regardless of the fact whether the data are only stored in the companies data bases or transferred upon request to the CDC.
- The WHO International Health Regulations (2005) also lay down specific requirements for the treatment of personal data: Article 45 requires health information which refers to an identified or identifiable person to be kept confidential and processed anonymously. Only where it would be essential for the purposes of assessing and managing a public health risk, as defined in the International Health Regulations (2005), State Parties and the WHO may process personal data. However they must ensure that the personal data are: (a) processed fairly and lawfully, and not further processed in a way incompatible with that purpose; (b) adequate, relevant and not excessive in relation to that purpose; (c) accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that data which are inaccurate or incomplete are erased or rectified; and (d) not kept longer than necessary.

4. CONCLUSIONS

The desire of States to put in place their own measures to control the spread of communicable diseases is a valuable goal shared by all nations and any measures in the fight against diseases must be fully supported. Most issues at stake mentioned in this opinion are beyond the competence of airline companies and have to be addressed by the EU Member States and as necessary by the European Commission.

For international travel purposes, the Working Party prefers global solutions over unilaterally imposed demands and measures. It has expressed this point of view in previous opinions with regard to requests by different countries to provide PNR data in order to fight terrorism and other serious crimes of a transnational nature.

1. The Working Party is of the opinion that the fight against communicable diseases goes alongside the protection and promotion of fundamental rights, such as the fundamental right to the protection of personal data. Furthermore the Working Party is of the opinion that economic aspects should be taken into account as well and that the costs related to the collection and processing of personal data should be proportionate.
2. The rules on the protection of personal data do not prevent health authorities to process necessary personal information in order to prevent the introduction, transmission or spread of communicable diseases.

3. In the case of a recognized and actual health threat, the EU data protection Directive 95/46/EC itself provides for several grounds for legitimately processing personal data, even sensitive data on health, e.g. with the freely given and informed consent of the person concerned, or when processing is necessary to protect the vital interests of the individual or to protect the rights and freedom of others (see Article 7 (a) and (d), Article 13 (g) of the Directive).
4. To prevent the spread of communicable diseases, the possibility of tracing passengers in specific cases may be necessary for public health reasons under certain circumstances. In the past, in case of a public health threat like Severe Acute Respiratory Syndrome (SARS), this has been done by asking passengers on concerned flights to fill in so-called "locator cards" thus directly providing for the necessary information.
5. However, the current US draft proposal regarding collection by airlines of passenger information to prevent the introduction of communicable diseases into the US would lead to the disproportionate and routine disclosure of information by airlines who are subject to the requirements of Directive 95/46/EC.
6. Regarding passenger rights it remains unclear whether the US proposal fully respects the provisions of Article 10, 11 and 12 of the Directive i.e. right to adequate information, the right to access and redress.
7. The Working Party is therefore of the opinion that the US proposals if adopted in its current version would be in conflict with the Data Protection Directive 95/46/EC.
8. In addition, the Working Party is of the opinion that the US proposal if adopted in its current version would also be in conflict with regulations and guidelines published by the WHO, in particular the International Health Regulations (2005).
9. The Working Party calls, therefore, upon States to work within the current framework of international agreements to ensure a consistent approach which incorporates essential data protection safeguards.

Done at Brussels, on 14 June 2006

For the Working Party
The Chairman
Peter SCHAAR