Opinion on a notification for Prior Checking received from the Data Protection Officer of the European Medicines Agency concerning the "Family Leave / Compel Personnel Database / Electronic Document Management Systems (EDMS)"

Brussels, 14 April 2008 (Case 2007-498)

1. Procedure

On 3 September 2007, the European Data Protection Supervisor (EDPS) received from the Data Protection Officer (DPO) of the European Medicines Agency (EMEA) a notification for prior checking concerning data protection operations related to Family Leave.

On 5 September 2007, the EDPS sent a request for additional information to the EMEA DPO. A partial reply provided on 19 October 2007 was accompanied by the following documents:
- Application for Parental or Family Leave (template);
- Data Protection Declaration;
- Decision of the EMEA Executive Director on the adoption of implementing rules relating to the protection of individuals with regard to the processing of personal data and on the free movement of such data dated 12 June 2007 (EMEA/253592/2007);
- Personal Data Access Request Form (template).

On 19 November 2007, the EDPS sent another information request together with the draft facts to the EMEA DPO. The reply was provided on 23 January 2008.

The draft opinion was sent to the EMEA DPO for comments on 17 March 2008. The comments, accompanied by a revised version of the Application for Parental or Family Leave, were received on 3 April 2008. In order to clarify the newly submitted facts, two more information requests were sent to the EMEA DPO on 4 and 8 April 2008. The replies to the first one were provided on 4 and 7 April 2008. The reply to the second one was received on 9 April 2008 and was accompanied by the Protocol agreement between EMEA and Rood Lane Medical Group for the provision of medical services signed in March 2005.

2. Facts

2.1. Description of the processing

Family leave for a total period of nine months can be granted upon application in case of medically certified serious illness or disability of certain relatives (Article 42b of the Staff Regulations read together with Articles 16 (1) and 91 of the Conditions of Employment of Other Servants of the European Communities (CEOS))\(^1\).

\(^1\) Special leave that could be granted in case of serious illness of spouse, a relative in the ascending line and a child, as well as very serious illness of a child has been analysed in a separate opinion (EDPS 2007-420)
The family leave request shall be submitted to the Appointing Authority through the applicant's immediate superior. The Application forms are collected in hard copies and the data area subsequently entered into the Compel Personnel Database.

The request shall be accompanied by a medical certificate of the person in respect of whom the family leave is to be taken. This medical certificate containing the diagnosis of the illness or handicap and confirming its seriousness shall be presented to Personnel & Budget Sector staff for validation at the latest within two weeks of the application. In regular cases (clear diagnosis), the certificate is immediately returned to the staff member concerned (and Personnel & Budget Sector staff confirms on the Application form that the medical certificate was presented and was found to be in order). No photocopy of the medical certificate is retained.

In case of doubts or uncertainty about the illness or handicap, the certificate is passed to an UK based external medical consultant (Rood Lane Medical Group) to be assessed. In this case, the name of the person is rendered anonymous. Once the external consultant has reviewed the certificate, it is returned to the staff member concerned. A letter confirming the seriousness of the family member's illness and the leave entitlement of the staff member is sent to the Head of the Personnel & Budget Sector, marked private and confidential (article 8 of the Protocol agreement between EMEA and Rood Lane Medical Group on the provision of medical services).

2.2. Data subjects

EMEA Staff Members consisting of Temporary and Contract Agents (but not Officials\(^2\)), as well as their following relatives: spouse, relatives in the ascending and descending line, brothers and sisters.

2.3. Categories of data processed

The following data have to be provided in the Application form:
- name, personnel number, sector and unit of the staff member requesting the family leave;
- contact address and phone number during the leave;
- first name, surname and date of birth of the respective family member;
- relationship between the staff member and the family member.

In addition, the medical certificate contains information about the diagnosis of the illness or handicap, as well as information confirming its seriousness.

2.4. Data transfers

The data collected for the purpose of Family leave may be disclosed to the following recipients:
- Head of Unit and Head of Sector of the applicant;
- Personnel & Budget Sector staff;
- Information Technology Sector staff (information other than the reason for the respective family leave or the health conditions of the family members);
- Security and Reception staff (information other than the reason for the respective family leave or the health conditions of the family members);

- duly authorised persons from external bodies (European Commission and Court of Auditors) dealing with personnel related matters, budgetary and accountancy issues;
- European Ombudsman;
- Civil Service Tribunal;
- EDPS;
- Rood Lane Medical Group (UK based external medical consultant).

2.5. Data retention

According to the information provided on 23 January, 3 and 9 April 2008, there are three different data storage periods applicable to the different categories of data processed in connection with family leave. The data contained in the medical certificates of family members are stored only until they have been validated by the Personnel & Budget Sector staff and/or reviewed by the external medical consultant. At that point, the medical certificates are returned to the respective staff member and no copies are retained.

In case the family leave has been granted, the data contained in the Application form are stored in the Personal Files and the Compel Personnel Database until the family leave is exhausted, plus two years further.

In case the family leave has not been granted, the data contained in the Application form are kept for six months in the Personal Files before the form is returned to the staff member concerned.

In addition, further processing for statistical purposes is envisaged on an anonymous basis.

2.6. Information to the data subjects

Staff Members: According to the additional information provided on 19 October 2007, the respective staff members are being informed in the following way:

- Some general information on the data protection principles are given during an introduction briefing which is held at the beginning of a new contract;
- Further details and information are provided in the EMEA (general) Data Protection Declaration which is placed on the Intranet and signed for acknowledgement by each staff member;
- On the EMEA Intranet, there is a specific section dedicated to (general) personal data protection;
- The DPO is also organising a specific training with the purpose of giving all data subjects involved further information on the general principles of data protection and on the rights and obligations of all data subjects involved.

The (general) data protection declaration provides certain information about:
- the purpose of the processing (administrative purposes and/or the purposes of the tasks pursued by the Agency within Article 57 of Regulation 726/2004);

3 nine months counted over the agent's entire career in terms of Article 42b of the Staff Regulations (read together with Articles 16 (1) and 91 CEOS)
- the data recipients (all authorised EMEA staff dealing with personnel related matters and with budgetary and accountancy issues and/or duly authorised persons from external bodies - European Commission and Court of Auditors);
- the time-limit for storage of the data (until the staff member's death and/or end of the pension payment to descendents);
- the existence of rights of access and rectification (requests to be sent to the EMEA Data Controller, Mr Andreas Pott, to the following email address: data-controller@emea.europa.eu);
- the right to lodge a complaint with the EDPS.

**Relatives:** According to the information provided on 19 October 2007, the actual family members are not directly informed about the processing of their health related data according to Article 12(2) of Regulation 45/2001. In fact, the provision of information listed in Article 12 may cause disproportionate effort on a part of the EMEA, due to the high number of family leave requests collected every year.

**2.7. Rights of data subjects**

The procedures to grant rights of data subjects are specified in Articles 9 - 18 of the Decision of the EMEA Executive Director on the adoption of implementing rules relating to the protection of individuals with regard to the processing of personal data and on the free movement of such data dated of 12 June 2007.

All requests shall be addressed to the data controller (Head of EMEA Administrative Unit - data.protection@europa.emea.eu). From 15 June 2007, all requests have to be submitted on the Personal Data Access Request Form available at the EMEA data protection Intranet webpage.

The following data have to be provided in the "Personal Data Access Request Form" and the attached "Declaration":
- name, surname, place and date of birth, nationality of the applicant;
- his contact details (home address, postcode, Tel and/or Fax number, e-mail address);
- type and number of an ID.

The controller has to acknowledge the receipt of the request within five working days. In case of rejection of requests for rectification, blocking, erasure, notification to third parties and objection, the controller has fifteen working days to inform the data subjects about the grounds for the rejection.

**Restrictions:** Article 9(6) of the EMEA Executive Director Decision states that "the requests to exercise a right may be rejected in the cases referred to in Article 20 of the Regulation, subject to application of Article 17 of this Decision".

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5 Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on protection of individuals with regard to processing of personal data by Community institutions and bodies and on the free movement of such data, OJ 2001 L 8/1
Pursuant to Article 18(1) of the EMEA Executive Director Decision, "the data controller may restrict the rights of access, rectification, blocking and erasure on the grounds set out in Article 20 (1) of the Regulation. He or she shall consult the DPO in advance".

Remedies: Article 17(1) of the EMEA Executive Director Decision provides that "any person employed by the EMEA may lodge a complaint pursuant to Article 33 of the Regulation with the EDPS. Lodging such a complaint shall not have the effect of stopping time running for the purposes of lodging a complaint pursuant to Article 90 of the Staff Regulations."

Article 17(2) of the EMEA Executive Decision states that "irrespective of the right referred to in paragraph 1, any person employed by the EMEA may lodge with the Appointing Authority a complaint pursuant to Article 90 of the Staff Regulation in respect of a matter relating to the processing of personal data. In that case, the DPO shall be consulted by the relevant departments."

2.8. Security measures

(...)  

3. Legal aspects

3.1. Prior checking

Applicability of the Regulation: The collection and subsequent processing of information contained in Family leave applications constitutes processing of personal data ("any information relating to an identified or identifiable natural person" - Article 2(a) of Regulation 45/2001). This processing is performed by a Community body in the exercise of activities falling within the scope of Community law (Article 3(1) of Regulation 45/2001). The processing is partly manual, but all data are subsequently entered into an automated filing system (Article 3(2) of Regulation 45/2001). Therefore, Regulation 45/2001 is applicable.

Grounds for prior checking: Article 27 (1) of Regulation 45/2001 subjects to prior checking by the EDPS all "processing operations likely to present specific risks to the rights and freedoms of data subjects by virtue of their nature, their scope or their purposes". Article 27(2) of Regulation 45/2001 contains a list of processing operations that are likely to present such risks. The present case clearly concerns "processing of data relating to health" (Article 27(2)(a) of Regulation 45/2001) and shall be therefore subjected to prior checking.

Ex-post prior checking: Since prior checking is designed to address situations that are likely to present certain risks, the opinion of the EDPS should be given prior to the start of the processing operation. In this case however the processing operation has already been established. In any case, this is not a serious problem in that any recommendations made by the EDPS may still be adopted accordingly.

Deadlines: The present notification was received on 3 September 2007. According to Article 27 (4) of Regulation 45/2001, the EDPS opinion must be delivered within a period of two months. The procedure was suspended for a total of 161 days (140 + 17 + 3 + 1). Consequently, the present opinion must be delivered no later than 14 April 2008 (13 April 2008 being a Sunday).
3.2. Lawfulness of the processing

Article 5 of Regulation 45/2001 provides criteria for making processing of personal data lawful. One of the criteria provided in Article 5(a) of Regulation 45/2001 is that the "processing is necessary for performance of a task carried out in the public interest on the basis of the Treaties establishing the European Communities or other legal instruments adopted on the basis thereof or in the legitimate exercise of official authority vested in the Community institutions or body". The processing of personal data for performance of tasks carried out in the public interest includes "the processing necessary for the management and functioning of those institutions and bodies" (recital 27).

The management of staff members' family leave requests is a part of the legitimate exercise of official authority vested in the Agency. The legal basis provided in Article 42b of the Staff Regulations (read together with Articles 16(1) and 91 of the CEOS) as implemented by the Commission decision C (2004) 1314 of 14 April 2004 confirms the lawfulness of the processing.

3.3. Processing of special categories of data

Pursuant to Article 10(1) of Regulation 45/2001, "the processing data concerning health (...) is prohibited" unless in specific predefined circumstances, such as when "the processing is necessary for the purpose of complying with the specific rights and obligations of the controller in the field of employment law insofar as it is authorised by legal instruments adopted on a basis of the Treaties establishing the European Communities" (Article 10(2)(b) of Regulation 45/2001).

As indicated above, in its quality as employer, the Agency is under an obligation to verify the justification of the family leave requests and is therefore authorised to process the respective health-related data in terms of Article 2.3 of the Commission decision C (2004) 1314 of 14 April 2004 on Article 42b of the Staff Regulations concerning family leave. Therefore, the EDPS considers that the processing of health related data for the purpose of family leave is in full compliance with Article 10 of Regulation 45/2001. (As regards the processing of health-related data on behalf of the Agency by an external medical consultant, see point 3.11 below.)

3.4. Data Quality

Adequacy, relevance and proportionality: According to Article 4(1)(c) of Regulation 45/2001, personal data must be "adequate, relevant and non excessive in relation to the purposes for which they are collected and/or further processed". The EDPS considers that the data collected for the purpose of family leave described in point 2.3 comply with Article 4(1)(c) of Regulation 45/2001.

However, the EDPS does have some recommendations on excessive personal data being required on the Personal Data Access Request Form. This issue is discussed in point 3.9 below.

Accuracy: Article 4(1)(d) of Regulation 45/2001 provides that personal data must be "accurate and, where necessary, kept up to date" and "every reasonable step must be taken to ensure that data which are inaccurate or incomplete are erased or rectified". The data processed for the purpose of family leave are provided by the respective staff member who can also make use of his rights of access and rectification to ensure the accuracy of personal
data processed (cf. point 3.9). Therefore, the EDPS considers that Article 4(1)(d) of Regulation 45/2001 is being complied with.

**Fairness and lawfulness:** Article 4(1)(a) of Regulation 45/2001 also provides that personal data must be "processed fairly and lawfully". Lawfulness has already been discussed (see point 3.2) and fairness will be dealt with in relation to information provided to data subjects (see point 3.10).

### 3.5. Data retention

Article 4 (1)(e) of Regulation 45/2001 states that personal data must be "kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the data were collected or for which they are further processed". In addition, "the personal data which are to be stored for longer periods for statistical purposes should be kept either in anonymous form only, or if that is not possible, only with the identity of the data subject encrypted" and "shall not be used for any other purpose".

As indicated above, three different storage periods are applicable in the present case in terms of the respective category of data processed:
- the data contained in the medical certificates are stored only until the certificate has been validated by Personnel and/or reviewed by the external consultant;
- in case the family leave has been granted, the data contained in the Application form are stored in the Personal Files and the Compel Personnel Database until the family leave is exhausted, plus an additional two years;
- in case the family leave has not been granted, the data contained in the Application form are kept for six months in the Personal Files before it is returned to the staff member concerned.

In addition, further processing for statistical purposes is envisaged on an anonymous basis.

The EDPS welcomes the fact that the data contained on the medical certificate are not kept beyond their validation/review and that they are immediately returned to the staff member concerned.

Furthermore, the EDPS considers that the storage of other data contained in the Application form for a further two years, after the total period of nine months counted over the agent's whole career, is necessary as to allow for possible review of the decision taken (in case of total or partial disagreements on start/end date or half-time working pattern etc.).

Finally, the storage of data contained in the Application forms for six months after the refusal of the family leave request seems reasonable in terms of the possible appeals.

### 3.6. Compatible use / Change of purpose

Article 4(1)(b) of Regulation 45/2001 provides that personal data must be "collected for specified, explicit and lawful purposes and not further processed in a way incompatible with those purposes".

According to the information provided in the notification, the data collected and subsequently entered into the Compel Personnel Database are processed only for the purpose of family leave. Therefore, Article 4 (1)(b) of Regulation 45/2001 is fully complied with.
3.7. Data transfers

**Internal transfers:** The transfers within the Agency (to the Head of Unit and Head of Sector of the applicant; the Personnel & Budget Sector staff, the Information Technology Sector staff and the Security and Reception staff), as well as the transfers to the duly authorised persons from external bodies (European Commission and Court of Auditors) dealing with personnel related matters, budgetary and accountancy issues; the European Ombudsman; the Civil Service Tribunal and the EDPS should be examined in light of Article 7 of the Regulation 45/2001.

This Article provides that "personal data can be transferred within or to other Community institutions or bodies if the data are necessary for the legitimate performance of the tasks covered by the competence of the recipient" (paragraph 1) and that "the recipient can process the data only for the purposes for which they were transmitted" (paragraph 3).

The EDPS notes that the above referred internal transfers fall within the legitimate performance of the tasks covered by the competence of the respective recipient. In particular, he notes that the transfers to the applicant's hierarchy, to the Personnel and Budget Sector staff, as well as to the Information Technology staff are necessary for administrative purposes. In addition, the transfers to the Security and Reception staff are necessary for security reasons since the person who is actually availing himself of any kind of long-term leave cannot have access to the building. The transfers to the Court of Auditors, European Ombudsman, Civil Service Tribunal, as well as EDPS are necessary for the performance of the respective supervisory task. Consequently, Article 7(1) of the Regulation is being complied with.

However, in order to ensure full compliance with Article 7(3) of Regulation 45/2001, the EDPS recommends that all recipients are reminded of their obligation not to use the data received for any further purposes than the one for which they were transmitted.

**External transfers:** The transmission of the data contained in the medical certificates to the UK based external medical consultant should be examined in light of Article 8 of Regulation 45/2001. This Article allows for transfers to recipients subject to (the national law adopted for the implementation of) Directive 95/46/EC "if the recipient establishes that the data are necessary for the performance of a task carried out in the public interest or subject to the exercise of public authority" (Article 8(a) of Regulation 45/2001).

The EDPS considers that the transfer of the medical data to the external medical consultant is necessary for the performance of a task carried out in the public interest since it occurs on behalf and upon instructions of the controller. The purpose of this transfer is to review the family member's medical certificate in case the EMEA Personnel & Budget Sector staff has doubts or uncertainty about its content. Article 8(a) of Regulation 45/2001 is therefore duly complied with.

In this context, the EDPS would like to point out that according to Article 2.3 of the Commission Decision C (2004) 1314 on Article 42b of the Staff Regulations concerning

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6 The fact that for the purpose of these transfers, the names of the family members concerned are rendered anonymous, does not alter the quality of the information processed as personal data in terms of Article 2(a) of Regulation 45/2001. In particular, the persons concerned remain identifiable to the controller.
family leave dated 15 June 2004, all medical certificates to be provided in connection with a family leave request shall be submitted to a medical service. Therefore, the EDPS would like to invite the EMEA to reconsider whether all medical certificates could be submitted for validation/review to the external medical consultant avoiding analysis by Personnel & Budget Sector staff.

3.8. Processing of the personnel number

Article 10(6) of Regulation 45/2001 provides that "the EDPS determines the conditions under which a personal number or other identifier of general application may be processed by a Community institution or body".

The family leave application form contains the personnel number of the respective staff member. The EDPS considers that the personnel number can be used in this context since it allows for the identification of the staff member and facilitates the follow-up in an appropriate way. There is no reason to determine any further conditions in this case.

3.9. Rights of access and rectification

Article 13 of Regulation 45/2001 establishes a right of access upon request by the data subject. Article 14 of Regulation 45/2001 provides the data subject with "the right to rectify inaccurate or incomplete data". These rights may be restricted in terms of Article 20(1) of Regulation 45/2001, in particular "where such a restriction constitutes a necessary measure to safeguard the protection of the data subject or the rights and freedoms of others".

As mentioned in point 2.7 above, EMEA has produced a particular form to be used for all access and rectification requests concerning personal data processed. The EDPS has already made recommendations concerning the need to revise the Personal Data Access Request Form in his Opinion on a notification for Prior Checking received from the EMEA DPO on the public declaration of interests dated of 6 December 2007 (Case 2007-0419). In particular, the EDPS has requested that the statement on mandatory use of the Personal Data Access Request Form is replaced by a simple recommendation to use the form, as well as that the identification data required on the form are limited to name, surname, telephone and/or fax number, email address and the ID number.

In addition, the EDPS notes that family members whose personal data are processed in the present case are not provided with a right of access and rectification. In principle, all data subjects should be entitled to these rights. Therefore, the EDPS recommends that EMEA provides these rights upon request of the respective family member unless one of the exceptions laid down in Article 20(1) of Regulation 45/2001 is applicable.

3.10. Information given to the data subjects

In order to ensure transparency and fairness of the processing of personal data, Regulation 45/2001 provides for certain information to be supplied to the data subjects. In the present case, both Articles 11 and 12 are applicable since certain personal data processed are provided by the respective data subjects (as regards staff member's own data) and certain personal data are obtained from other sources (as regards personal data of family members).

**Staff Members (Article 11 of Regulation 45/2001):** As indicated above, the (general) Data Protection Declaration signed for acknowledgement by each staff member and placed on the Intranet contains the following information:
- identity of the controller;
- **general** purpose of processing;
- certain data recipients;
- existence of rights of access and rectification;
- general time limit applicable to the storage of personal files;
- right of recourse to the EDPS.

In addition, information about the applicable legal basis is provided on the Application for Parental or Family Leave form.

In order to ensure full compliance with Article 11 of Regulation 45/2001, the EDPS recommends that:

- Information about the specific purpose of the processing, all data recipients, as well as about the specific data retention periods are provided to the data subjects. This information should be added to the Application for Parental or Family Leave.
- The existing Data Protection Declaration should be provided with an introductory paragraph outlining the general nature of this document and stating that further information on specific data processing operations can be found in the links in the annex.
- An annex should be added to the existing Data Protection Declaration with link to the Application for Parental or Family Leave as referred above.
- The controller's email address provided in the Data Protection Declaration should correspond with that provided on the Personal Data Access Request Form.

**Relatives (Article 12 of Regulation 45/2001):** The EDPS notes that the direct provision of information to family members may involve disproportionate effort on the part of EMEA in terms of Article 12(2) of Regulation 45/2001. In any case, there are other steps EMEA could take which would be appropriate, such as instructing its staff members applying for a leave to inform their respective family members about the processing of their personal data. In particular, the family members should be informed about the possible transfers of their medical certificates to the UK based external medical consultant.

### 3.11. Processing on behalf of controller

**Determination of the controller and the processor:** As indicated above, data contained in the medical certificate of the family member in respect of whom the leave is to be taken may be processed by the UK based Rood Lane Medical Group. This external consultant processes the relevant data on behalf of the Head of the EMEA Administration Unit who determines the purpose and the means of the actual processing (Article 2 (d) and (e) of the Regulation).

**Contract concluded between the controller and the processor:** Article 23 of Regulation 45/2001 stipulates that the controller must "choose a processor providing sufficient guarantees in respect of the technical and organisational security measures required by Article 22 of Regulation 45/2001" (paragraph 1) and that "the carrying out of a processing operation by way of a processor must be governed by a contract or legal act binding the processor to the controller" stipulating, in particular, that the processor has also to comply with obligations of confidentiality and security as set out in the national law transposing Articles 16 and 17 (3) of the Directive 95/46/EC (paragraph 2).

According Article 16 of the Directive 95/46/EC, the processor "shall not process personal data except on instructions from the controller, unless required to do so by law" ("confidentiality of processing").
Article 17 (3) of the Directive 95/46/EC specify that appropriate technical and organisational measures must be adopted by the controller and the processor "to ensure a level of security appropriate to the risks represented by the processing and the nature of the personal data to be protected. Such measures shall be taken in particular to prevent any unauthorised disclosure or access, accidental or unlawful destruction or accidental loss, or alteration, and to prevent all other unlawful forms of processing".

The rules for the medical certificate reviews are set out in Article 8 of the Protocol agreement between EMEA and Rood Lane Medical Group for the provision of medical services signed in March 2005. In particular, the medical confidentiality of the review of such medical certificates must be at its utmost, especially in relation to sick leave certificates of third parties (relatives). A letter confirming the seriousness of the third party illness and entitlement of the staff member under the leave rules must be sent to the Head of Sector for Personnel & Budget, marked private and confidential.

(...)  

3.12. Security measures

(...)  

4. Conclusion

There is no reason to believe that there is a breach of the provisions of Regulation 45/2001 provided that the above considerations are fully taken into account. In particular, the EMEA should:
- remind the data recipients of their obligation not to use the data received for any further purpose than the one for which they were transmitted (Article 7(3) of Regulation 45/2001);
- reconsider whether all family members' medical certificates could be submitted for validation / review to the external medical consultant, avoiding analysis by the Personnel & Budget Sector staff;
- modify the Personal Data Access Request Form in such a way that the statement on its mandatory use is replaced by a simple recommendation to use it, as well as that the identification data required on the form are limited to name, surname, telephone and/or fax number, email address and the ID number (Articles 13 and 14 of Regulation 45/2001);
- provide family members whose personal data are processed in connection with family leave with rights of access and rectification upon their request (Articles 13 and 14 of Regulation 45/2001);
- revise and complete information provided in the Data Protection Declaration, as well as on the Application for the Parental or Family Leave according to recommendations provided in point 3.10 (Article 11 of Regulation 45/2001);
- put in place appropriate measures to inform family members involved in the processing in accordance with recommendation provided in point 3.10 (Article 12 of Regulation 45/2001);
- (...)

Done at Brussels, 14 April 2008  
(signed)

Peter HUSTINX  
European Data Protection Supervisor