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### Information and Notices

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EN

Price:  
EUR 3

<sup>(1)</sup> Text with EEA relevance

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## II

*(Information)*INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES  
AND AGENCIES

## EUROPEAN COMMISSION

**Non-opposition to a notified concentration****(Case COMP/M.7038 — Nippon Express/Panasonic Corporation/Panasonic Logistics)****(Text with EEA relevance)**

(2013/C 358/01)

On 28 November 2013, the Commission decided not to oppose the above notified concentration and to declare it compatible with the common market. This decision is based on Article 6(1)(b) of Council Regulation (EC) No 139/2004. The full text of the decision is available only in English and will be made public after it is cleared of any business secrets it may contain. It will be available:

- in the merger section of the Competition website of the Commission (<http://ec.europa.eu/competition/mergers/cases/>). This website provides various facilities to help locate individual merger decisions, including company, case number, date and sectoral indexes,
- in electronic form on the EUR-Lex website (<http://eur-lex.europa.eu/en/index.htm>) under document number 32013M7038. EUR-Lex is the online access to the European law.

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**Non-opposition to a notified concentration****(Case COMP/M.7043 — GDF Suez/Balfour Beatty (UK Facilities Management))****(Text with EEA relevance)**

(2013/C 358/02)

On 29 November 2013, the Commission decided not to oppose the above notified concentration and to declare it compatible with the common market. This decision is based on Article 6(1)(b) of Council Regulation (EC) No 139/2004. The full text of the decision is available only in English and will be made public after it is cleared of any business secrets it may contain. It will be available:

- in the merger section of the Competition website of the Commission (<http://ec.europa.eu/competition/mergers/cases/>). This website provides various facilities to help locate individual merger decisions, including company, case number, date and sectoral indexes,
  - in electronic form on the EUR-Lex website (<http://eur-lex.europa.eu/en/index.htm>) under document number 32013M7043. EUR-Lex is the online access to the European law.
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**Communication from the Commission concerning the quantity not applied for to be added to the quantity fixed for the subperiod 1 April to 30 June 2014 under certain quotas opened by the European Union for poultrymeat products**

(2013/C 358/03)

Commission Regulation (EC) No 616/2007 <sup>(1)</sup> opened tariff quotas for imports of products in the poultrymeat sector. The applications for import licences lodged during the first seven days of October 2013 for the subperiod 1 January to 31 March 2014 are, for quotas 09.4212, 09.4217, 09.4218 and 09.4256, for quantities smaller than those available. Pursuant to the second sentence of Article 7(4) of Commission Regulation (EC) No 1301/2006 <sup>(2)</sup>, the quantities that were not applied for are to be added to the quantity fixed for the following quota subperiod, from 1 April to 30 June 2014; they are set out in the Annex to this communication.

<sup>(1)</sup> OJ L 142, 5.6.2007, p. 3.

<sup>(2)</sup> OJ L 238, 1.9.2006, p. 13.

ANNEX

Quota order number	Quantities not applied for, to be added to the quantity fixed for the subperiod 1 April to 30 June 2014 (in kg)
09.4212	44 864 920
09.4217	12 369 400
09.4218	9 276 800
09.4256	3 245 004

## IV

(Notices)

## NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

## COUNCIL

## COUNCIL DECISION

of 2 December 2013

**appointing the members and alternate members of the Advisory Committee on Safety and Health at Work for Croatia, Hungary, Portugal and the United Kingdom**

(2013/C 358/04)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Decision of 22 July 2003 setting up an Advisory Committee on Safety and Health at Work <sup>(1)</sup>, and in particular Article 3 thereof,

Having regard to the lists of nominations for appointment submitted to the Council by the Governments of the Member States,

Whereas:

(1) By its Decision of 22 April 2013 <sup>(2)</sup>, the Council appointed the members and alternate members of the

Advisory Committee on Safety and Health at Work for the period from 22 April 2013 to 28 February 2016, with the exception of certain members.

(2) The Governments of Croatia, Hungary, Portugal and the United Kingdom have submitted nominations for a number of posts to be filled,

HAS ADOPTED THIS DECISION:

*Article 1*

The following are hereby appointed members and alternate members of the Advisory Committee on Safety and Health at Work for the period ending on 28 February 2016:

## I. GOVERNMENT REPRESENTATIVES

Country	Member	Alternate
Croatia	Mr Zdravko MURATTI	Ms Inga ŽIC Mr Ilija TADIĆ
Portugal		Mr António SANTOS

## II. TRADE UNION REPRESENTATIVES

Country	Member	Alternate
Hungary	Mr Károly GYÖRGY	Mr Szilárd SOMLAI

<sup>(1)</sup> OJ C 218, 13.9.2003, p. 1.<sup>(2)</sup> OJ C 120, 26.4.2013, p. 7.

## III. EMPLOYERS' REPRESENTATIVES

Country	Member	Alternate
Croatia	Ms Admir RIBIČIĆ	Mr Nenad SEIFERT Ms Milica JOVANOVIĆ
United Kingdom		Ms Hannah MURPHY

*Article 2*

The Council will appoint the members and alternate members not yet nominated at a later date.

*Article 3*

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 2 December 2013.

*For the Council*  
*The President*  
E. GUSTAS

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## COUNCIL DECISION

of 2 December 2013

**appointing the members and alternate members of the Governing Board of the European  
Foundation for the Improvement of Living and Working Conditions**

(2013/C 358/05)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EEC) No 1365/75 of 26 May 1975 on the creation of a European Foundation for the Improvement of Living and Working Conditions <sup>(1)</sup>, and in particular Article 6 thereof,

Having regard to the lists of nominations for appointment submitted to the Council by the Governments of the Member States and by the employees' and employers' organisations,

Whereas:

- (1) By its Decisions of 22 November 2010 <sup>(2)</sup>, 7 March 2011 <sup>(3)</sup>, 12 July 2011 <sup>(4)</sup>, 20 September 2011 <sup>(5)</sup> and 29 October 2012 <sup>(6)</sup>, the Council appointed the members and alternate members of the Governing

Board of the European Foundation for the Improvement of Living and Working Conditions for the period from 1 December 2010 to 30 November 2013.

- (2) The members and alternate members of the Governing Board, representing the Governments of the Member States and employees' and employers' organisations, should be appointed for a period of three years.
- (3) It is for the Commission to appoint its own representatives on the Governing Board,

HAS ADOPTED THIS DECISION:

*Article 1*

The following shall be appointed members and alternate members of the Governing Board of the European Foundation for the Improvement of Living and Working Conditions for the period from 1 December 2013 to 30 November 2016:

I. GOVERNMENT REPRESENTATIVES

Country	Members	Alternates
Belgium	Mr Michel DE GOLS	Mr Alain PIETTE
Bulgaria	Ms Teodora TODOROVA	Mr Iskren ANGELOV
Czech Republic	Mr Vlastimil VÁŇA	Ms Veronika ŽIDLÍKOVÁ
Denmark	Ms Lone HENRIKSEN	Ms Lis WITSØ-LUND
Germany	Mr Andreas HORST	Mr Sebastian JOBELIUS
Estonia	Ms Eva PÕLDIS	Ms Ester RÜNKLA
Ireland	Mr Paul CULLEN	Ms Mary O'SULLIVAN
Greece	Ms Stamatia PISIMISI	Mr Ioannis KONSTANTAKOPOULOS
Croatia	Ms Narcisa MANOJLOVIĆ	Ms Olivera FIŠEKOVIĆ
Spain	Ms Paloma GARCÍA GARCÍA	Mr José Ignacio MARTÍN FERNÁNDEZ
France	Ms Valérie DELAHAYE-GUILLOCHEAU	Ms Marie-Soline CHOMEL
Italy	Ms Aviana Maria Teresa BULGARELLI	Ms Carla ANTONUCCI

<sup>(1)</sup> OJ L 139, 30.5.1975, p. 1.

<sup>(2)</sup> OJ C 322, 27.11.2010, p. 8.

<sup>(3)</sup> OJ C 83, 17.3.2011, p. 4.

<sup>(4)</sup> OJ C 208, 14.7.2011, p. 3.

<sup>(5)</sup> OJ C 278, 22.9.2011, p. 2.

<sup>(6)</sup> OJ C 334, 31.10.2012, p. 2.

Country	Members	Alternates
Cyprus	Mr Andreas MYLONAS	Mr Orestis MESSIOS
Latvia	Ms Ineta TĀRE	Ms Ineta VJAKSE
Lithuania	Ms Rita SKREBIŠKIENĖ	Mr Evaldas BACEVIČIUS
Luxembourg	Ms Nadine WELTER	Mr Gary TUNSCH
Hungary		
Malta	Mr Roderick MIZZI	Mr Anthony AZZOPARDI
Netherlands	Mr Roel GANS	Mr Martin BLOMSMA
Austria	Ms Stephanie MATTES	Ms Petra PENCs
Poland	Mr Jerzy CIECHAŃSKI	Ms Joanna MACIEJEWSKA
Portugal	Mr Manuel MADURO ROXO	Ms Isilda FERNANDES
Romania	Mr Alexandru ALEXE	Ms Liliana Ramona MOȘTENESCU
Slovenia	Ms Vladka KOMEL	Mr Andraž BOBOVNIK
Slovakia	Ms Silvia GREGORCOVÁ	
Finland	Mr Antti NÄRHINEN	Ms Maija LYLÿ-YRJÄNÄINEN
Sweden	Mr Hannes KANTELIUS	Mr Håkan NYMAN
United Kingdom	Mr Ciaran DEVLIN	Ms Shyamala BALENDRA

## II. REPRESENTATIVES OF EMPLOYEES' ORGANISATIONS

Country	Members	Alternates
Belgium	Mr Herman FONCK	Mr François PHILIPS
Bulgaria	Mr Ivan KOKALOV	Mr Vesselin MITOV
Czech Republic	Ms Hana MÁLKOVÁ	Mr Tomáš PAVELKA
Denmark	Mr Jan KAHR FREDERIKSEN	Ms Heidi RØNNE MØLLER
Germany	Ms Marika HÖHN	Ms Ghazaleh NAZZIBI
Estonia	Mr Kalle KALDA	Ms Kadi ALATALU
Ireland	Ms Sally Anne KINAHAN	Mr Peter RIGNEY
Greece	Mr Panagiotis SYRIOPOULOS	Mr Panagiotis KORDATOS
Croatia	Ms Marija HANŽEVAČKI	Ms Dijana ŠOBOTA
Spain	Ms Antonia RAMOS YUSTE	Mr Ramon BAEZA
France	Mr Emmanuel COUVREUR	Mr Rafaël NEDZYNSKI
Italy	Mr Fausto DURANTE	Ms Cinzia DEL RIO
Cyprus	Mr Nicolaos EPISTITHIOU	



Country	Members	Alternates
Latvia	Ms Ruta PORNIECE	
Lithuania	Ms Kristina KRUPAVIČIENĖ	Ms Danute ŠLIONSKIENĖ
Luxembourg	Ms Véronique EISCHEN	Mr Vincent JACQUET
Hungary	Ms Melinda KELEMEN	Ms Erzsébet HANTI
Malta		
Netherlands	Mr Erik PENTENGA	Ms Sonja BALJEU
Austria	Ms Dinah DJALINOUS-GLATZ	Mr Adi BUXBAUM
Poland	Mr Bogdan OLSZEWSKI	Mr Piotr OSTROWSKI
Portugal	Mr Armando da COSTA FARIAS	Mr Vítor Manuel VICENTE COELHO
Romania	Mr Adrian MARIN	Ms Luminița VINTILĂ
Slovenia	Mr Pavle VRHOVEC	Ms Maja KONJAR
Slovakia	Mr Erik MACÁK	
Finland	Mr Juha ANTILA	Ms Leila KURKI
Sweden	Mr Mats ESSEMYR	Mr Sten GELLERSTEDT
United Kingdom	Mr Paul SELLERS	Ms Elena CRASTA

### III. REPRESENTATIVES OF EMPLOYERS' ORGANISATIONS

Country	Members	Alternates
Belgium	Mr Kris DE MEESTER	Mr Roland WAEYAERT
Bulgaria	Mr Dimiter BRANKOV	Mr Nikola ZIKATANOV
Czech Republic	Ms Vladimíra DRBALOVÁ	Ms Pavla BŘEČKOVÁ
Denmark	Ms Karen ROIY	Ms Berit TOFT FIHL
Germany	Mr Lutz MÜHL	Ms Renate HORNUNG-DRAUS
Estonia	Ms Eve PÄÄRENDSON	Ms Marika MERILAI
Ireland	Mr Brendan MCGINTY	Mr Eamonn MCCOY
Greece	Ms Rena BARDANI	Ms Katerina DASKALAKI
Croatia	Mr Davor MAJETIC	Mr Nenad SEIFERT
Spain	Mr Miguel CANALES GUTIÉRREZ	Mr Javier BLASCO de LUNA
France	Mr Emmanuel JAHAN	
Italy	Ms Stefania ROSSI	Ms Paola ASTORRI
Cyprus	Ms Lena PANAYIOTOU	Mr Polyvios POLYVIOU
Latvia	Ms Ilona KIUKUCĀNE	Ms Anita LĪCE
Lithuania		

Country	Members	Alternates
Luxembourg	Mr Fabio STUPICI	Ms Magalie LYSIAK
Hungary	Mr Antal CSUPOORT	Ms Adrienn BALINT
Malta	Mr Martin BORG	
Netherlands	Mr W.M.J.M. VAN MIERLO	Mr Gerard A. M. VAN DER GRIND
Austria	Ms Katharina LINDNER	Ms Heidrun MAIER-DE-KRUIJFF
Poland	Ms Anna KWIATKIEWICZ	
Portugal	Mr Marcelino Peralta PENA COSTA	Mr António VERGUEIRO
Romania	Mr Doru Claudian FRUNZULICĂ	Mr Ștefan RĂDEANU
Slovenia	Ms Tatjana PAJNKIHAR	Mr Igor ANTAUER
Slovakia	Mr Martin HOŠTÁK	
Finland	Ms Jenni RUOKONEN	Ms Minna ETU-SEPPÄLÄ
Sweden	Mr Sverker RUDEBERG	Mr Niklas BECKMAN
United Kingdom	Mr Neil CARBERRY	Mr Rob WALL

*Article 2*

The Council will appoint the members and alternate members not yet nominated at a later date.

*Article 3*

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 2 December 2013.

*For the Council*  
*The President*  
E. GUSTAS

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# EUROPEAN COMMISSION

## Euro exchange rates <sup>(1)</sup>

**6 December 2013**

(2013/C 358/06)

**1 euro =**

Currency			Exchange rate		
Currency			Exchange rate		
USD	US dollar	1,3661	AUD	Australian dollar	1,5065
JPY	Japanese yen	139,63	CAD	Canadian dollar	1,4548
DKK	Danish krone	7,4600	HKD	Hong Kong dollar	10,5937
GBP	Pound sterling	0,83580	NZD	New Zealand dollar	1,6663
SEK	Swedish krona	8,9261	SGD	Singapore dollar	1,7119
CHF	Swiss franc	1,2231	KRW	South Korean won	1 444,01
ISK	Iceland króna		ZAR	South African rand	14,3055
NOK	Norwegian krone	8,4340	CNY	Chinese yuan renminbi	8,3103
BGN	Bulgarian lev	1,9558	HRK	Croatian kuna	7,6425
CZK	Czech koruna	27,480	IDR	Indonesian rupiah	16 298,17
HUF	Hungarian forint	302,25	MYR	Malaysian ringgit	4,4192
LTL	Lithuanian litas	3,4528	PHP	Philippine peso	60,139
LVL	Latvian lats	0,7030	RUB	Russian rouble	45,0410
PLN	Polish zloty	4,1938	THB	Thai baht	44,133
RON	Romanian leu	4,4610	BRL	Brazilian real	3,2237
TRY	Turkish lira	2,7876	MXN	Mexican peso	17,8348
			INR	Indian rupee	84,1550

<sup>(1)</sup> Source: reference exchange rate published by the ECB.

# EUROPEAN DATA PROTECTION SUPERVISOR

## **Executive summary of the Opinion of the European Data Protection Supervisor on the Commission proposals for a regulation on medical devices and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and regulation (EC) No 1223/2009 and a regulation on in vitro diagnostic medical devices**

*(The full text of this Opinion can be found in English, French and German on the EDPS website: <http://www.edps.europa.eu>)*

(2013/C 358/07)

### **1. Introduction**

#### *1.1. Consultation of the EDPS*

1. On 26 September 2012, the Commission adopted two proposals for a regulations on medical devices ('the proposed MD Regulation') <sup>(1)</sup>, and a regulation on in vitro diagnostic medical devices ('the proposed IVD regulation') <sup>(2)</sup>. These proposals were sent to the EDPS for consultation on 2 October 2012.

2. The EDPS welcomes the fact that he is consulted by the Commission and recommends that a reference to the consultation be included in the preambles of the proposed regulations.

#### *1.2. Objectives and scope of the proposed regulation*

3. The proposed regulations aim at ensuring the safety of medical devices ('MDs') <sup>(3)</sup> and in vitro diagnostic medical devices ('IVDs') <sup>(4)</sup> and their free circulation within the internal market. They amend and clarify the scope of the existing legislation, to take into account scientific and technological progress. The proposed regulations contain legal frameworks to utilise an existing electronic database (Eudamed database) <sup>(5)</sup> at EU level to facilitate coordination between authorities to ensure rapid and consistent responses to safety issues, to increase devices traceability throughout the supply chain and to clarify the obligations and responsibilities of manufacturers, importers and distributors. They furthermore strengthen the different levels of supervision by clarifying and enhancing the position and powers of public authorities vis-à-vis economic actors.

#### *1.3. Aim of the EDPS Opinion*

4. The proposed regulations will affect the rights of individuals related to the processing of their personal data. Amongst other issues, they deal with the processing of sensitive data (health data), a central EU-level database which includes personal data, market surveillance <sup>(6)</sup> and record keeping.

5. The EDPS welcomes that the Commission has made an effort to guarantee the correct application of EU rules concerning the protection of personal data in the proposed regulations. However, the EDPS sees a need for some clarifications with particular regards to sensitive data, especially when this category of personal data comes to the processing and storage in the database suggested by the proposed regulations.

<sup>(1)</sup> COM(2012) 542 final.

<sup>(2)</sup> COM(2012) 541 final.

<sup>(3)</sup> Medical devices include products such as sticking plasters, contact lenses, dental filling materials, x-ray machines, pacemakers, breast implants or hip replacements.

<sup>(4)</sup> In vitro diagnostic medical devices include products such as devices used to ensure the safety of blood transfusion (e.g. blood grouping), detect infectious diseases (e.g. HIV), monitor diseases (e.g. diabetes) and perform blood chemistry (e.g. cholesterol measurement).

<sup>(5)</sup> Established by Commission Decision 2010/227/EU (OJ L 102, 23.4.2010, p. 45).

<sup>(6)</sup> For example regarding the market surveillance plan, where manufacturers are required to institute and keep up to date a systematic procedure to collect and review experience gained from devices placed on the market. This would entail the collection, recording and investigation of complaints and reports from healthcare professionals, patients or users on suspected incidents related to devices.

Indeed, the EDPS has identified certain ambiguities and inconsistencies in the way the proposed regulations deal with the issue of whether and what categories of personal data will be processed, in particular where sensitive data regarding health might be processed and stored.

### 3. Conclusions

40. The EDPS welcomes the attention paid specifically to data protection in the proposed regulations, but identified some scope for further improvement.

41. The EDPS recommends:

- that Article 85 of the proposed MD Regulation and Article 81 of the proposed IVD Regulation clarify the reference to Directive 95/46/EC by specifying that the provisions will apply in accordance with the national rules which implement Directive 95/46/EC,
- inserting in Article 85 of the proposed MD Regulation and in Article 81 of the proposed IVD Regulation explicit reference to Article 8 of Directive 95/46/EC and Article 10 of Regulation (EC) No 45/2001,
- inserting similar paragraphs regarding purposes for data processing, data subject rights and data retention periods as in Article 27 of the proposed MD Regulation into Article 25 of the proposed IVD Regulation, subject to the modifications suggested in this Opinion,
- including a definition of the term 'subject' in the proposed regulations,
- unambiguously preventing the inclusion of all patients' health data in the clinical investigations module of the Eudamed database,
- inserting provisions in the proposed MD Regulation and the proposed IVD Regulation that clearly define in which situations and subject to which safeguards information containing patient health data will be processed and stored in the Eudamed database concerning vigilance and post-market surveillance. In particular, the proposed regulation should require that a risk assessment be carried out by the Commission before the processing and storage of any patient health data in the Eudamed database,
- including, in a recital of both proposed regulations, that any implementing measures to be adopted under the proposed regulations should specify in detail the data protection implications of the functional and technical characteristics of the Eudamed database and the EDPS should be consulted,
- explicitly mentioning that periodic reports in Article 61 of the proposed MD Regulation and Article 59 of the proposed IVD Regulation should only be using anonymous data,
- adding the following sentence to Article 8(6) of both proposed regulations: 'Before any processing of data concerning health of patients takes place, manufacturers shall obtain explicit consent from the data subject pursuant to Article 8(2)(a) of Directive 95/46/EC',
- inserting provisions regulating how personal data should be managed as regards the surveillance by competent authorities in the proposed regulations,

- inserting a maximum retention period for personal data under the proposed regulations. The chosen period should be necessary and proportionate for the purposes for which personal data are collected and processed.
- consulting the EDPS in relation to any delegated or implementing act adopted pursuant to the proposed regulations which might have an impact on the processing of personal data.

Done at Brussels, 8 February 2013.

Giovanni BUTTARELLI  
*Assistant European Data Protection Supervisor*

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**Executive summary of the Opinion of the European Data Protection Supervisor on the Communication from the Commission on ‘eHealth Action Plan 2012-2020 — Innovative healthcare for the 21st century’**

*(The full text of this Opinion can be found in English, French and German on the EDPS website <http://www.edps.europa.eu>)*

(2013/C 358/08)

## **1. Introduction**

### *1.1. Consultation of the EDPS*

1. On 6 December 2012, the Commission adopted a Communication on the ‘eHealth Action Plan 2012-2020 — Innovative healthcare for the 21st century’ (the Communication) <sup>(1)</sup>. This proposal was sent to the EDPS for consultation on 7 December 2012.

2. Before the adoption of the Communication, the EDPS was given the possibility to provide informal comments to the Commission. He welcomes that some of his comments have been taken into account in the Communication.

### *1.2. Objectives and scope of the Communication and aim of the EDPS Opinion*

3. The Communication establishes an eHealth Action Plan for 2012-2020. The Action Plan presents the view that information and communication technologies (ICT) applied to healthcare and well-being can improve the efficiency and effectiveness of healthcare systems, empower the individual citizen and unlock innovation in the health and well-being markets.

4. This EDPS Opinion is to be seen in the light of the growing importance of eHealth in the evolving information society and of the ongoing policy debate within the EU on eHealth. The Opinion focuses especially on the implications of the fundamental right to data protection for eHealth initiatives. It also comments on the areas for further action identified in the Communication.

## **3. Conclusions**

33. The EDPS welcomes the attention paid specifically to data protection in the proposed Communication, but identified some scope for further improvement.

34. The EDPS underlines that data protection requirements should be appropriately considered by industry, Member States and the Commission when implementing initiatives within the eHealth area. In particular he:

- emphasizes that personal data processed in the context of eHealth and well-being ICT often relate to health data, which require a higher level of data protection and underlines the guidance already given to controllers and processors in the area,
- notes that the Communication does not refer to the current data protection legal framework set forth under Directive 95/46/EC and Directive 2002/58/EC, which contains the relevant data protection principles that are currently applicable and reminds the Commission that these rules are to be respected for any action to be taken in the short to medium term until the proposed revised data protection regulation enters into force,
- notes that the importance of the data subject’s rights of access and information in the context of eHealth has not been made clear in the Communication. He therefore encourages the Commission to draw the attention of controllers active in the field of eHealth on the necessity to provide clear information to individuals about the processing of their personal data in eHealth applications,

<sup>(1)</sup> COM(2012) 736 final.

- notes that the availability of guidance in respect of eHealth processing operations taking place under the current legal framework has not been emphasized in the Communication with specific references to the relevant documents and recommends that the Commission consults the Article 29 Working Party, in which the EU national data protection authorities are represented, and the EDPS in the preparation of such guidance,
- recommends consulting the EDPS before the adoption by the Commission of a green paper on an EU framework applicable to mHealth and health and well-being mobile apps,
- notes that the Communication does not underline that any data mining using non-anonymous health data is only acceptable under very limited circumstances and provided that full account is taken of data protection rules and encourages the Commission to draw the attention of controllers to this fact,
- underlines that profiling should only be done in very limited circumstances and provided that strict data protection requirements must be met (e.g. as set forth in Article 20 of the proposed data protection regulation) and encourages the Commission to remind controllers of this important obligation,
- reminds the Commission that any future work in the areas of facilitating wider deployment, supporting user skills and literacy should be pursued in due observance of the principles of data protection,
- recommends that the Commission carries out a data protection impact assessment in the context of the development of a common European eHealth Interoperability Framework, before any further action is undertaken,
- urges the Commission, when examining the interoperability of health records, to look into possible legislative initiatives at EU level, as he believes that such interoperability would benefit from a strong legal basis, which would include specific data protection safeguards.

Done at Brussels, 27 March 2013.

Giovanni BUTTARELLI  
*Assistant European Data Protection Supervisor*

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**Executive summary of the Opinion of the European Data Protection Supervisor on the Commission proposal for a Regulation amending Council Regulation (EC) No 1346/2000 on insolvency proceedings**

(The full text of this Opinion can be found in English, French and German on the EDPS website <http://www.edps.europa.eu>)

(2013/C 358/09)

## **1. Introduction**

### *1.1. Consultation of the EDPS*

1. On 12 December 2012, the Commission adopted a proposal for a Regulation amending Council Regulation (EC) No 1346/2000 on insolvency proceedings ('the proposed Regulation') <sup>(1)</sup>. This Proposal was sent to the EDPS for consultation on 13 December 2012.

2. The EDPS welcomes the fact that he is consulted by the Commission and that a reference to this Opinion is included in the preambles of the proposed legal instrument.

3. Before the adoption of the proposed Regulation, the EDPS was given the opportunity to provide informal comments to the Commission.

4. The EDPS regrets that only a few of his comments have been taken into account in the proposed Regulation. Even though an article is now dedicated to data protection, safeguards have not been strengthened accordingly.

### *1.2. Objectives and scope of the proposed Regulation*

5. The proposed Regulation amends the Insolvency Regulation in order to cope with weaknesses revealed in its practical application <sup>(2)</sup>. It *inter alia* addresses issues relating to the scope of the Regulation, the determination of the Member State competent to open the proceedings, the opening of secondary proceedings and the rules on publicity of decisions opening and closing insolvency proceedings.

6. Amongst the measures proposed that will impact data protection, the Proposal provides for a mandatory publication of the decisions opening or closing a proceeding and encourages and organises cross-border exchanges of information between stakeholders.

7. Information thus published and/or exchanged may identify (either directly or indirectly) debtors, creditors, and liquidators involved in the proceeding. Therefore, EU data protection legislation applies. In particular, Directive 95/46/EC will apply to the processing of data by stakeholders in Member States and by national competent authorities, while Regulation (EC) No 45/2001 will apply to the processing of data by the Commission through the e-Justice Portal.

### *1.3. Aim of the EDPS Opinion*

8. The proposed Regulation may affect the rights of individuals related to the processing of their personal data as, amongst other issues, it deals with the publication of personal data in a register accessible to the public on the Internet, free of charge, with the interconnection of existing national registers and with cross border exchange of information between stakeholders.

9. Although the EDPS welcomes the effort made by the Commission to guarantee the correct application of EU rules concerning the protection of personal data in the proposed Regulation, he has identified some shortcomings and inconsistencies in the way the proposed Regulation deals with issues related to/concerning personal data.

## **3. Conclusions**

54. The EDPS welcomes the attention paid specifically to data protection in the proposed Regulation, but identified some scope for further improvement.

55. The EDPS recommends that:

— references to this Opinion are included in the preambles of all proposals,

<sup>(1)</sup> COM(2012) 744 final.

<sup>(2)</sup> Proposal for a Regulation of the European Parliament and of the Council amending Council Regulation (EC) No 1346/2000 on insolvency proceedings (hereinafter: 'the Proposal').

- Article 46(a) of the proposed Regulation clarifies the reference to Directive 95/46/EC by specifying that the provisions will apply in accordance with the national rules which implement Directive 95/46/EC,
- concrete and effective data protection safeguards are put in place for any situation in which personal data processing is envisaged,
- the necessity and the proportionality of the proposed system for the Internet publication of decisions opening and closing insolvency proceedings is assessed and it is verified whether the publication obligation does not go beyond what is necessary to achieve the public interest objective pursued and whether there are not less restrictive measures to attain the same objective. Subject to the outcome of this proportionality test, the publication obligation should in any event be supported by adequate safeguards to ensure full respect of the rights of the persons concerned, the security/accuracy of the data and their deletion after an adequate period of time.

56. The EDPS furthermore recommends that:

- the modalities of the functioning of national databases and the EU database with regard to data protection issues are clarified by introducing more detailed provisions in the proposed Regulations, in compliance with Directive 95/46/EC and Regulation (EC) No 45/2001. In particular, the provision establishing the database(s) must (i) identify the purpose of the processing operations and establish which are the compatible uses; (ii) identify which entities (competent authorities, Commission) will have access to which data stored in the database and will have the possibility to modify the data; (iii) ensure the right of access and appropriate information for all the data subjects whose personal data may be stored and exchanged (iv) define and limit the retention period for the personal data to the minimum necessary for the performance of such purpose,
- at least core principles of the decentralised system for the interconnection of insolvency registers such as necessity and proportionality are established in the present Proposal (while further safeguards are expected to be provided in the forthcoming Commission's legislative proposal for the e-Justice portal),
- it is specified whether any data will be stored in the e-Justice portal. If this is the case, specific safeguards should be added.

Done at Brussels, 27 March 2013.

Giovanni BUTTARELLI  
*Assistant European Data Protection Supervisor*

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**Executive summary of the Opinion of the European Data Protection Supervisor on the Communication from the Commission on 'The Digital Agenda for Europe — Driving European growth digitally'**

*(The full text of this Opinion can be found in English, French and German on the EDPS website <http://www.edps.europa.eu>)*

(2013/C 358/10)

**I. Introduction**

*1.1. Consultation of the EDPS*

1. On 18 December 2012, the Commission adopted a Communication on 'The Digital Agenda for Europe — Driving European growth digitally' (hereafter 'the Communication') <sup>(1)</sup>.

2. Before the adoption of the Communication, the EDPS was given the possibility to provide informal comments to the Commission. He welcomes that some of his comments have been taken into account in the Communication.

3. In the light of the importance of the subject, the EDPS has decided to adopt this Opinion on his own initiative.

*1.2. Objectives and scope of the Communication and aim of the EDPS Opinion*

4. The Communication is put forward by the Commission as part of the Europe 2020 Strategy. It complements the Digital Agenda adopted on 19 May 2010 <sup>(2)</sup>. The objective of this new Communication on the Digital Agenda is to further strengthen European digital leadership and to help complete the Digital Single Market by 2015.

5. The Communication identifies seven key policy areas where the Commission will be deploying particular efforts to enable and stimulate the development of the digital economy:

- A European borderless economy — the Digital Single Market
- Speeding up public sector innovation
- Very fast internet supply and demand
- Cloud computing
- Trust and security
- Entrepreneurship and digital jobs and skills
- Beyond R&D&I <sup>(3)</sup>: An industrial agenda for key enabling technologies

6. The EDPS welcomes the proposed policy actions aimed to stimulate the use of new technologies by businesses and individuals. The EDPS however underlines that these measures must be accompanied by appropriate activities to ensure the respect of data protection and privacy.

<sup>(1)</sup> COM(2012) 784 final.

<sup>(2)</sup> COM(2010) 245 final.

<sup>(3)</sup> Stands for 'Research, Development and Innovation'.

7. Some of the main data protection challenges raised in the context of the EU policy actions in the field of the Digital Agenda have already been underlined and analysed by the EDPS in his Opinion of 18 March 2010 in relation to the 2010 Communication on the Digital Agenda <sup>(1)</sup>. The EDPS particularly emphasised the need to embed privacy by design and privacy by default in the design of new ICT. In this Opinion, the EDPS will therefore focus on providing comments on the areas for further action identified in the Communication.

### III. Conclusions

26. The EDPS welcomes that some attention has been given to privacy and data protection in the Communication. However, the EDPS underlines that data protection requirements should receive appropriate consideration from industry, Member States and the Commission when implementing initiatives foreseen in the Digital Agenda. In particular he:

- regrets that the Communication did not put any prominent emphasis in its introduction on the importance of the respect of privacy and data protection in the deployment of the actions foreseen therein. He therefore draws the attention of data controllers on the necessity to respect privacy and data protection rules in the design and deployment of new ICT for the digital environment;
- regrets that the Communication did not refer to the current data protection legal framework set forth under Directive 95/46/EC and Directive 2002/58/EC, and to the proposal for a general Data Protection Regulation, which contain the relevant rules and principles to be taken into account for the deployment of ICT in the digital environment;
- regrets that the principle of 'privacy by design', which would become a legal obligation under Article 23 of the proposed Data Protection Regulation, has not been emphasised in the Communication. He therefore reminds controllers and ICT designers of the necessity to embed privacy by design in the development of new ICT for the digital environment;
- recommends that R&D instruments are used to increase Europe's capacity to apply the principle of privacy by design in all relevant disciplines and that work programmes and calls for proposals take this objective into account;
- underlines that the interoperability of national databases should only be practiced in full respect of data protection principles, in particular purpose limitation. He furthermore reminds the Commission that there should be an appropriate legal basis for the use of interoperability as a means to facilitate data sharing, together with appropriate data protection safeguards;
- recommends consulting the EDPS before the adoption by the Commission of a Recommendation on safeguarding the open internet for consumers;
- reminds controllers and users that, while cloud computing presents specific challenges in terms of data protection, extensive guidance has been provided by data protection authorities on the application of current data protection law and by the EDPS on the impact of the proposed Data Protection Regulation on those challenges. This guidance should be relied upon in order to foster trust from individuals and from customers, which in turn will ensure the successful deployment of these new technological means.

Done at Brussels, 10 April 2013.

Peter HUSTINX

*European Data Protection Supervisor*

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<sup>(1)</sup> See EDPS Opinion on 'Promoting Trust in the Information Society by Fostering Data Protection and Privacy', 18 March 2010, available on EDPS website at <http://www.edps.europa.eu>

**Executive summary of the Opinion of the European Data Protection Supervisor on the Commission Proposal for a Regulation on occurrence reporting in civil aviation and repealing Directive 2003/42/EC, Commission Regulation (EC) No 1321/2007, Commission Regulation (EC) No 1330/2007 and Article 19 of Regulation (EU) No 996/2010**

*(The full text of this Opinion can be found in English, French and German on the EDPS website <http://www.edps.europa.eu>)*

(2013/C 358/11)

## **1. Introduction**

### *1.1. Consultation of the EDPS*

1. On 18 December 2012, the Commission adopted a Proposal for a Regulation on occurrence reporting in civil aviation and repealing Directive 2003/42/EC, Commission Regulation (EC) No 1321/2007, Commission Regulation (EC) No 1330/2007 and Article 19 of Regulation (EU) No 996/2010 ('the Proposal')<sup>(1)</sup>. This Proposal was sent to the EDPS for consultation on 8 January 2013.

2. The EDPS welcomes the fact that he is consulted by the Commission and that a reference to this Opinion is included in the Preamble of the Proposal. Before the adoption of the Proposal, the EDPS was given the opportunity to provide informal comments to the Commission.

### *1.2. Objectives and scope of the Proposal*

3. The three instruments to be repealed by the Proposal organise occurrence reporting in the following way: Directive 2003/42/EC<sup>(2)</sup> requires each Member State to set up a mandatory occurrence reporting system (hereinafter 'MORS'). Under this legislation, aviation professionals are obliged to report occurrences<sup>(3)</sup> in their daily operational work through the system established by their organisation<sup>(4)</sup>. In addition, Member States are requested to collect, store, protect and disseminate among themselves information on occurrences. Two implementing rules complete this legislation: Commission Regulation (EC) No 1321/2007<sup>(5)</sup>, which establishes a European Central Repository (ECR) regrouping all civil aviation occurrences collected by Member States, and Commission Regulation (EC) No 1330/2007<sup>(6)</sup>, which lays down rules regarding the dissemination of the information contained in the ECR.

4. The Proposal builds on Directive 2003/42/EC to improve the existing occurrence reporting systems in civil aviation both at national and European level. Amongst other changes, it proposes the following:

- ensuring that all relevant occurrences are reported and that the data reported and stored are complete and of high quality,
- adding a voluntary reporting system to the mandatory system,
- requiring not only Member States but also organisations to report occurrences and to organise the transmission of these reports to the ECR,
- encouraging the reporting through a harmonised protection from hierarchical punishment or prosecution of individuals reporting occurrences,

<sup>(1)</sup> COM(2012) 776 final.

<sup>(2)</sup> Directive 2003/42/EC of the European Parliament and of the Council of 13 June 2003 on occurrence reporting in civil aviation (OJ L 167, 4.7.2003, p. 23).

<sup>(3)</sup> Occurrences are any significant aviation safety event, including incidents, accidents and serious incidents (See Article 2(8) of the Proposal).

<sup>(4)</sup> 'Organisation' is defined in the proposal as 'any organisation providing aviation products and/or services and encompasses notably aircraft operators, approved maintenance organisations, organisations responsible for type design and/or manufacture of aircraft, air navigation service providers and certified aerodromes' (See Article 2(9) of the Proposal).

<sup>(5)</sup> Commission Regulation (EC) No 1321/2007 of 12 November 2007 laying down implementing rules for the integration into a central repository of information on civil aviation occurrences (OJ L 294, 13.11.2007, p. 3).

<sup>(6)</sup> Commission Regulation (EC) No 1330/2007 of 24 September 2007 laying down implementing rules for the dissemination to interested parties of information on civil aviation occurrences (OJ L 295, 14.11.2007, p. 7).

- ensuring adequate access to information contained in the ECR.

### 1.3. Aim of the EDPS Opinion

5. It follows from the Proposal that occurrences will be reported by employees to their organisations, who will then store them in a database and report them to national designated competent authorities or to the European Aviation Safety Agency (EASA). These authorities, together with EASA and the Commission, will transfer information on civil aviation occurrences to the ECR, managed by the Commission. In addition, the Commission will process data relating to interested parties requesting access to the information stored in the ECR.

6. The EDPS acknowledges the fact that the purpose of the Proposal is not to regulate the processing of personal data. However, the information that will be stored, reported and transferred may relate to natural persons who are either directly or indirectly identifiable, such as reporters, third parties involved in the reported occurrence and interested parties applying for access <sup>(1)</sup>. The reported information might not only involve technical problems but also, for instance, violent passengers, crew incapacitation or health incidents <sup>(2)</sup>.

7. Therefore, the present Opinion will analyse the elements of the Proposal which concern the processing of personal data. It builds on a previous EDPS Opinion <sup>(3)</sup> on one of the Regulations which are being repealed by the Proposal <sup>(4)</sup>.

### 4. Conclusions

46. The EDPS welcomes the attention paid to the protection of personal data, particularly through the engagement taken to 'disidentify' a major part of the data processed under occurrence reporting. However, he reminds that the data processed will still be personal data and thus welcomes the references to the applicability of EU data protection legislation. What is provided for amounts at best to partial anonymisation.

47. The EDPS recommends clarifying the scope of 'disidentification'. In particular, he proposes the following improvements to the text:

- in the Preamble, clarifying that disidentification in the sense of the Proposal is relative and does not correspond to full anonymisation. In addition, in line with the above recommendations, the Preamble should also explain that disidentification and full anonymisation measures are to be applied in different contexts,
- in Article 16: specifying that data available to independent handlers should also be disidentified or deleted as soon as possible, unless the necessity of storing the data is justified, e.g., to comply with other legal obligations of the organisations,
- in order to clarify the scope of disidentification, the EDPS recommends replacing in Articles 16(1) and 16(2) 'personal data' by 'personal details' and adding a reference to the possibility of identification through technical details, in accordance with Article 2(1),
- Article 5(6) allows Member States and organisations to establish additional reporting systems. It should be specified that this information should also be disidentified. The EDPS therefore recommends clarifying in Article 16(2) that personal data contained in the safety information collection and processing systems established in accordance with Article 5(6) should also be disidentified,

<sup>(1)</sup> See on personal data notably Section 3.1.

<sup>(2)</sup> See Annex I of the Proposal 'List of incidents to be reported under the mandatory occurrence reporting system'.

<sup>(3)</sup> See EDPS Opinion on the proposal for a Regulation of the European Parliament and of the Council on investigation and prevention of accidents and incidents in civil aviation (OJ C 132, 21.5.2010, p. 1).

<sup>(4)</sup> Regulation (EU) No 996/2010 of the European Parliament and of the Council of 20 October 2010 on the investigation and prevention of accidents and incidents in civil aviation and repealing Directive 94/56/EC Text with EEA relevance (OJ L 295, 12.11.2010, p. 35).

- in Article 13(10): specify that the information should be anonymised <sup>(1)</sup> before its publication,
- in Article 11(4): specify that information made available to interested parties listed in Annex III and not relating to their own equipment, operations or field of activity, should not only be aggregated or disidentified, as requested by Article 11(4), but fully anonymised.

48. The EDPS advises specifying in the Proposal who will be the controller of every database. He also recommends defining in the Annexes I and II, in Article 5(6) all the categories of data to be processed and clarifying Articles 7(1) and 11(1) accordingly. If it is not possible to specify all the occurrences and data fields to be processed according to Articles 7(1), 5(3), 5(6) and 11(1), these Articles should at least mention that additional information not required by the Proposal should not contain special categories of data as defined by Article 8 of Directive 95/46/EC and Article 10 of Regulation (EC) No 45/2001 ('sensitive data').

49. The EDPS also recommends specifying the periods during which data shall be stored in the databases, the rights of data subjects and the security measures to be implemented.

50. In case of transfers to third country organisations or international organisations, these should commit to respect adequate safeguards to be provided in a binding instrument. These safeguards could be based on the data protection principles contained in the Standard Contractual Clauses for the transfers of personal data to third countries adopted by the Commission and could be added in the Annex of the Proposal.

51. As regards the processing of data of interested parties requesting access to the ECR, the EDPS recommends specifying in the Proposal the data protection measures that will apply to the processing of data relating to third parties (e.g., for how long the data will be stored after access has been granted or denied and who has access to these data). In addition, the form contained in Annex IV should include, apart from the notice on access to information <sup>(2)</sup>, a privacy notice.

52. Finally, the necessity of processing sensitive data for any of the grounds contained in Article 8(2-4) of Directive 95/46/EC and Article 10(2-4) of Regulation (EC) No 45/2001 should be justified in the Preamble. The EDPS also recommends adopting additional safeguards as regards the processing of special categories of data, such as stricter security measures, the prohibition to disclose the related categories of data to third parties not subject to EU data protection law and the restriction of its disclosure to other interested parties. In addition, the processing of these categories of data may be subject to prior check by EU national data protection authorities and by the EDPS.

Done at Brussels, 10 April 2013.

Giovanni BUTTARELLI  
*Assistant European Data Protection Supervisor*

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<sup>(1)</sup> That is, making sure that individuals are not identifiable taking into account all the means likely reasonably to be used either by the controller or by any other person.

<sup>(2)</sup> Point 7 of Annex IV.



## V

*(Announcements)*PROCEDURES RELATING TO THE IMPLEMENTATION OF COMPETITION  
POLICY

## EUROPEAN COMMISSION

**Prior notification of a concentration****(Case COMP/M.6927 — Goldman Sachs/TPG Lundy/Barclays/Intertain)****Candidate case for simplified procedure****(Text with EEA relevance)**

(2013/C 358/12)

1. On 29 November 2013, the Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 <sup>(1)</sup> by which Goldman Sachs Group, Inc. ('Goldman Sachs'), TPG LundyCO, L.P. ('TPG') and Barclays PLC ('Barclays') acquire, within the meaning of Article 3(1)(b) of the Merger Regulation joint control of Intertain Limited ('Intertain') by way of purchase of shares.

2. The business activities of the undertakings concerned are:

- Goldman Sachs is a global investment banking, securities and investment management firm that provides a wide range of services worldwide to a diversified client base that includes corporations, financial institutions, governments and high-net-worth individuals,
- TPG is an investment vehicle belonging to the TPG Group, a global private investment firm that manages a family of funds that invest in a variety of companies through acquisitions and corporate restructurings,
- Barclays is the operating company of the Barclays Group, that is a global financial services provider engaged in personal banking, credit cards, corporate and investment banking, and wealth and investment management services,
- Intertain is an English limited company that operates bars and comedy venues in the United Kingdom.

3. On preliminary examination, the Commission finds that the notified transaction could fall within the scope the EC Merger Regulation. However, the final decision on this point is reserved. Pursuant to the Commission Notice on a simplified procedure for treatment of certain concentrations under the Merger Regulation <sup>(2)</sup> it should be noted that this case is a candidate for treatment under the procedure set out in the Notice.

4. The Commission invites interested third parties to submit their possible observations on the proposed operation to the Commission.

<sup>(1)</sup> OJ L 24, 29.1.2004, p. 1 (the 'EC Merger Regulation').

<sup>(2)</sup> OJ C 56, 5.3.2005, p. 32 ('Notice on a simplified procedure').



Observations must reach the Commission not later than 10 days following the date of this publication. Observations can be sent to the Commission by fax (+32 22964301), by e-mail to COMP-MERGER-REGISTRY@ec.europa.eu or by post, under reference number COMP/M.6927 — Goldman Sachs/TPG Lundy/Barclays/Intertain, to the following address:

European Commission  
Directorate-General for Competition  
Merger Registry  
1049 Bruxelles/Brussel  
BELGIQUE/BELGIË

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**Prior notification of a concentration****(Case COMP/M.6817 — Allianz/Axa/Covéa/Generali/CSCA/Netproassur)****Candidate case for simplified procedure****(Text with EEA relevance)**

(2013/C 358/13)

1. On 2 December 2013, the Commission received notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 <sup>(1)</sup> by which the undertakings Allianz IARD SA ('Allianz', France) belonging to the Allianz Group (Germany), Axa France IARD SA ('Axa', France) belonging to the Axa Group (France), Covéa Risk SA ('Covéa', France) belonging to the Covéa Group (France), Generali France Assurances SA ('Generali', France) belonging to the Assicurazioni Generali Group (Italy) and Chambre Syndicale des Courtiers d'Assurances ('CSCA', France) acquire within the meaning of Article 3(1)(b) of the Merger Regulation joint control of Netproassur SASU ('Netproassur', France) by way of purchase of shares in a newly created company constituting a joint venture.

2. The business activities of the undertakings concerned are:

- Allianz: insurance company (selling insurance products covering property and liability (fire, motor vehicle liability and damage to property) in France),
- Axa: insurance company (selling insurance products for fire, motor vehicle liability and damage to property in France),
- Covéa: insurance company (selling insurance products for fire, motor vehicle liability and damage to property in France),
- Generali: insurance company (selling products for life insurance and damage to property in France),
- CSCA: French insurance brokerage employers' organisation, set up as a trade union confederation,
- Netproassur: development, implementation and operation of information and communication technology projects relating to insurance and reinsurance brokerage.

3. On preliminary examination, the Commission finds that the notified transaction could fall within the scope of the EC Merger Regulation. However, the final decision on this point is reserved. Pursuant to the Commission Notice on a simplified procedure for treatment of certain concentrations under the EC Merger Regulation <sup>(2)</sup> it should be noted that this case is a candidate for treatment under the procedure set out in the Notice.

4. The Commission invites interested third parties to submit their possible observations on the proposed operation to the Commission.

Observations must reach the Commission not later than ten days following the date of this publication. Observations can be sent to the Commission by fax (+32 22964301), by email to COMP-MERGER-REGISTRY@ec.europa.eu or by post, under reference number COMP/M.6817 — Allianz/Axa/Covéa/Generali/CSCA/Netproassur, to the following address:

European Commission  
Directorate-General for Competition  
Merger Registry  
1049 Bruxelles/Brussel  
BELGIQUE/BELGIË

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<sup>(1)</sup> OJ L 24, 29.1.2004, p. 1 (the 'EC Merger Regulation').

<sup>(2)</sup> OJ C 56, 5.3.2005, p. 32 ('Notice on a simplified procedure').

V *Announcements*

## PROCEDURES RELATING TO THE IMPLEMENTATION OF COMPETITION POLICY

**European Commission**

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<sup>(1)</sup> Text with EEA relevance

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