

Official Journal of the European Union

C 99



English edition

Information and Notices

Volume 64

23 March 2021

Contents

II *Information*

INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

European Commission

2021/C 99/01	Non-opposition to a notified concentration (Case M.10099 — Arch/Kelso/Warburg/Watford) ⁽¹⁾	1
--------------	---	---

IV *Notices*

NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

Council

2021/C 99/02	Notice for the attention of persons subject to the restrictive measures provided for in Council Decision (CFSP) 2020/1999, as amended by Council Decision (CFSP) 2021/481 and in Council Regulation (EU) 2020/1998, as implemented by Council Implementing Regulation (EU) 2021/478 concerning restrictive measures against serious human rights violations and abuses	2
2021/C 99/03	Notice for the attention of the data subjects to whom the restrictive measures provided for in Council Decision (CFSP) 2020/1999 and Council Regulation (EU) 2020/1998 concerning restrictive measures against serious human rights violations and abuses apply	3
2021/C 99/04	Notice for the attention of the persons subject to the restrictive measures provided for in Council Decision 2013/184/CFSP, as amended by Council Decision (CFSP) 2021/483, and in Council Regulation (EU) No 401/2013, as implemented by Council Implementing Regulation (EU) 2021/480 concerning restrictive measures against Myanmar/Burma	5
2021/C 99/05	Notice for the attention of the data subjects to whom the restrictive measures provided for in Council Decision 2013/184/CFSP and Council Regulation (EU) No 401/2013 concerning restrictive measures against Myanmar/Burma apply	6
2021/C 99/06	Notice for the attention of persons subject to the restrictive measures provided for in Council Decision 2013/184/CFSP and in Council Regulation (EU) 401/2013 concerning restrictive measures against Myanmar/Burma	7

EN

⁽¹⁾ Text with EEA relevance.

European Commission

2021/C 99/07	Euro exchange rates — 22 March 2021	8
--------------	---	---

European Data Protection Supervisor

2021/C 99/08	Summary of the Opinion of the European Data Protection Supervisor on the New pact on Migration and Asylum (<i>The full text of this Opinion can be found in English, French and German on the EDPS website www.edps.europa.eu</i>)	9
2021/C 99/09	Summary of the Preliminary Opinion of the European Data Protection Supervisor on the European Health Data Space (<i>The full text of this Opinion can be found in English, French and German on the EDPS website www.edps.europa.eu</i>)	13

V Announcements

PROCEDURES RELATING TO THE IMPLEMENTATION OF COMPETITION POLICY

European Commission

2021/C 99/10	Prior notification of a concentration (Case M.10185 — Pierer Industrie/Palfinger/FSS/Jetfly) – Candidate case for simplified procedure ⁽¹⁾	17
2021/C 99/11	Prior notification of a concentration (Case M.10133 — Astorg/Nordic Capital/Novo/Bioclinica) ⁽¹⁾	19

⁽¹⁾ Text with EEA relevance.

II

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

EUROPEAN COMMISSION

Non-opposition to a notified concentration**(Case M.10099 — Arch/Kelso/Warburg/Watford)****(Text with EEA relevance)**

(2021/C 99/01)

On 17 March 2021, the Commission decided not to oppose the above notified concentration and to declare it compatible with the internal market. This decision is based on Article 6(1)(b) of Council Regulation (EC) No 139/2004 ⁽¹⁾. 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/homepage.html?locale=en>) under document number 32021M10099. EUR-Lex is the online access to European law.

⁽¹⁾ OJ L 24, 29.1.2004, p. 1.

IV

*(Notices)*NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND
AGENCIES

COUNCIL

**Notice for the attention of persons subject to the restrictive measures provided for in Council
Decision (CFSP) 2020/1999, as amended by Council Decision (CFSP) 2021/481 and in Council
Regulation (EU) 2020/1998, as implemented by Council Implementing Regulation (EU) 2021/478
concerning restrictive measures against serious human rights violations and abuses**

(2021/C 99/02)

The following information is brought to the attention of the persons that appear in the Annex to Council Decision (CFSP) 2020/1999 ⁽¹⁾, as amended by Council Decision (CFSP) 2021/481 ⁽²⁾, and in Annex I to Council Regulation (EU) 2020/1998 ⁽³⁾ as implemented by Council Implementing Regulation (EU) 2021/478 ⁽⁴⁾, concerning restrictive measures against serious human rights violations and abuses.

The Council of the European Union has decided that those persons should be included on the list of persons subject to restrictive measures provided for in Decision (CFSP) 2020/1999 and Regulation (EU) 2020/1998. The grounds for designations of those persons appear in the relevant entries in those Annexes.

The attention of the persons concerned is drawn to the possibility of making an application to the competent authorities of the relevant Member State(s) as indicated in the websites in Annex II to Regulation (EU) 2020/1998, in order to obtain an authorisation to use frozen funds for basic needs or specific payments (cf. Article 4 of the Regulation).

The persons concerned may submit a request to the Council before 31 October 2021, together with supporting documentation that the decision to include them on the abovementioned list should be reconsidered, to the following address:

Council of the European Union
General Secretariat
RELEX.1.C
Rue de la Loi/Wetstraat 175
1048 Bruxelles/Brussel
BELGIQUE/BELGIË

Email: sanctions@consilium.europa.eu

Any observations received will be taken into account for the purpose of the Council's periodic review, pursuant to Article 10 of Decision (CFSP) 2020/1999, of the list of designated persons and entities.

⁽¹⁾ OJ L 410 I, 7.12.2020, p. 13.

⁽²⁾ OJ L 99 I, 22.3.2021, p. 25.

⁽³⁾ OJ L 410 I, 7.12.2020, p. 1.

⁽⁴⁾ OJ L 99 I, 22.3.2021, p. 1.

Notice for the attention of the data subjects to whom the restrictive measures provided for in Council Decision (CFSP) 2020/1999 and Council Regulation (EU) 2020/1998 concerning restrictive measures against serious human rights violations and abuses apply

(2021/C 99/03)

The attention of data subjects is drawn to the following information in accordance with Article 16 of Regulation (EU) 2018/1725 of the European Parliament and of the Council ⁽¹⁾.

The legal basis for this processing operation are Council Decision (CFSP) 2020/1999 ⁽²⁾, as amended by Council Decision (CFSP) 2021/481 ⁽³⁾, and Council Regulation (EU) 2020/1998 ⁽⁴⁾, as implemented by Council Implementing Regulation (EU) 2021/478 ⁽⁵⁾.

The controller of this processing operation is the Department RELEX.1.C in the Directorate-General for External Relations - RELEX of the General Secretariat of the Council (GSC), that can be contacted at:

Council of the European Union
General Secretariat
RELEX.1.C
Rue de la Loi/Wetstraat 175
1048 Bruxelles/Brussel
BELGIQUE/BELGIË

Email: sanctions@consilium.europa.eu

The GSC's Data Protection Officer can be contacted at:

Data Protection Officer

data.protection@consilium.europa.eu

The purpose of the processing operation is the establishment and updating of the list of persons subject to restrictive measures in accordance with Decision (CFSP) 2020/1999, as amended by Decision (CFSP) 2021/481, and Regulation (EU) 2020/1998 as implemented by Implementing Regulation (EU) 2021/478, concerning restrictive measures against serious human rights violations and abuses.

The data subjects are the natural persons who fulfil the listing criteria as laid down in Council Decision (CFSP) 2020/1999 and Regulation (EU) 2020/1998.

The personal data collected includes data necessary for the correct identification of the person concerned, the statement of reasons and any other data related thereto.

The personal data collected may be shared as necessary with the European External Action Service and the Commission.

Without prejudice to restrictions pursuant to Article 25 of Regulation (EU) 2018/1725, the exercise of the rights of the data subjects such as the right of access, as well as the rights to rectification or to object will be answered in accordance with Regulation (EU) 2018/1725.

⁽¹⁾ OJ L 295, 21.11.2018, p. 39.

⁽²⁾ OJ L 410 I, 7.12.2020, p. 13.

⁽³⁾ OJ L 99 I, 22.3.2021, p. 25.

⁽⁴⁾ OJ L 410 I, 7.12.2020, p. 1.

⁽⁵⁾ OJ L 99 I, 22.3.2021, p. 1.

Personal data will be retained for 5 years from the moment the data subject has been removed from the list of persons subject to the restrictive measures or the validity of the measure has expired, or for the duration of court proceedings in the event they had been started.

Without prejudice to any judicial, administrative or non-judicial remedy, data subjects may lodge a complaint with the European Data Protection Supervisor in accordance with Regulation (EU) 2018/1725 (edps@edps.europa.eu).

Notice for the attention of the persons subject to the restrictive measures provided for in Council Decision 2013/184/CFSP, as amended by Council Decision (CFSP) 2021/483, and in Council Regulation (EU) No 401/2013, as implemented by Council Implementing Regulation (EU) 2021/480 concerning restrictive measures against Myanmar/Burma

(2021/C 99/04)

The following information is brought to the attention of the persons that appear in Annex I to Council Decision 2013/184/CFSP ⁽¹⁾, as amended by Council Decision (CFSP) 2021/483 ⁽²⁾ and in Annex IV to Council Regulation (EU) No 401/2013 ⁽³⁾, as implemented by Council Implementing Regulation (EU) 2021/480 ⁽⁴⁾ concerning restrictive measures against Myanmar/Burma.

The Council of the European Union, after having reviewed the list of designated persons, has decided that the persons that appear in the above-mentioned Annexes should continue to be included in the list of persons subject to the restrictive measures provided for in Decision 2013/184/CFSP and Regulation (EU) No 401/2013 concerning restrictive measures against Myanmar/Burma. The grounds for the listing of the persons concerned appear in the relevant entries in those Annexes.

The attention of the persons concerned is drawn to the possibility of making an application to the competent authorities of the relevant Member State(s) as indicated on the websites in Annex II to Regulation (EU) No 401/2013 concerning restrictive measures in respect of Myanmar/Burma, in order to obtain an authorisation to use frozen funds for basic needs or specific payments (cf. Article 4b of the Regulation).

The persons concerned may submit a request to the Council, together with supporting documentation, that the decision to include them on the above-mentioned lists should be reconsidered, before 1 November 2021, to the following address:

Council of the European Union
General Secretariat
RELEX.1.C
Rue de la Loi/Wetstraat 175
1048 Bruxelles/Brussel
BELGIQUE/BELGIË
Email: sanctions@consilium.europa.eu

Any observations received will be taken into account for the purpose of the Council's periodic review, in accordance with Article 12 of Decision 2013/184/CFSP and Article 4i(4) of Regulation (EU) No 401/2013.

The attention of the persons concerned is also drawn to the possibility of challenging the Council's decision before the General Court of the European Union, in accordance with the conditions laid down in Article 275, second paragraph, and Article 263, fourth and sixth paragraphs, of the Treaty on the Functioning of the European Union.

⁽¹⁾ OJ L 111, 23.4.2013, p. 75.

⁽²⁾ OJ L 99 I, 22.3.2021, p. 40

⁽³⁾ OJ L 121, 3.5.2013, p. 1.

⁽⁴⁾ OJ L 99 I, 22.3.2021, p. 15

Notice for the attention of the data subjects to whom the restrictive measures provided for in Council Decision 2013/184/CFSP and Council Regulation (EU) No 401/2013 concerning restrictive measures against Myanmar/Burma apply

(2021/C 99/05)

The attention of data subjects is drawn to the following information in accordance with Article 16 of Regulation (EU) 2018/1725 of the European Parliament and of the Council ⁽¹⁾.

The legal basis for this processing operation are Council Decision 2013/184/CFSP ⁽²⁾, as amended by Council Decision (CFSP) 2021/483 ⁽³⁾, and Council Regulation (EU) No 401/2013 ⁽⁴⁾, as implemented by Council Implementing Regulation (EU) 2021/480 ⁽⁵⁾.

The controller of this processing operation is the Department RELEX.1.C in the Directorate-General for External Relations – RELEX of the General Secretariat of the Council (GSC), that can be contacted at:

Council of the European Union
General Secretariat
RELEX.1.C
Rue de la Loi/Wetstraat 175
1048 Bruxelles/Brussel
BELGIQUE/BELGIË

Email: sanctions@consilium.europa.eu

The purpose of the processing operation is the establishment and updating of the list of persons subject to restrictive measures in accordance with Decision 2013/184/CFSP, as amended by Decision (CFSP) 2021/483, and Regulation (EU) No 401/2013, as implemented by Implementing Regulation (EU) 2021/480.

The data subjects are the natural persons who fulfil the listing criteria as laid down in Decision 2013/184/CFSP and Regulation (EU) No 401/2013.

The personal data collected includes data necessary for the correct identification of the person concerned, the statement of reasons and any other data related thereto.

The personal data collected may be shared as necessary with the European External Action Service and the Commission.

Without prejudice to restrictions pursuant to Article 25 of Regulation (EU) 2018/1725, the exercise of the rights of the data subjects such as the right of access, as well as the rights to rectification or to object will be answered in accordance with Regulation (EU) 2018/1725.

Personal data will be retained for 5 years from the moment the data subject has been removed from the list of persons subject to the restrictive measures or the validity of the measure has expired, or for the duration of court proceedings in the event they had been started.

Without prejudice to any judicial, administrative or non-judicial remedy, data subjects may lodge a complaint with the European Data Protection Supervisor in accordance with Regulation (EU) 2018/1725.

⁽¹⁾ OJ L 295, 21.11.2018, p. 39.

⁽²⁾ OJ L 111, 23.4.2013, p. 75.

⁽³⁾ OJ L 99 I, 22.3.2021, p. 40

⁽⁴⁾ OJ L 121, 3.5.2013, p. 1.

⁽⁵⁾ OJ L 99 I, 22.3.2021, p. 15

Notice for the attention of persons subject to the restrictive measures provided for in Council Decision 2013/184/CFSP and in Council Regulation (EU) 401/2013 concerning restrictive measures against Myanmar/Burma

(2021/C 99/06)

The following information is brought to the attention of Mr Aung Aung and Mr Khin Hlaing, persons appearing in the Annex to Council Decision 2013/184/CFSP ⁽¹⁾ and in Annex IV to Council Regulation (EU) No 401/2013 ⁽²⁾ concerning restrictive measures against Myanmar/Burma.

The Council intends to maintain the restrictive measures against the abovementioned persons with a new statement of reasons. These persons are hereby informed that they may submit a request to the Council to obtain the intended statement of reasons for their designation, by 30 March 2021, to the following address:

Council of the European Union

General Secretariat
RELEX.1.C
Rue de la Loi/Wetstraat 175
1048 Bruxelles/Brussel
BELGIQUE/BELGIË

Email: sanctions@consilium.europa.eu

⁽¹⁾ OJ L 111, 23.4.2013, p. 75.

⁽²⁾ OJ L 121, 3.5.2013, p. 1

EUROPEAN COMMISSION

Euro exchange rates ⁽¹⁾

22 March 2021

(2021/C 99/07)

1 euro =

Currency			Exchange rate		
Currency			Exchange rate		
USD	US dollar	1,1926	CAD	Canadian dollar	1,4903
JPY	Japanese yen	129,77	HKD	Hong Kong dollar	9,2614
DKK	Danish krone	7,4360	NZD	New Zealand dollar	1,6617
GBP	Pound sterling	0,86233	SGD	Singapore dollar	1,5992
SEK	Swedish krona	10,1580	KRW	South Korean won	1 344,78
CHF	Swiss franc	1,1023	ZAR	South African rand	17,5657
ISK	Iceland króna	151,20	CNY	Chinese yuan renminbi	7,7582
NOK	Norwegian krone	10,1393	HRK	Croatian kuna	7,5740
BGN	Bulgarian lev	1,9558	IDR	Indonesian rupiah	17 176,42
CZK	Czech koruna	26,075	MYR	Malaysian ringgit	4,9064
HUF	Hungarian forint	366,90	PHP	Philippine peso	57,843
PLN	Polish zloty	4,6017	RUB	Russian rouble	88,9011
RON	Romanian leu	4,8862	THB	Thai baht	36,816
TRY	Turkish lira	9,4097	BRL	Brazilian real	6,5917
AUD	Australian dollar	1,5400	MXN	Mexican peso	24,6337
			INR	Indian rupee	86,2895

⁽¹⁾ Source: reference exchange rate published by the ECB.

EUROPEAN DATA PROTECTION SUPERVISOR

Summary of the Opinion of the European Data Protection Supervisor on the New pact on Migration and Asylum

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

(2021/C 99/08)

On 23 September 2020, the European Commission presented the New Pact on Migration and Asylum encompassing five legislative proposals: i) an amended Proposal for a Eurodac Regulation; ii) an amended Proposal for Asylum Procedure; iii) a Proposal for an Asylum and Migration Management Regulation; iv) a Proposal for a Screening Regulation; v) a Proposal for a Crisis and Force Majeure Regulation. It also includes a number of non-legislative initiatives.

The EDPS acknowledges the need for a more effective management of migration and asylum. At the same time, as stated in the EDPS Strategy 2020-24, data protection is one of the last lines of defence for vulnerable individuals, such as migrants and asylum seekers approaching the EU external borders. Therefore, the EDPS considers that the proposed comprehensive approach must be based on full respect to the fundamental rights of persons who seek international protection and other migrants, including their right to data protection and privacy.

In general, the EDPS considers that an in-depth fundamental rights and data protection impact assessment should be carried out. He is also of the view that the legislative proposals should clearly allocate the respective responsibilities of the different actors involved for processing personal data. In addition, taking into account the fact that most of the proposals in the New Pact on Migration and Asylum build upon the proposals to reform the Common European Asylum System from 2016, the EDPS considers that the recommendations in his Opinion 07/2016 on the first reform package on the Common European Asylum System, in particular those on Eurodac, remain fully valid.

More specifically, with regard to the amended Proposal for a Eurodac Regulation, the EDPS recommends that the authorities of Member States and the Union bodies continue to be able to see only the data that is relevant for the performance of their specific tasks, even if the data sets are linked in a sequence. The EDPS also recommends that the amended proposal explicitly introduces the single model of coordinated supervision in line with Article 62 of the EUDPR. The EDPS also recommends that before the start of the operational use of the modified system, the security framework for the Eurodac's business and technical environment is properly updated and that the proposal clarifies what data would be stored in the Common Identity Repository and in the Eurodac Central System, respectively.

With regard to the Proposal for a Screening Regulation, the EDPS underlines that accuracy of the information processed is of key importance and that the right to rectify and/or supplement the personal data of third country nationals should be ensured in all cases. Furthermore, the EDPS considers that the proposal remains very general when it comes to the methods that can be used to gather data provided by or obtained from the third-country national for their identification or verification, especially taking into account the wide range of practices used at national level, with different degrees of intrusiveness and efficacy. The EDPS also recommends clarifying the purpose and modalities related to the processing of personal data for verifying whether the third country nationals constitute a risk to security.

The Opinion provides for some additional recommendations related to data protection that should also be taken into consideration in the legislative process.

1. INTRODUCTION AND BACKGROUND

1. The European Commission presented the New Pact on Migration and Asylum on 23 September 2020 ⁽¹⁾. It is one of the key policy initiatives of the Commission and has been envisaged in its Work Programme, published on 29 January 2020, under the fifth priority – ‘Promoting our European Way of Life’ ⁽²⁾.
2. The New Pact on Migration and Asylum consists of several legislative proposals as well as non-legislative instruments. It builds upon the Commission proposals to reform the Common European Asylum System (CEAS) presented by the Commission in 2016 and 2018, on which the Parliament and the Council have already found tentative political agreement but have not concluded the negotiations yet.
3. In this context, the Commission presented two amended and three new legislative proposals:
 - an Amended proposal for a Regulation of the European Parliament and of the Council on the establishment of ‘Eurodac’ for the comparison of biometric data for the effective application of Regulation on Asylum and Migration Management (hereinafter ‘amended Proposal for a Eurodac Regulation’) ⁽³⁾,
 - an Amended proposal for a Regulation of the European Parliament and of the Council establishing a common procedure for international protection in the Union and repealing Directive 2013/32/EU (hereinafter ‘amended Proposal for Asylum Procedure’) ⁽⁴⁾,
 - a Proposal on asylum and migration management and amending Council Directive 2003/109/EC and the proposed Regulation (EU) XXX/XXX [Asylum and Migration Fund] (hereinafter the ‘Proposal for an Asylum and Migration Management Regulation’) ⁽⁵⁾,
 - a Proposal for a Regulation of the European Parliament and of the Council introducing a screening of third country nationals at the external borders and amending Regulations (EC) 767/2008, (EU) 2017/2226, (EU) 2018/1240 and (EU) 2019/817 (hereinafter the ‘Proposal for a Screening Regulation’) ⁽⁶⁾,
 - a Proposal for a Regulation of the European Parliament and of the Council addressing situations of crisis and force majeure in the field of migration and asylum (hereinafter the ‘Proposal for a Crisis and Force Majeure Regulation’) ⁽⁷⁾.

In addition, the new Pact includes the following non-legislative initiatives:

- a new recommendation on Migration Preparedness and Crisis Blueprint ⁽⁸⁾,
- a new recommendation on Resettlement and Complementary pathways ⁽⁹⁾,
- a new recommendation on Search and Rescue Operations by Private Vessels ⁽¹⁰⁾,
- a new guidance on the Facilitators Directive ⁽¹¹⁾.

⁽¹⁾ COM(2020) 609 final, <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1601287338054&uri=COM:2020:609:FIN>

⁽²⁾ COM(2020) 37 final, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0037>

⁽³⁾ COM(2020) 614 final, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2020:614:FIN>

⁽⁴⁾ COM(2020) 611 final, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2020:611:FIN>

⁽⁵⁾ COM(2020) 610 final, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2020:610:FIN>

⁽⁶⁾ COM(2020) 612 final, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2020:612:FIN>

⁽⁷⁾ COM(2020) 613 final, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2020:613:FIN>

⁽⁸⁾ Commission Recommendation (EU) 2020/1366 of 23 September 2020 on an EU mechanism for preparedness and management of crises related to migration (Migration Preparedness and Crisis Blueprint), <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020H1366>

⁽⁹⁾ Commission Recommendation (EU) 2020/1364 of 23 September 2020 on legal pathways to protection in the EU: promoting resettlement, humanitarian admission and other complementary pathways, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020H1364>

⁽¹⁰⁾ Commission Recommendation (EU) 2020/1365 of 23 September 2020 on cooperation among Member States concerning operations carried out by vessels owned or operated by private entities for the purpose of search and rescue activities, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2020.317.01.0023.01.ENG&toc=OJ%3AL%3A2020%3A317%3ATOC

⁽¹¹⁾ Commission Guidance on the implementation of EU rules on definition and prevention of the facilitation of unauthorised entry, transit and residence, C(2020) 6470 final.

4. The EDPS was consulted by the Commission informally on 27 July 2020 on the amended Proposal for a Eurodac Regulation and communicated his informal comments to the Commission in August. The EDPS welcomes the fact that his views have been sought at an early stage of the procedure and encourages the Commission to continue with this good practice.
5. The EDPS was subsequently formally consulted by the Commission on 5 October 2020 on the amended Proposal for a Eurodac Regulation. However, the consultation does not cover the other elements of the Migration and Asylum package, adopted on 23 September 2020, that might also have impact on the right to data protection and thus fall within the scope of Article 42(1) of Regulation (EU) 2018/1725 (hereinafter the 'EUDPR').
6. At the same time, the amended Proposal for a Eurodac Regulation refers to a number of other legislative proposals, part of the New Pact on Migration and Asylum, such as the Regulation on Asylum and Migration Management, Asylum Procedure Regulation, Screening Regulation, etc. Therefore, while the primary focus of this opinion is the amended Proposal for a Eurodac Regulation, it contains also certain comments and recommendations on the other legislative proposals.

5. CONCLUSIONS

The EDPS understands the need for a more coherent and effective management of migration and asylum. At the same time, as already stated in the EDPS Strategy 2020-24, '[d]ata protection is one of the last lines of defence for vulnerable individuals, such as migrants and asylum seekers approaching EU external borders.'. Therefore, the proposed comprehensive approach must be based on full respect to the fundamental rights of persons who seek international protection and other migrants, including their right to data protection and privacy.

36. To this end, the EDPS, in his advisory role, provides in this Opinion some specific recommendations in terms of data protection and privacy. While the primary focus of this Opinion is the amended Proposal for a Eurodac Regulation, it also contains a number of comments and recommendations on the other legislative proposals. The comprehensive approach envisaged by the New Pact on Migration and Asylum, together with the potential impact of such framework on fundamental rights, including on privacy and data protection, call for an in-depth fundamental rights and data protection impact assessment.
37. In addition, the integrated approach of the New Pact on Migration and Asylum assigns specific tasks to a variety of actors at national and Union level, including EU agencies, such as the European Border and Coast Guard (Frontex) and the European Asylum Support Office (EASO). Based on his experience of supervising the EU large-scale IT systems, the EDPS considers that the legislative proposals should clearly allocate the respective responsibilities for processing personal data, which is essential for the attribution of controllership pursuant to the EUDPR and the GDPR.

Regarding the amended Proposal for a Eurodac Regulation, the EDPS considers that the recommendations made in his Opinion 07/2016 on the first reform package on the Common European Asylum System ⁽¹³⁾, in particular those on Eurodac, remain fully valid. In addition, with regard to the novelties introduced by the amended Proposal for a Eurodac Regulation, the EDPS considers important to ensure that the authorities of the Member States and the Union bodies continue to be able to see only the data that is relevant for the performance of their specific tasks, even if the data sets are linked in a sequence. Furthermore, the EDPS recommends to explicitly introduce the single model of coordinated supervision in line with Article 62 of the EUDPR. The EDPS also recommends that before the start of the operational use of the modified system, the security framework for the Eurodac's business and technical environment is properly updated and that the proposal clarifies what data would be stored in the Common Identity Repository (CIR) and in the Eurodac Central System, respectively.

⁽¹³⁾ European Asylum System (Eurodac, EASO and Dublin regulations).

38. Regarding the other proposals, and in particular the Proposal for a Screening Regulation, the EDPS underlines that accuracy of the information processed is key and that the right to rectify and/or supplement the personal data of third country nationals should be ensured in all cases. Furthermore, the EDPS considers that the proposal remains very general when it comes to the methods that can be used to gather data from the third-country nationals for their identification, especially taking into account the wide range of practices used at national level, with different degrees of intrusiveness and efficacy. The EDPS also recommends clarifying the purpose and modalities related to the processing of personal data for verifying whether the third country nationals constitute a risk to security.
39. Finally, the EDPS notes that the new legislative proposals either lack entirely any substantive legal provisions on personal data protection, or the proposed texts are not fully in line with the relevant Union law. Therefore, the EDPS recommends that the legislative proposals as a minimum refer explicitly to the relevant Union legal framework on data protection, i.e. GDPR, EUDPR and, if relevant, Directive (EU) 2018/680.

Brussels, 30 November 2020.

Wojciech Rafał WIEWIÓROWSKI

Summary of the Preliminary Opinion of the European Data Protection Supervisor on the European Health Data Space

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

(2021/C 99/09)

Text of executive summary

On 19 February 2020, the European Commission presented its Communication on 'A European strategy for data'. This communication envisages the creation of a common space in the area of health, namely the European Health Data Space ('EHDS'), presented as an essential tool for the prevention, detection and cure of diseases as well as for the taking of evidence-based decisions and to enhance effectiveness, accessibility and sustainability of the healthcare systems.

Whereas the EDPS strongly supports the objectives of promoting health-data exchange and fostering medical research, it underlines the necessity for data protection safeguards to be defined at the outset of the creation of the EHDS. Thus, with this preliminary opinion the EDPS highlights the essential elements that should be considered in the development of the EHDS from the data protection perspective.

The EDPS calls for the establishment of a thought-through legal basis for the processing operations under the EHDS in line with Article 6(1) GDPR and also recalls that such processing must comply with Article 9 GDPR for the processing of special categories of data.

Moreover, the EDPS highlights that due to the sensitivity of the data to be processed within the EHDS, the boundaries of what constitutes a lawful processing and a compatible further processing of the data must be crystal-clear for all the stakeholders involved. Therefore, the transparency and the public availability of the information relating to the processing on the EHDS will be key to enhance public trust in the EHDS.

The EDPS also calls on the Commission to clarify the roles and responsibilities of the parties involved and to clearly identify the precise categories of data to be made available to the EHDS. Additionally, he calls on the Member States to establish mechanisms to assess the validity and quality of the sources of the data.

The EDPS underlines the importance of vesting the EHDS with a comprehensive security infrastructure, including both organisational and state-of-the-art technical security measures to protect the data fed into the EHDS. In this context, he recalls that Data Protection Impact Assessments may be a very useful tool to determine the risks of the processing operations and the mitigation measures that should be adopted.

The EDPS recommends paying special attention to the ethical use of data within the EHDS framework, for which he suggests taking into account existing ethics committees and their role in the context of national legislation.

The EDPS is convinced that the success of the EHDS will depend on the establishment of a strong data governance mechanism that provides for sufficient assurances of a lawful, responsible, ethical management anchored in EU values, including respect for fundamental rights. The governance mechanism should regulate, at least, the entities that will be allowed to make data available to the EHDS, the EHDS users, the Member States' national contact points/ permit authorities, and the role of DPAs within this context.

The EDPS is interested in policy initiatives to achieve 'digital sovereignty' and has a preference for data being processed by entities sharing European values, including privacy and data protection. Moreover, the EDPS calls on the Commission to ensure that the stakeholders taking part in the EHDS, and in particular, the controllers, do not transfer personal data unless data subjects whose personal data are transferred to a third country are afforded a level of protection essentially equivalent to that guaranteed within the European Union.

The EDPS calls on Member States to guarantee the effective implementation of the right to data portability specifically in the EHDS, together with the development of the necessary technical requirements. In this regard, he considers that a gap analysis might be required regarding the need to integrate the GDPR safeguards with other regulatory safeguards, provided e.g. by competition law or ethical guidelines.

I. INTRODUCTION AND SCOPE OF THE OPINION

1. On 19 February 2020, the European Commission ('Commission') presented its Communication on 'A European strategy for data' ⁽¹⁾. This was part of a package of documents, including a Communication on Shaping Europe's digital future ⁽²⁾ and a White Paper on Artificial Intelligence - A European approach to excellence and trust ⁽³⁾.
2. One of the key initiatives of the European strategy for data ('Data Strategy') is to create Common European data spaces in strategic sectors and domains of public interest, which would increase the possibilities for public authorities and business to access high quality data, boost growth and create value. More generally, the various initiatives of the Data Strategy go in line with the Commission's ambition to have the '(...) EU at the forefront of the data-agile economy, while respecting and promoting the fundamental values that are the foundation of European societies' ⁽⁴⁾.
3. The EDPS released its Opinion 3/2020 on the European strategy for data ('Opinion 3/2020') in June 2020 ⁽⁵⁾, after an informal consultation on a draft version by the Commission in January 2019. Opinion 3/2020 presents the EDPS' views on the Data Strategy, and touches particularly on certain relevant concepts from a data protection perspective, including the notion of 'public good', Open Data, use of data for scientific research, data intermediaries, data altruism and international data sharing.
4. The EDPS notes that eHealth is a key area of public interest where the Commission's Data Strategy envisages the creation of a common space, namely the European Health Data Space ('EHDS'). In accordance with the Data Strategy, the EHDS will be essential for the prevention, detection and cure of diseases, as well as for evidence-based decisions in order to enhance effectiveness, accessibility and sustainability of the healthcare systems ⁽⁶⁾.
5. In its recent meeting of October 2020, also the European Council welcomed '(...) the European strategy for data, which supports the EU's global digital ambitions to build a true European competitive data economy, while ensuring European values and a high level of data security, data protection, and privacy. It stresses the need to make high-quality data more readily available and to promote and enable better sharing and pooling of data, as well as interoperability. The European Council welcomes the creation of common European data spaces in strategic sectors, and in particular invites the Commission to give priority to the health data space, which should be set up by the end of 2021.' ⁽⁷⁾.
6. Whereas the EDPS strongly supports the objectives of promoting health-data exchange and fostering research on new preventive strategies, treatments, medicines, medical devices, it also underlines the necessity for data protection safeguards to be defined at the outset. In the context of the Covid19 pandemic, the European Union has seen more than ever the need for the GDPR data processing principles to be fully applied. In line with the recent European Council Conclusions, the EDPS recalls the fundamental rights to data protection and privacy, and calls for data protection principles to be integrated in the future eHealth solutions that will soon be at the heart of all European eHealth systems. In this context, we highlight that data protection safeguards must be embedded in the core of the upcoming EHDS, with the aim of guaranteeing the respect of fundamental rights of individuals, including the right to privacy and to the protection of personal data of Articles 7 and 8 of the Charter of Fundamental Rights of the European Union ('the Charter').
7. The aim of this preliminary opinion is to contribute to the Commission's work on the future EHDS, in particular through identifying of the essential elements that should be considered in the development of the EHDS from the data protection perspective. This preliminary opinion should be read in conjunction with other relevant EDPS Opinions, including the Opinion on the European Strategy for Data ⁽⁸⁾, the preliminary Opinion on scientific research ⁽⁹⁾, the Opinion on Open Data ⁽¹⁰⁾, the Opinion on the European Commission's White Paper on Artificial Intelligence ⁽¹¹⁾ and the EDPS Opinion on the proposal for a recast of the Public Sector Information (PSI) re-use Directive ⁽¹²⁾. It is worth underlining that this preliminary opinion is without prejudice to any future EDPS opinion that may be issued in accordance with Article 42 of Regulation (EU) 2018/1725 on the related forthcoming legislative proposals of the Commission.

IV. CONCLUSIONS AND RECOMMENDATIONS

In light of the above, the EDPS makes the following recommendations:

46. Supports the initiative to create a common European Health Data Space and acknowledges its key role to improve access to and quality of healthcare, by helping competent authorities in taking evidence-based policy decisions and by supporting scientific research. However, the EDPS calls for the adoption of necessary data protection safeguards in parallel to the works towards the creation of the EHDS.
47. Recalls that all processing operations resulting from the EHDS' establishment will require a robust legal basis in line with EU data protection law, particularly Article 6(1) GDPR and Article 9 GDPR for the processing of special categories of data.
48. Considers that the forthcoming legislative initiative on the EHDS should also aim at contributing to a mitigation of the current fragmentation of rules applicable to the processing of health data and to scientific research, thus also aimed at guaranteeing a lawful and ethical use and re-use of the data within the EHDS.
49. Advocates for additional clarity on the boundaries of what constitutes a lawful processing and a compatible further processing of the data for all stakeholders involved in the EHDS process, while also strengthening the transparency of data processed by making the conditions for re-use publicly available.
50. Considers essential the setting of clear rules to the Member States for the identification of controllers within the context of the EHDS, before whom individuals may be able to exercise their data protection rights, in line with current legislation (GDPR and Regulation 2018/1725).
51. Requests that the main actors involved and the categories of data processed within the EHDS are clearly identified and considers fundamental for the European Data Protection Authorities ('DPAs') to be clearly involved in its supervision and data protection compliance.
52. Calls for the adoption of a comprehensive security infrastructure, including both organisational and state-of-the-art technical security measures to protect the sensitive data fed into the EHDS.
53. Recalls the essential role of Data Protection Impact Assessments ('DPIAs'), and recommends, whenever possible, making public the results of such assessments, as an enhancing measure of trust and transparency.
54. Calls for the establishment of a strong data governance mechanism that providing for sufficient assurances of a lawful, responsible and ethical management of the data processed within the EHDS.
55. Has a preference for data being processed by entities sharing European values, including privacy and data protection.
56. Strongly supports the achievement of data sovereignty where data generated in Europe is converted into value for European companies and individuals, and processed in accordance with EU rules and regulations.
57. Calls on the Commission to ensure that the stakeholders taking part in the EHDS, and in particular, the controllers, do not transfer personal data unless data subjects whose personal data are transferred to a third country are afforded a level of protection essentially equivalent to that guaranteed within the European Union.
58. Invites the Commission to ensure in its legislative proposal that Member States guarantee the application of the right to data portability together with the development of the necessary technical requirements in the EHDS that allow and effective exercise of such right by data subjects.
59. Recommends performing a gap analysis regarding the need to integrate the GDPR safeguards with other regulatory safeguards, provided e.g. by competition law or ethical guidelines.

Brussels, 17 November 2020.

Wojciech Rafał WIEWIÓROWSKI

-
- (¹) COM 2020 66 final https://ec.europa.eu/info/sites/info/files/communication-european-strategy-data-19feb2020_en.pdf
- (²) COM(2020) 67 final, https://ec.europa.eu/info/strategy/priorities-2019-2024/europe-fit-digital-age/shaping-europedigital-future_en
- (³) COM(2020) 65 final, https://ec.europa.eu/info/strategy/priorities-2019-2024/europe-fit-digital-age/excellence-trustartificial-intelligence_en
- (⁴) COM (2020) 66 final <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0066&from=EN>, p. 2.
- (⁵) EDPS Opinion 3/2020 on the European Strategy for Data https://edps.europa.eu/sites/edp/files/publication/20-06-16_opinion_data_strategy_en.pdf
- (⁶) COMM 2020 66 final https://ec.europa.eu/info/sites/info/files/communication-european-strategy-data-19feb2020_en.pdf, p. 22.
- (⁷) See <https://data.consilium.europa.eu/doc/document/ST-13-2020-INIT/en/pdf>
- (⁸) EDPS Opinion 3/2020 on the European Strategy for Data https://edps.europa.eu/sites/edp/files/publication/20-06-16_opinion_data_strategy_en.pdf
- (⁹) EDPS Preliminary Opinion on data protection and scientific research https://edps.europa.eu/sites/edp/files/publication/20-01-06_opinion_research_en.pdf
- (¹⁰) EDPS Opinion on the 'Open-Data Package' of the European Commission including a Proposal for a Directive amending Directive 2003/98/EC on re-use of public sector information (PSI), a Communication on Open Data and Commission Decision 2011/833/EU on the reuse of Commission documents, https://edps.europa.eu/sites/edp/files/publication/12-04-18_open_data_en.pdf
- (¹¹) EDPS Opinion 4/2020 EDPS on the European Commission's White Paper on Artificial Intelligence– A European approach to excellence and trust https://edps.europa.eu/sites/edp/files/publication/20-06-19_opinion_ai_white_paper_en.pdf
- (¹²) EDPS Opinion 5/2018 on the proposal for a recast of the Public Sector Information (PSI) re-use Directive https://edps.europa.eu/sites/edp/files/publication/18-07-11_psi_directive_opinion_en.pdf
-

V

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

EUROPEAN COMMISSION

Prior notification of a concentration
(Case M.10185 — Pierer Industrie/Palfinger/FSS/Jetfly)
Candidate case for simplified procedure*(Text with EEA relevance)*

(2021/C 99/10)

1. On 15 March 2021, the Commission received notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 ⁽¹⁾.

This notification concerns the following undertakings:

- Pierer Industrie AG ('PIAG', Austria),
- Palfinger AG ('Palfinger', Austria),
- FSS Vermögensverwaltung GmbH ('FSS', Austria),
- Jetfly Airline GmbH ('Jetfly', Austria).

PIAG, Palfinger and FSS acquire within the meaning of Article 3(1)(b) and 3(4) of the Merger Regulation joint control of Jetfly.

The concentration is accomplished by way of purchase of shares.

2. The business activities of the undertakings concerned are:

- PIAG: global industrial investment group active in the production and distribution of motorcycles, electric bicycles and components for powered two-wheelers; the development, production, maintenance and distribution of high-tech mechanical systems for dynamic components for racing, luxury cars and aeronautics; and the production of CO₂-efficient brakes, pumps and engine components;
- Palfinger: global manufacturers of hydraulic lifting and loading devices used on commercial vehicles, vessels and stationary equipment;
- FSS: global asset management company active in the production of tools and technical moulded parts; research and development of audio, navigation and telematics systems for the automotive industry; research, development and operation of information and communication technologies; and digital signage;
- Jetfly: a global airline operator providing commercial charter services to charter customers.

3. On preliminary examination, the Commission finds that the notified transaction could fall within the scope of the Merger Regulation. However, the final decision on this point is reserved.

⁽¹⁾ OJ L 24, 29.1.2004, p. 1 (the 'Merger Regulation').

Pursuant to the Commission Notice on a simplified procedure for treatment of certain concentrations under Council Regulation (EC) No 139/2004 ⁽²⁾, 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 10 days following the date of this publication. The following reference should always be specified:

Case M.10185 — Pierer Industrie/Palfinger/FSS/Jetfly

Observations can be sent to the Commission by email, by fax, or by post. Please use the contact details below:

Email: COMP-MERGER-REGISTRY@ec.europa.eu

Fax +32 22964301

Postal address:

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

⁽²⁾ OJ C 366, 14.12.2013, p. 5.

Prior notification of a concentration
(Case M.10133 — Astorg/Nordic Capital/Novo/Bioclinica)

(Text with EEA relevance)

(2021/C 99/11)

1. On 16 March 2021, the Commission received notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 ⁽¹⁾.

This notification concerns the following undertakings:

- Astorg Asset Management S.à r.l. ('Astorg', Luxembourg)
- Nordic Capital IX Limited ('Nordic Capital', Jersey)
- Novo Holdings A/S ('Novo', Denmark)
- Bioclinica Holding I LP ('Bioclinica', USA)

Astorg, Nordic Capital and Novo acquire within the meaning of Article 3(1)(b) of the Merger Regulation joint control of the whole of Bioclinica through eResearch Technology, Inc ('ERT', USA).

The concentration is accomplished by way of purchase of shares.

2. The business activities of the undertakings concerned are the following:

- for Astorg: a global private equity firm,
- for Nordic Capital: a private equity firm focused on healthcare, technology & payments, financial services, and industrial & business services,
- for Novo: a holding company responsible for the management of the assets of the Novo Nordisk Foundation through investments in the life sciences and related areas and through minority investments of a financial and venture capital nature,
- Astorg, Nordic Capital, and Novo jointly control ERT, a provider of software-enabled clinical research solutions,
- for Bioclinica: a provider of software-enabled clinical research solutions, including medical imaging and cardiac safety services, clinical adjudication, randomization and trial supply management and optimization solutions, electronic and eSource data capture, clinical trial management software, and drug safety solutions.

3. On preliminary examination, the Commission finds that the notified transaction could fall within the scope of the Merger Regulation. However, the final decision on this point is reserved.

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 10 days following the date of this publication. The following reference should always be specified:

M.10133 — Astorg/Nordic Capital/Novo/Bioclinica

⁽¹⁾ OJ L 24, 29.1.2004, p. 1 (the 'Merger Regulation').

Observations can be sent to the Commission by email, by fax, or by post. Please use the contact details below:

Email: COMP-MERGER-REGISTRY@ec.europa.eu

Fax +32 22964301

Postal address:

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

ISSN 1977-091X (electronic edition)
ISSN 1725-2423 (paper edition)



Publications Office
of the European Union
L-2985 Luxembourg
LUXEMBOURG

EN