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Contents

II *Non-legislative acts*

REGULATIONS

- ★ **Council Implementing Regulation (EU) 2019/1337 of 8 August 2019 implementing Article 2(3) of Regulation (EC) No 2580/2001 on specific restrictive measures directed against certain persons and entities with a view to combating terrorism, and repealing Implementing Regulation (EU) 2019/24** 1
- ★ **Commission Regulation (EU) 2019/1338 of 8 August 2019 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food⁽¹⁾** 5
- ★ **Commission Implementing Regulation (EU) 2019/1339 of 8 August 2019 granting a transitional period for use of the protected designation of origin ‘Cidre Cotentin’/‘Cotentin’ (PDO)** 8

DECISIONS

- ★ **Council Decision (CFSP) 2019/1340 of 8 August 2019 appointing the European Union Special Representative in Bosnia and Herzegovina** 10
- ★ **Council Decision (CFSP) 2019/1341 of 8 August 2019 updating the list of persons, groups and entities subject to Articles 2, 3 and 4 of Common Position 2001/931/CFSP on the application of specific measures to combat terrorism, and repealing Decision (CFSP) 2019/25** 15

RULES OF PROCEDURE

- ★ **Decision of the Management Board of the European Medicines Agency of 12 June 2019 on internal rules concerning restrictions of certain rights of data subjects in relation to processing of personal data in the framework of the functioning of the Agency** 19

⁽¹⁾ Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

II

(Non-legislative acts)

REGULATIONS

COUNCIL IMPLEMENTING REGULATION (EU) 2019/1337

of 8 August 2019

implementing Article 2(3) of Regulation (EC) No 2580/2001 on specific restrictive measures directed against certain persons and entities with a view to combating terrorism, and repealing Implementing Regulation (EU) 2019/24

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Regulation (EC) No 2580/2001 of 27 December 2001 on specific restrictive measures directed against certain persons and entities with a view to combating terrorism ⁽¹⁾, and in particular Article 2(3) thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

- (1) On 8 January 2019, the Council adopted Implementing Regulation (EU) 2019/24 ⁽²⁾ implementing Article 2(3) of Regulation (EC) No 2580/2001, establishing an updated list of persons, groups and entities to which Regulation (EC) No 2580/2001 applies ('the list').
- (2) The Council has provided, where practically possible, all the persons, groups and entities with statements of reasons explaining why they were entered into the list.
- (3) By way of a notice published in the *Official Journal of the European Union*, the Council informed the persons, groups and entities on the list that it had decided to keep them thereon. The Council also informed the persons, groups and entities concerned that it was possible to request a statement of the Council's reasons for entering them into the list where such a statement had not already been communicated to them.
- (4) The Council has reviewed the list as required by Article 2(3) of Regulation (EC) No 2580/2001. When carrying out that review, the Council took into account the observations submitted to it by those concerned as well as the updated information received from the competent national authorities on the status of listed individuals and entities at the national level.
- (5) The Council has verified that competent authorities, as referred to in Article 1(4) of Council Common Position 2001/931/CFSP ⁽³⁾, have taken decisions with regards to all persons, groups and entities on the list to the effect that they have been involved in terrorist acts within the meaning of Article 1(2) and (3) of Common Position 2001/931/CFSP. The Council has also concluded that the persons, groups and entities to which Articles 2, 3 and 4 of Common Position 2001/931/CFSP apply should continue to be subject to the specific restrictive measures provided for in Regulation (EC) No 2580/2001.
- (6) The list should be updated accordingly and Implementing Regulation (EU) 2019/24 should be repealed,

⁽¹⁾ OJ L 344, 28.12.2001, p. 70.

⁽²⁾ Council Implementing Regulation (EU) 2019/24 of 8 January 2019 implementing Article 2(3) of Regulation (EC) No 2580/2001 on specific restrictive measures directed against certain persons and entities with a view to combating terrorism, and repealing Implementing Regulation (EU) 2018/1071 (OJ L 6, 9.1.2019, p. 2).

⁽³⁾ Council Common Position 2001/931/CFSP of 27 December 2001 on the application of specific measures to combat terrorism (OJ L 344, 28.12.2001, p. 93).

HAS ADOPTED THIS REGULATION:

Article 1

The list provided for in Article 2(3) of Regulation (EC) No 2580/2001 is set out in the Annex to this Regulation.

Article 2

Implementing Regulation (EU) 2019/24 is hereby repealed.

Article 3

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 8 August 2019.

For the Council
The President
T. TUPPURAINEN

ANNEX

LIST OF PERSONS, GROUPS AND ENTITIES REFERRED TO IN ARTICLE 1

I. PERSONS

1. ABDOLLAHI Hamed (a.k.a. Mustafa Abdullahi), born 11.8.1960 in Iran. Passport: D9004878.
2. AL-NASSER, Abdelkarim Hussein Mohamed, born in Al Ihsa (Saudi Arabia), citizen of Saudi Arabia.
3. AL YACIOUB, Ibrahim Salih Mohammed, born 16.10.1966 in Tarut (Saudi Arabia), citizen of Saudi Arabia.
4. ARBABSAR Manssor (a.k.a. Mansour Arbabsar), born 6.3.1955 or 15.3.1955 in Iran. Iranian and US national. Passport: C2002515 (Iran); Passport: 477845448 (USA). National ID no.: 07442833, expiry date 15.3.2016 (USA driving licence).
5. ASADI Assadollah, born 22.12.1971 in Teheran (Iran), Iranian national. Iranian diplomatic passport number: D9016657.
6. BOUYERI, Mohammed (a.k.a. Abu ZUBAIR, a.k.a. SOBIAR, a.k.a. Abu ZOUBAIR), born 8.3.1978 in Amsterdam (The Netherlands).
7. EL HAJJ, Hassan Hassan, born 22.3.1988 in Zaghdraiya, Sidon, Lebanon, Canadian citizen. Passport number: JX446643 (Canada).
8. HASHEMI MOGHADAM Saeid, born 6.8.1962 in Teheran (Iran), Iranian national. Passport number: D9016290, valid until 4.2.2019.
9. IZZ-AL-DIN, Hasan (a.k.a. GARBAYA, Ahmed, a.k.a. SA-ID, a.k.a. SALWWAN, Samir), Lebanon, born 1963 in Lebanon, citizen of Lebanon.
10. MELIAD, Farah, born 5.11.1980 in Sydney (Australia), Australian citizen. Passport number: M2719127 (Australia).
11. MOHAMMED, Khalid Shaikh (a.k.a. ALI, Salem, a.k.a. BIN KHALID, Fahd Bin Adballah, a.k.a. HENIN, Ashraf Refaat Nabith, a.k.a. WADOOD, Khalid Abdul), born 14.4.1965 or 1.3.1964 in Pakistan, passport No 488555.
12. ŞANLI, Dalokay (a.k.a. Sinan), born 13.10.1976 in Pülümür (Turkey).
13. SHAHLAI Abdul Reza (a.k.a. Abdol Reza Shala'i, a.k.a. Abd-al Reza Shalai, a.k.a. Abdorreza Shahlai, a.k.a. Abdolreza Shahla'i, a.k.a. Abdul-Reza Shahlaee, a.k.a. Hajj Yusef, a.k.a. Haji Yusif, a.k.a. Hajji Yasir, a.k.a. Hajji Yusif, a.k.a. Yusuf Abu-al-Karkh), born circa 1957 in Iran. Addresses: (1) Kermanshah, Iran, (2) Mehran Military Base, Ilam Province, Iran.
14. SHAKURI Ali Gholam, born circa 1965 in Tehran, Iran.
15. SOLEIMANI Qasem (a.k.a. Ghasem Soleymani, a.k.a. Qasmi Sulayman, a.k.a. Qasem Soleymani, a.k.a. Qasem Solaimani, a.k.a. Qasem Salimani, a.k.a. Qasem Solemani, a.k.a. Qasem Sulaimani, a.k.a. Qasem Sulemani), born 11.3.1957 in Iran. Iranian national, Passport: 008827 (Iran Diplomatic), issued 1999. Title: Major General.

II. GROUPS AND ENTITIES

1. 'Abu Nidal Organisation' — 'ANO' (a.k.a. 'Fatah Revolutionary Council', a.k.a. 'Arab Revolutionary Brigades', a.k.a. 'Black September', a.k.a. 'Revolutionary Organisation of Socialist Muslims').
2. 'Al-Aqsa Martyrs' Brigade'.
3. 'Al-Aqsa e.V'.
4. 'Babbar Khalsa'.
5. 'Communist Party of the Philippines', including 'New People's Army' — 'NPA', Philippines.
6. 'Directorate for Internal Security of the Iranian Ministry for Intelligence and Security'.
7. 'Gama'a al-Islamiyya' (a.k.a. 'Al-Gama'a al-Islamiyya') ('Islamic Group' — 'IG').

8. 'İslami Büyük Doğu Akıncılar Cephesi' — 'IBDA-C' ('Great Islamic Eastern Warriors Front').
 9. 'Hamas', including 'Hamas-Izz al-Din al-Qassem'.
 10. 'Hizballah Military Wing' (a.k.a. 'Hezbollah Military Wing', a.k.a. 'Hizbullah Military Wing', a.k.a. 'Hizbollah Military Wing', a.k.a. 'Hezbollah Military Wing', a.k.a. 'Hisbollah Military Wing', a.k.a. 'Hizbu'llah Military Wing' a.k.a. 'Hizb Allah Military Wing', a.k.a. 'Jihad Council' (and all units reporting to it, including the External Security Organisation)).
 11. 'Hizbul Mujahideen' — 'HM'.
 12. 'Khalistan Zindabad Force' — 'KZF'.
 13. 'Kurdistan Workers' Party' — 'PKK', (a.k.a. 'KADEK', a.k.a. 'KONGRA-GEL').
 14. 'Liberation Tigers of Tamil Eelam' — 'LTTE'.
 15. 'Ejército de Liberación Nacional' ('National Liberation Army').
 16. 'Palestinian Islamic Jihad' — 'PIJ'.
 17. 'Popular Front for the Liberation of Palestine' — 'PFLP'.
 18. 'Popular Front for the Liberation of Palestine — General Command' (a.k.a. 'PFLP — General Command').
 19. 'Devrimci Halk Kurtuluş Partisi-Cephesi' — 'DHKP/C' (a.k.a. 'Devrimci Sol' ('Revolutionary Left'), a.k.a. 'Dev Sol') ('Revolutionary People's Liberation Army/Front/Party').
 20. 'Sendero Luminoso' — 'SL' ('Shining Path').
 21. 'Teyrbazen Azadiya Kurdistan' — 'TAK' (a.k.a. 'Kurdistan Freedom Falcons', a.k.a. 'Kurdistan Freedom Hawks').
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COMMISSION REGULATION (EU) 2019/1338**of 8 August 2019****amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC ⁽¹⁾, and in particular points (a), (d), (e), and (i) of Article 5(1), Article 11(3) and Article 12(3) and (6) thereof,

Whereas:

- (1) Annex I to Commission Regulation (EU) No 10/2011 ⁽²⁾ establishes a Union list of authorised substances which may be used in the manufacture of plastic materials and articles intended to come into contact with food.
- (2) Since the last amendment to Regulation (EU) No 10/2011, the European Food Safety Authority ('the Authority') has published a scientific opinion on the permitted uses of an already authorised substance that may be used in food contact materials ('FCM'). In order to ensure that Regulation (EU) No 10/2011 reflects the most recent findings of the Authority, that Regulation should be amended.
- (3) The substance poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate) (FCM substance No 1059, CAS number 147398-31-0) has been authorised by Commission Regulation (EU) 2019/37 ⁽³⁾ to be used either alone or blended with other polymers in contact with dry or solid foods for which food simulant E is assigned in Table 2 of Annex III to Regulation (EU) No 10/2011 on the basis of two scientific opinions ⁽⁴⁾ ⁽⁵⁾ published by the Authority. The Authority has adopted a new favourable scientific opinion ⁽⁶⁾ extending the use of this substance alone or blended with other polymers in the manufacture of plastics intended to come into contact with all foods. In the later opinion, the Authority concluded that this substance is not of a safety concern for the consumer if it is used either alone or blended with other polymers in contact with all foods under contact conditions of 6 months or more at room temperature or below, including hot fill or short heating-up phases, provided that the migration of all oligomers with a molecular weight below 1 000 Da does not exceed 5,0 mg/kg food or food simulant. The Authority's conclusion is based on the worst-case migration testing conditions set out in point 2.1.4 of Chapter 2 of Annex V to Regulation (EU) No 10/2011 for long term contact conditions (6 months or more) with food at room temperature or below. In accordance with the provisions of point 2.1.5 of Chapter 2, of Annex V to that Regulation, these worst-case migration testing conditions also address contact conditions of less than 6 months at room temperature or below. Therefore, the use of this substance alone or blended with other polymers in the manufacture of plastics intended to come into contact with all foods under contact conditions of less than 6 months at room temperature or below, including hot fill or short heating-up phases will also be of no safety concern, provided that the migration of all oligomers with a molecular weight below 1 000 Da does not exceed 5,0 mg/kg food or food simulant. In addition, the Authority also confirmed in this opinion that the specific migration limit of 0,05 mg/kg food set for the degradation product crotonic acid in the previous authorisation of FCM substance No 1059, should also apply under this extended use. The entry for this substance in Table 1 of point 1 of Annex I to Regulation (EU) No 10/2011 should therefore include the uses of this substance with all foods and in all conditions, in column 10 of that Table.
- (4) The authorisation of the FCM substance No 1059 provided for in this Regulation, requires that the total migration of all oligomers with a molecular weight below 1 000 Da does not exceed 5,0 mg/kg food or food simulant. As analytical methods to determine the migration of these oligomers are complex, a description of

⁽¹⁾ OJ L 338, 13.11.2004, p. 4.

⁽²⁾ Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1).

⁽³⁾ Commission Regulation (EU) 2019/37 of 10 January 2019 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (OJ L 9, 11.1.2019, p. 88.).

⁽⁴⁾ EFSA Journal 2016;14(5):4464.

⁽⁵⁾ EFSA Journal 2018;16(7):5326.

⁽⁶⁾ EFSA Journal 2019;17(1):5551.

those methods is not necessarily available to competent authorities. Without that description, it is not possible for the competent authority to verify that the migration of oligomers from the material or article complies with the migration limit for these oligomers. Therefore, business operators placing on the market the final article or material containing that substance should be required to include in the supporting documentation referred to in Article 16 of Regulation (EU) No 10/2011 a description of the method and a calibration sample if required by the method.

- (5) Annex I to Regulation (EU) No 10/2011 should therefore be amended accordingly.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EU) No 10/2011 is amended in accordance with the Annex to this Regulation.

Article 2

Plastic materials and articles intended to come into contact with food complying with Regulation (EU) No 10/2011 as applicable before the entry into force of this Regulation may be placed on the market until 29 August 2020 and may remain on the market until exhaustion of stocks.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in *the Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 8 August 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

In Annex I to Regulation (EU) No 10/2011, the entry of Table 1 concerning FCM substance No 1059 is replaced by the following:

'1059		147398-31-0	Poly((R)-3-hydroxy-butyrate-co-(R)-3-hydroxyhexanoate)	no	yes	no		(35)	Only to be used either alone or blended with other polymers in contact with all foods under contact conditions of up to 6 months and/or 6 months and more, at room temperature or below, including hot fill or a short heating up phase. The migration of all oligomers with a molecular weight below 1 000 Da shall not exceed 5,0 mg/kg food.	(23)'
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COMMISSION IMPLEMENTING REGULATION (EU) 2019/1339**of 8 August 2019****granting a transitional period for use of the protected designation of origin ‘Cidre Cotentin’/‘Cotentin’ (PDO)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs ⁽¹⁾, and in particular Article 15(1) thereof,

Whereas:

- (1) By letter received on 16 November 2016, the French authorities notified the Commission that the Cidrerie de la Brique, 23 Route de la Brique, 50700 Saint-Joseph, which had been legally marketing the product in question under the name ‘Cidre Cotentin’/‘Cotentin’ continuously for more than five years, had raised an objection during the national opposition procedure. Considering that this company met the conditions laid down in Article 15(1) of Regulation (EU) No 1151/2012, the French authorities asked the European Commission to grant it a transitional period lasting until 30 June 2020.
- (2) By means of Commission Implementing Regulation (EU) 2018/939 ⁽²⁾, the Commission entered the name ‘Cidre Cotentin’/‘Cotentin’ (PDO) in the register of protected designations of origin and protected geographical indications, without granting the Cidrerie de la Brique the transitional period provided for in Article 15(1) as requested by the French authorities. Implementing Regulation (EU) 2018/939 entered into force on 23 July 2018.
- (3) By emails sent on 10 and 12 April 2019, the French authorities explained why the Cidrerie de la Brique was eligible for a transitional period under Article 15(1) of Regulation (EU) No 1151/2012 and once again asked the Commission to grant it.
- (4) The company in question, established within the geographical area defined in the specification for the protected designation of origin ‘Cidre Cotentin’/‘Cotentin’, does not follow the specification and would therefore contravene Article 13(1) of Regulation (EU) No 1151/2012 if it were to use the designation concerned.
- (5) The Cidrerie de la Brique therefore met the conditions laid down in Article 15(1) of Regulation (EU) No 1151/2012 for the granting of a transitional period in which to make legal use of the sales name after its registration. A transitional period lasting until 30 June 2020 should therefore be granted, during which time the Cidrerie de la Brique may make use of the protected name ‘Cidre Cotentin’/‘Cotentin’ (PDO).
- (6) Since the name has been protected since 23 July 2018, when Implementing Regulation (EU) 2018/939 registering the name ‘Cidre Cotentin’/‘Cotentin’ (PDO) entered into force, the authorisation to use the protected name should apply retroactively from that date.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Agricultural Product Quality Policy Committee,

HAS ADOPTED THIS REGULATION:

Article 1

The Cidrerie de la Brique, 23 Route de la Brique, 50700 Saint-Joseph, is hereby authorised to use the registered name ‘Cidre Cotentin’/‘Cotentin’ (PDO) for a transitional period lasting until 30 June 2020.

This transitional period shall apply retroactively from 23 July 2018.

⁽¹⁾ OJ L 343, 14.12.2012, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2018/939 of 26 June 2018 entering a name in the register of protected designations of origin and protected geographical indications (‘Cidre Cotentin’/‘Cotentin’ (PDO)) (OJ L 166, 3.7.2018, p. 3).

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.

Done at Brussels, 8 August 2019.

For the Commission

The President

Jean-Claude JUNKER

DECISIONS

COUNCIL DECISION (CFSP) 2019/1340

of 8 August 2019

appointing the European Union Special Representative in Bosnia and Herzegovina

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 33 and Article 31(2) thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

- (1) On 19 January 2015, the Council adopted Decision (CFSP) 2015/77 ⁽¹⁾ appointing Mr Lars-Gunnar WIGEMARK as the European Union Special Representative (EUSR) in Bosnia and Herzegovina. The EUSR's mandate is to expire on 31 August 2019.
- (2) Mr Johann SATTLER should be appointed as the EUSR in Bosnia and Herzegovina for the period from 1 September 2019 to 31 August 2021.
- (3) The EUSR will implement the mandate in the context of a situation which may deteriorate and could impede the achievement of the objectives of the Union's external action as set out in Article 21 of the Treaty,

HAS ADOPTED THIS DECISION:

Article 1

European Union Special Representative

Mr Johann SATTLER is hereby appointed as the European Union Special Representative in Bosnia and Herzegovina from 1 September 2019 until 31 August 2021. The Council may decide that the EUSR's mandate be terminated earlier, based on an assessment by the Political and Security Committee (PSC) and a proposal from the High Representative of the Union for Foreign Affairs and Security Policy (HR).

Article 2

Policy objectives

1. The EUSR's mandate shall be based on the following policy objectives of the Union in Bosnia and Herzegovina (BiH):
 - (a) continuing progress in the Stabilisation and Association Process;
 - (b) ensuring a stable, viable, peaceful, multi-ethnic and united BiH that cooperates peacefully with its neighbours; and
 - (c) ensuring that BiH is irreversibly on track towards Union membership, following the publication of the Commission Opinion on Bosnia and Herzegovina's application for membership of the European Union on 29 May 2019.
2. The Union will also continue to support the implementation of the General Framework Agreement for Peace in BiH.

⁽¹⁾ Council Decision (CFSP) 2015/77 of 19 January 2015 appointing the European Union Special Representative in Bosnia and Herzegovina (OJ L 13, 20.1.2015, p. 7).

*Article 3***Mandate**

In order to achieve the policy objectives, the EUSR's mandate shall be to:

- (a) offer the Union's advice and facilitate the political process, in particular with the promotion of dialogue between the different levels of government;
- (b) ensure consistency and coherence of Union action;
- (c) facilitate progress on political, economic and Union priorities, in particular by encouraging further work on the coordination mechanism on Union matters and the continued implementation of the European agenda for reform;
- (d) support domestic efforts in line with European standards to ensure that election results can be implemented;
- (e) monitor and advise the executive and legislative authorities at all levels of government in BiH, and liaise with the authorities and political parties in BiH;
- (f) ensure the implementation of the Union's efforts in the whole range of activities in the field of the rule of law and the security sector reform, promote overall Union coordination of, and give local political direction to, Union efforts in tackling organised crime, corruption and terrorism and, in that context, provide the HR and the Commission with assessments and advice as necessary;
- (g) provide support for a reinforced and more effective interface between criminal justice and the police in BiH, as well as for initiatives which aim to strengthen the efficiency and impartiality of the judicial institutions, in particular the Structured Dialogue on Justice;
- (h) without prejudice to the military chain of command, offer the EU Force Commander political guidance on military issues with a local political dimension, in particular concerning sensitive operations, and on relations with local authorities and with the local media; consult with the EU Force Commander before taking political action that may have an impact on the security situation and coordinate regarding coherent messages to local authorities and other international organisations; contribute to the consultations on the Strategic Review of EUFOR/ALTHEA;
- (i) coordinate and implement the Union's communication efforts on Union issues towards the public in BiH;
- (j) promote the process of Union integration through targeted public diplomacy and Union outreach activities designed to ensure a broader understanding and support among the BiH public on Union-related matters, including by means of engagement of local civil society actors;
- (k) contribute to the development and consolidation of respect for human rights and fundamental freedoms in BiH, in accordance with the EU human rights policy and EU Guidelines on Human Rights;
- (l) engage with relevant BiH authorities with regard to their full cooperation with the International Residual Mechanism for Criminal Tribunals;
- (m) in line with the Union integration process, advise, assist, facilitate and monitor political dialogue on the necessary constitutional and relevant legislative changes;
- (n) maintain close contacts and close consultations with the UN High Representative in BiH and other relevant international organisations working in the country; in that context, inform the Council about discussions on the ground regarding the international presence in the country, including the Office of the UN High Representative in BiH;
- (o) provide advice to the HR as necessary concerning natural or legal persons on whom restrictive measures could be imposed in view of the situation in BiH;
- (p) without prejudice to the applicable chains of command, help to ensure that all Union instruments in the field are applied coherently to attain the Union's policy objectives.

*Article 4***Implementation of the mandate**

1. The EUSR shall be responsible for the implementation of the mandate, acting under the authority of the HR.

2. The PSC shall maintain a privileged link with the EUSR and shall be the EUSR's primary point of contact with the Council. The PSC shall provide the EUSR with strategic guidance and political direction within the framework of the mandate, without prejudice to the powers of the HR.
3. The EUSR shall work in close coordination with the European External Action Service (EEAS) and the relevant departments thereof.

Article 5

Financing

1. The financial reference amount intended to cover the expenditure related to the EUSR's mandate for the period from 1 September 2019 to 31 August 2021 shall be EUR 13 700 000.
2. The expenditure shall be managed in accordance with the procedures and rules applicable to the general budget of the Union. Participation of natural and legal persons in the award of procurement contracts by the EUSR shall be open without limitations. Furthermore, no rule of origin for the goods purchased by the EUSR shall apply.
3. The management of the expenditure shall be subject to a contract between the EUSR and the Commission. The EUSR shall be accountable to the Commission for all expenditure.

Article 6

Constitution and composition of the team

1. Within the limits of the EUSR's mandate and the corresponding financial means made available, the EUSR shall be responsible for constituting a team. The team shall include the expertise on specific policy issues as required by the mandate. The EUSR shall keep the Council and the Commission promptly informed of the composition of the team.
2. Member States, institutions of the Union and the EEAS may propose the secondment of staff to work with the EUSR. The salary of such seconded personnel shall be covered by the Member State, the institution of the Union concerned or the EEAS, respectively. Experts seconded by Member States to the institutions of the Union or the EEAS may also be posted to work with the EUSR. International contracted staff shall have the nationality of a Member State.
3. All seconded personnel shall remain under the administrative authority of the sending Member State, the sending institution of the Union or the EEAS and shall carry out their duties and act in the interest of the EUSR's mandate.

Article 7

Privileges and immunities of the EUSR and the EUSR's staff

The privileges, immunities and further guarantees necessary for the completion and smooth functioning of the EUSR's mission and the members of the EUSR's staff shall be agreed with the host parties, as appropriate. Member States and the EEAS shall grant all necessary support to such effect.

Article 8

Security of EU classified information

The EUSR and the members of the EUSR's team shall respect the security principles and minimum standards established by Council Decision 2013/488/EU ⁽²⁾.

Article 9

Access to information and logistical support

1. Member States, the Commission and the General Secretariat of the Council shall ensure that the EUSR is given access to any relevant information.
2. The Union delegation and/or Member States, as appropriate, shall provide logistical support in the region.

⁽²⁾ Council Decision 2013/488/EU of 23 September 2013 on the security rules for protecting EU classified information (OJ L 274, 15.10.2013, p. 1).

*Article 10***Security**

In accordance with the Union's policy on the security of personnel deployed outside the Union in an operational capacity under Title V of the Treaty, the EUSR shall take all reasonably practicable measures, in accordance with the EUSR's mandate and the security situation in the area of responsibility, for the security of all personnel under the EUSR's direct authority, in particular by:

- (a) establishing a specific security plan based on guidance from the EEAS, including specific physical, organisational and procedural security measures, governing the management of the secure movement of personnel to, and within, the area of responsibility, as well as management of security incidents and providing for a contingency and evacuation plan;
- (b) ensuring that all personnel deployed outside the Union are covered by high-risk insurance, as required by the conditions in the area of responsibility;
- (c) ensuring that all members of the EUSR's team to be deployed outside the Union, including locally contracted personnel, have received appropriate security training before or upon arriving in the area of responsibility, based on the risk ratings assigned to that area by the EEAS;
- (d) ensuring that all agreed recommendations made following regular security assessments are implemented and providing the Council, the HR and the Commission with written reports on their implementation and on other security issues within the framework of the progress report and the report on the implementation of the mandate.

*Article 11***Reporting**

The EUSR shall regularly provide the HR and the PSC with reports. The EUSR shall also report to Council working parties as necessary. Regular reports shall be circulated through the COREU network. The EUSR may provide the Foreign Affairs Council with reports. In accordance with Article 36 of the Treaty, the EUSR may be involved in briefing the European Parliament.

*Article 12***Coordination**

1. The EUSR shall contribute to the unity, consistency and effectiveness of the Union's action and shall help ensure that all Union instruments and Member States' actions are engaged consistently, to attain the Union's policy objectives. The activities of the EUSR shall be coordinated with those of the Commission, as well as those of other EUSRs active in the region, as appropriate. The EUSR shall provide regular briefings to Member States' missions and Union delegations.
2. In the field, close liaison shall be maintained with the Heads of Union delegations in the region and Member States' Heads of Mission. They shall make every effort to assist the EUSR in the implementation of the mandate. The EUSR shall also liaise with international and regional actors in the field, and in particular maintain close coordination with the UN High Representative in BiH.
3. In support of Union crisis management operations, the EUSR, with other Union actors present in the field, shall improve the dissemination and sharing of information by those Union actors with a view to achieving a high degree of common situation awareness and assessment.

*Article 13***Assistance in relation to claims**

The EUSR and the EUSR's staff shall assist in providing elements to respond to any claims and obligations arising from the mandates of the previous EUSRs in BiH, and shall provide administrative assistance and access to relevant files for such purposes.

*Article 14***Review**

The implementation of this Decision and its consistency with other contributions from the Union to the region shall be kept under regular review. Every year the EUSR shall present the Council, the HR and the Commission with a progress report by the end of October and a comprehensive mandate implementation report by the end of May.

*Article 15***Entry into force**

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

It shall apply from 1 September 2019.

Done at Brussels, 8 August 2019.

For the Council
The President
T. TUPPURAINEN

COUNCIL DECISION (CFSP) 2019/1341**of 8 August 2019****updating the list of persons, groups and entities subject to Articles 2, 3 and 4 of Common Position 2001/931/CFSP on the application of specific measures to combat terrorism, and repealing Decision (CFSP) 2019/25**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 29 thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

- (1) On 27 December 2001, the Council adopted Common Position 2001/931/CFSP ⁽¹⁾.
- (2) On 8 January 2019, the Council adopted Decision (CFSP) 2019/25 ⁽²⁾ updating the list of persons, groups and entities subject to Articles 2, 3 and 4 of Common Position 2001/931/CFSP ('the list').
- (3) In accordance with Article 1(6) of Common Position 2001/931/CFSP, it is necessary to review at regular intervals the names of persons, groups and entities in the list to ensure that there are grounds for keeping them thereon.
- (4) This Decision sets out the result of the review that the Council has carried out in respect of persons, groups and entities to which Articles 2, 3 and 4 of Common Position 2001/931/CFSP apply.
- (5) The Council has verified that competent authorities, as referred to in Article 1(4) of Common Position 2001/931/CFSP, have taken decisions with regard to all persons, groups and entities on the list to the effect that they have been involved in terrorist acts within the meaning of Article 1(2) and (3) of Common Position 2001/931/CFSP. The Council has also concluded that the persons, groups and entities to which Articles 2, 3 and 4 of Common Position 2001/931/CFSP apply should continue to be subject to the specific restrictive measures provided for therein.
- (6) The list should be updated accordingly and Decision (CFSP) 2019/25 should be repealed,

HAS ADOPTED THIS DECISION:

Article 1

The list of persons, groups and entities to which Articles 2, 3 and 4 of Common Position 2001/931/CFSP apply is set out in the Annex to this Decision.

Article 2

Decision (CFSP) 2019/25 is hereby repealed.

⁽¹⁾ Council Common Position 2001/931/CFSP of 27 December 2001 on the application of specific measures to combat terrorism (OJ L 344, 28.12.2001, p. 93).

⁽²⁾ Council Decision (CFSP) 2019/25 of 8 January 2019 amending and updating the list of persons, groups and entities subject to Articles 2, 3 and 4 of Common Position 2001/931/CFSP on the application of specific measures to combat terrorism, and repealing Decision (CFSP) 2018/1084 (OJ L 6, 9.1.2019, p. 6).

Article 3

This Decision shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 8 August 2019.

For the Council
The President
T. TUPPURAINEN

ANNEX

LIST OF PERSONS, GROUPS AND ENTITIES REFERRED TO IN ARTICLE 1

I. PERSONS

1. ABDOLLAHI Hamed (a.k.a. Mustafa Abdullahi), born 11.8.1960 in Iran. Passport: D9004878.
2. AL-NASSER, Abdelkarim Hussein Mohamed, born in Al Ihsa (Saudi Arabia), citizen of Saudi Arabia.
3. AL YACIOUB, Ibrahim Salih Mohammed, born 16.10.1966 in Tarut (Saudi Arabia), citizen of Saudi Arabia.
4. ARBABSAR Manssor (a.k.a. Mansour Arbabsar), born 6.3.1955 or 15.3.1955 in Iran. Iranian and US national. Passport: C2002515 (Iran); Passport: 477845448 (USA). National ID no.: 07442833, expiry date 15.3.2016 (USA driving licence).
5. ASADI Assadollah, born 22.12.1971 in Teheran (Iran), Iranian national. Iranian diplomatic passport number: D9016657.
6. BOUYERI, Mohammed (a.k.a. Abu ZUBAIR, a.k.a. SOBIAR, a.k.a. Abu ZOUBAIR), born 8.3.1978 in Amsterdam (The Netherlands).
7. EL HAJJ, Hassan Hassan, born 22.3.1988 in Zaghdraya, Sidon, Lebanon, Canadian citizen. Passport number: JX446643 (Canada).
8. HASHEMI MOGHADAM Saeid, born 6.8.1962 in Teheran (Iran), Iranian national. Passport number: D9016290, valid until 4.2.2019.
9. IZZ-AL-DIN, Hasan (a.k.a. GARBAYA, Ahmed, a.k.a. SA-ID, a.k.a. SALWWAN, Samir), Lebanon, born 1963 in Lebanon, citizen of Lebanon.
10. MELIAD, Farah, born 5.11.1980 in Sydney (Australia), Australian citizen. Passport number: M2719127 (Australia).
11. MOHAMMED, Khalid Shaikh (a.k.a. ALI, Salem, a.k.a. BIN KHALID, Fahd Bin Adballah, a.k.a. HENIN, Ashraf Refaat Nabith, a.k.a. WADOOD, Khalid Abdul), born 14.4.1965 or 1.3.1964 in Pakistan, passport No 488555.
12. ŞANLI, Dalokay (a.k.a. Sinan), born 13.10.1976 in Pülümür (Turkey).
13. SHAHLAI Abdul Reza (a.k.a. Abdol Reza Shala'i, a.k.a. Abd-al Reza Shalai, a.k.a. Abdorreza Shahlai, a.k.a. Abdolreza Shahla'i, a.k.a. Abdul-Reza Shahlaee, a.k.a. Hajj Yusef, a.k.a. Haji Yusif, a.k.a. Hajji Yasir, a.k.a. Hajji Yusif, a.k.a. Yusuf Abu-al-Karkh), born circa 1957 in Iran. Addresses: (1) Kermanshah, Iran, (2) Mehran Military Base, Ilam Province, Iran.
14. SHAKURI Ali Gholam, born circa 1965 in Tehran, Iran.
15. SOLEIMANI Qasem (a.k.a. Ghasem Soleymani, a.k.a. Qasmi Sulayman, a.k.a. Qasem Soleymani, a.k.a. Qasem Solaimani, a.k.a. Qasem Salimani, a.k.a. Qasem Solemani, a.k.a. Qasem Sulaimani, a.k.a. Qasem Sulemani), born 11.3.1957 in Iran. Iranian national, Passport: 008827 (Iran Diplomatic), issued 1999. Title: Major General.

II. GROUPS AND ENTITIES

1. 'Abu Nidal Organisation' — 'ANO' (a.k.a. 'Fatah Revolutionary Council', a.k.a. 'Arab Revolutionary Brigades', a.k.a. 'Black September', a.k.a. 'Revolutionary Organisation of Socialist Muslims').
2. 'Al-Aqsa Martyrs' Brigade'.
3. 'Al-Aqsa e.V'.
4. 'Babbar Khalsa'.
5. 'Communist Party of the Philippines', including 'New People's Army' — 'NPA', Philippines.
6. 'Directorate for Internal Security of the Iranian Ministry for Intelligence and Security'.

7. 'Gama'a al-Islamiyya' (a.k.a. 'Al-Gama'a al-Islamiyya') ('Islamic Group' — 'IG').
 8. 'İslami Büyük Doğu Akıncılar Cephesi' — 'IBDA-C' ('Great Islamic Eastern Warriors Front').
 9. 'Hamas', including 'Hamas-Izz al-Din al-Qassem'.
 10. 'Hizballah Military Wing' (a.k.a. 'Hezbollah Military Wing', a.k.a. 'Hizbullah Military Wing', a.k.a. 'Hizbollah Military Wing', a.k.a. 'Hezbollah Military Wing', a.k.a. 'Hisbollah Military Wing', a.k.a. 'Hizbu'llah Military Wing' a.k.a. 'Hizb Allah Military Wing', a.k.a. 'Jihad Council' (and all units reporting to it, including the External Security Organisation)).
 11. 'Hizbul Mujahideen' — 'HM'.
 12. 'Khalistan Zindabad Force' — 'KZF'.
 13. 'Kurdistan Workers' Party' — 'PKK', (a.k.a. 'KADEK', a.k.a. 'KONGRA-GEL').
 14. 'Liberation Tigers of Tamil Eelam' — 'LTTE'.
 15. 'Ejército de Liberación Nacional' ('National Liberation Army').
 16. 'Palestinian Islamic Jihad' — 'PIJ'.
 17. 'Popular Front for the Liberation of Palestine' — 'PFLP'.
 18. 'Popular Front for the Liberation of Palestine — General Command' (a.k.a. 'PFLP — General Command').
 19. 'Devrimci Halk Kurtuluş Partisi-Cephesi' — 'DHKP/C' (a.k.a. 'Devrimci Sol' ('Revolutionary Left'), a.k.a. 'Dev Sol') ('Revolutionary People's Liberation Army/Front/Party').
 20. 'Sendero Luminoso' — 'SL' ('Shining Path').
 21. 'Teyrbazen Azadiya Kurdistan' — 'TAK' (a.k.a. 'Kurdistan Freedom Falcons', a.k.a. 'Kurdistan Freedom Hawks').
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RULES OF PROCEDURE

DECISION OF THE MANAGEMENT BOARD OF THE EUROPEAN MEDICINES AGENCY

of 12 June 2019

on internal rules concerning restrictions of certain rights of data subjects in relation to processing of personal data in the framework of the functioning of the Agency

THE MANAGEMENT BOARD OF THE EUROPEAN MEDICINES AGENCY,

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

Having regard to Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC ⁽¹⁾, and in particular Article 25 thereof,

Having regard to Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 ⁽²⁾,

Having regard to the Staff Regulations of Officials of the European Union, in particular Article 2(3) and Article 30 of Annex IX thereto, and the Conditions of Employment of Other Servants of the European Union,

Having regard to EMA implementing rules on the conduct of administrative enquiries and disciplinary procedures of 8 June 2012 ⁽³⁾,

Having regard to the EDPS Guidance issued on 18 December 2018 and to the notification to the EDPS for the purposes of Article 41(2) of Regulation (EU) 2018/1725,

After consulting the Staff Committee,

Whereas:

- (1) The European Medicines Agency ('EMA' or 'the Agency') was set up by Regulation (EC) No 726/2004 of the European Parliament and of the Council ⁽⁴⁾ for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products;
- (2) The Agency conducts administrative inquiries and disciplinary proceedings in line with the rules laid down in the Staff Regulations of Officials of the European Union, and the Conditions of Employment of Other Servants of the European Union, the Agency may also carry out preliminary activities related to cases of potential irregularities reported to OLAF (according to Regulation (EU, Euratom) No 883/2013), process whistleblowing cases, process (formal and informal) procedures of harassment, process internal and external complaints, conduct internal audits, carry out investigations by the Data Protection Officer in line with Article 45(2) of Regulation (EU) 2018/1725 and (IT) security investigations handled internally or with external involvement (e.g. CERT-EU);
- (3) The Agency processes several categories of personal data, such as identification data, contact data, professional data. The European Medicines Agency represented by its Executive Director is responsible as data controller. Internally, the Head of Administration and Corporate Management Division has been appointed to act by delegation as data controller for the activities concerned by this Decision (for the purpose hereof, hereinafter

⁽¹⁾ OJ L 295, 21.11.2018, p. 39.

⁽²⁾ OJ L 248, 18.9.2013, p. 1.

⁽³⁾ Doc. ref. 7.20/08.

⁽⁴⁾ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, (OJ L 136, 30.4.2004, p. 1).

referred as 'Controller'). If the administrative enquiry or disciplinary proceedings concerns the Head of Administration and Corporate Management Division, the Deputy Executive Director shall be the Controller for that the relevant enquiry or proceedings. The personal data are stored in an electronic file and in paper form. The paper file is stored in a locked cupboard which is only accessible to staff members authorised by senior management. The electronic files are stored in a secure electronic environment which is designed and maintained to prevent accidental or unlawful destruction, loss, alteration, transfer, unauthorised disclosure of, or access to, personal data to internal and external partners who are not authorised to have access to such data;

- (4) The personal data processed are retained in accordance with Article 13 of the EMA implementing rules on the conduct of administrative enquiries and disciplinary procedures of 8 June 2012, as explained in Article 2(3) of this Decision;
- (5) This Decision on internal rules should apply to all processing operations carried out by the Agency in the performance of its administrative inquiries and disciplinary proceedings, as well as in the performance of preliminary activities related to cases of potential irregularities reported to OLAF, process whistleblowing cases, process (formal and informal) procedures of harassment, process internal and external complaints, conduct internal audits, carry out investigations by the Data Protection Officer in line with Article 45(2) of Regulation (EU) 2018/1725 and (IT) security investigations handled internally or with external involvement (e.g. CERT-EU). This Decision should apply to processing operations carried out prior to the opening of the procedures referred to above, during these procedures and during the monitoring of the follow-up to the outcome of these procedures.
- (6) This Decision on internal rules should also apply to activities linked to assistance and cooperation provided by the Agency outside of its administrative enquiries to other Union institutions, bodies, offices and agencies, competent authorities of the Member States and international organisations to protect their processing operations; as well as to activities related to cooperation with, and the transmission of information regarding an administrative enquiry or disciplinary proceedings to, EU institutions and bodies. To that effect, the Agency should consult those institutions, bodies, offices, agencies, authorities or organisations on the relevant grounds for imposing restrictions and on the necessity and proportionality of the restrictions;
- (7) The Agency has to give justifications explaining why the restrictions are strictly necessary and proportionate in a democratic society and respect the essence of the fundamental rights and freedoms;
- (8) Within this framework the Agency is bound to respect, to the maximum extent possible, the fundamental rights of the data subjects during the above procedures, in particular but not limited to those relating to the right of access and rectification, right to erasure, as enshrined in Regulation (EU) 2018/1725;
- (9) However, the Agency may be obliged to defer the information to data subject and other data subject's rights in order to protect, in particular, its own investigations and procedures, the investigations and proceedings of other public authorities, as well as the rights of other persons related to its investigations and procedures;
- (10) The Agency may thus defer the information for the purposes to protect its administrative inquiries and disciplinary proceedings, the investigations and proceedings of other public authorities as well as to protect the identity of informants and other persons involved in the procedures, including whistle-blowers and witnesses who should not suffer negative repercussions in relation to their cooperation. In particular, Article 5(3) of the EMA implementing rules on the conduct of administrative enquiries and disciplinary procedures of 8 June 2012 provides for an obligation to inform any staff member who may personally be involved in an investigation, provided that such notification does not hinder the inquiry. This constitutes a restriction of the application of data subjects' rights, in particular Articles 14 to 21, 35 and 36 of Regulation (EU) 2018/1725. Therefore, in accordance with Article 25 of the same Regulation, internal rules shall be laid down to ensure that such a restriction respects the essence of the fundamental rights and freedoms and is a necessary and proportionate measure in a democratic society;
- (11) Pursuant to Article 25(8) of Regulation (EU) 2018/1725, the Controller may defer or refrain from providing information on the reasons for the application of a restriction to the data subject, if the notification would in any way compromise the purpose of the restriction. In order to ensure that the data subject's right to be informed in accordance with Articles 16 and 35 of Regulation (EU) 2018/1725 is restricted only as long as the reasons for the deferral last, the Agency should regularly review its position.
- (12) Where a restriction of other data subjects' rights is applied, the Controller should assess on a case-by-case basis whether the communication of the restriction would compromise its purpose;

- (13) In accordance with the principle of proportionality, the Agency should monitor regularly (about every six months) that the conditions which justify a particular restriction still exist. Accordingly, the Agency should lift the restriction when the conditions that justify the restriction no longer apply;
- (14) The Agency should consult the Data Protection Officer (the 'DPO') at the moment of deferral of information or when other restriction of data subjects' right is applied, as well as on the occasion of the assessment of the conditions as to whether the restriction is still justified,

HAS ADOPTED THIS DECISION:

Article 1

Subject matter and scope

1. This Decision lays down rules relating to the conditions under which the Agency in the framework of administrative inquiries and disciplinary proceedings, when notifying cases to OLAF according to Regulation (EU, Euratom) No 883/2013, may restrict, pursuant to Article 25 of the Regulation (EU) 2018/1725, the application of the rights enshrined in Articles 14 to 21, 35 and 36, as well as Article 4 in so far as its provisions correspond to the rights and obligations provided for in Articles 14 to 21.

2. This Decision applies to the processing operations of personal data by the Agency for the purpose of conducting administrative inquiries and disciplinary proceedings, as well as to carry out preliminary activities related to cases of potential irregularities reported to OLAF (according to Regulation (EU, Euratom) No 883/2013), process whistleblowing cases, process (formal and informal) procedures of harassment, process internal and external complaints, conduct internal audits, carry out investigations by the Data Protection Officer in line with Article 45(2) of Regulation (EU) 2018/1725 and (IT) security investigations handled internally or with external involvement (e.g. CERT-EU).

This Decision should also apply to the Agency's activities of assistance and cooperation provided by the Agency outside of its administrative enquiries to other Union institutions, bodies, offices and agencies, competent authorities of the Member States and international organisations to protect their processing operations.

In addition, this decision applies to activities related to cooperation with, and the transmission of information regarding an administrative enquiry or disciplinary proceedings to, EU institutions and bodies, when such information is necessary for the recipient to evaluate the grounds for opening formal investigation or proceedings.

3. The Agency processes several categories of personal data, such as identification data, contact data, professional data. The categories of data concerned can be hard data (for example, administrative details, telephone, private address, electronic communications, and traffic data) and/or soft data (for example appraisal reports, opening of inquiries, reports on preliminary investigations, records/minutes of witness' statements and investigation hearings, social activities and behaviour of staff members, comments on the abilities and efficiency of the concerned staff member(s) etc.)

4. The categories of data subjects who may be subject to this Decision are staff and former staff of the Agency, i.e. (former) agents, officers/administrators, seconded national experts and trainees, as well as (former) contractors of the Agency.

5. Subject to the conditions set out in this Decision, the restrictions may apply to the following rights: provision of information and communication of a personal data breach to the data subjects in accordance with Articles 16 and 35 of Regulation (EU) 2018/1725; right of access by data subject in accordance with Article 17 of Regulation (EU) 2018/1725; right of rectification, erasure, restriction of processing and notification of rectification or erasure in accordance with Articles 18, 19(1), 20 and 21 of Regulation (EU) 2018/1725.

Article 2

Specification of the controllers and safeguards

1. The European Medicines Agency represented by its Executive Director is responsible as data controller. Internally, the Head of Administration and Corporate Management Division has been appointed to act by delegation as Controller for the activities concerned by this Decision. If the administrative enquiry or disciplinary proceedings concerns the Head of Administration and Corporate Management Division, the Deputy Executive Director shall be the Controller for that the relevant enquiry or proceedings.

2. The personal data are stored in an electronic file and/or in paper form. The safeguards in place to avoid personal data breaches, leakages or unauthorised disclosure are the following:
 - (a) The paper file is stored in a locked cupboard which is only accessible to authorised staff members on a need-to-know basis. The security system of the premises, internal record management policies, staff training and audits are also in place to ensure proper safeguards.
 - (b) The electronic files are stored in a secure electronic environment which is designed and maintained to prevent accidental or unlawful destruction, loss, alteration, transfer, unauthorised disclosure of, or access to, personal data to internal and external partners who are not authorised to have access to such data
 - (c) The strict rules of confidentiality and professional secrecy applicable to the appointed investigators and/or to anyone who is otherwise involved in the administrative enquiry or disciplinary proceedings as required in the EMA implementing rules on the conduct of administrative enquiries and disciplinary procedures of 8 June 2012, as well as in the Staff Regulations and CEOS, ensure a high level of protection against the risks to the rights and freedoms of data subjects involved by the processing.
 - (d) In accordance with the principle of data minimisation, the Agency will only collect and process personal data that are adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed. Additional safeguards apply where special categories of data are processed, as well as where personal data relating to criminal convictions and offences or related security measures are processed.
3. The storage and retention periods applicable are the following:
 - (a) According to Article 13 of the EMA implementing rules on the conduct of administrative enquiries and disciplinary procedures of 8 June 2012, where no charge is made against the staff member or where a charge is made but no disciplinary action was taken, the paper and electronic file of administrative inquiry proceedings, as well as the copy in the personal file of the initial notification to the staff member according to Article 5 of the same Implementing Rules, are held for 5 years after the date of the decision that no charge or disciplinary action is needed. This provision is not applicable to the decision inserted in the staff member's personal file upon his/her request in accordance with Article 1(3) of Annex IX of the Staff Regulations and Article 5(5) of the EMA implementing rules on the conduct of administrative enquiries and disciplinary procedures of 8 June 2012. Such decision is only removed from the personal file upon the request of the staff member concerned.
 - (b) Where a charge is made against the staff member, paper and electronic files as well as the copy in the personal file of the initial notification to the staff member are retained for 10 years after the date of the decision of disciplinary action. In exceptional cases, where it is in the interest of the Agency to retain the administrative inquiry file following the expiry of the 10 years, a reasoned decision shall be issued six months before the expiry of the 10-year period, and it shall be communicated to the staff member concerned. The reasoned decision shall state the further period for which the administrative inquiry file shall be retained. In such cases, the notification in the staff member's personal file is also retained.
4. The risk to the rights and freedoms of the data subject may entail risks to the right to respect the confidentiality of his/her private communications, to the right to freedom of expression and information and to the right of defence and to be heard. These risks will be balanced against the grounds and purposes justifying the application of the restrictions provided in this Decision. This balancing operation shall be duly documented and be performed on the basis of a case-by-case analysis to ensure that a restriction is only applied where necessary and in a proportionate way, as well as in accordance with the rules set out in this Decision.

Article 3

Restrictions

1. Pursuant to Article 25(1) of Regulation (EU) 2018/1725 any restriction shall only be applied to safeguard:
 - (a) the prevention, investigation, detection and prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security;
 - (b) other important objectives of general public interest of the Union or of a Member State, in particular an important interest of the Union or of a Member State, including public health and social security;

- (c) the internal security of Union institutions and bodies, including of their electronic communications networks;
- (d) the prevention, investigation, detection and prosecution of breaches of ethics for regulated professions;
- (e) a monitoring, inspection or regulatory function connected, even occasionally, to the exercise of official authority in the cases referred to in points (a) to (c).
- (f) the protection of the data subject, or the rights and freedoms of others.

2. As a specific application of the purposes described in paragraph 1 above, the Agency may apply restrictions in relation to personal data exchanged with Commission services or other Union institutions, bodies, agencies and offices, competent authorities of Member States or third countries or international organisations, in the following circumstances:

- (a) where the exercise of those rights and obligations could be restricted by Commission services or other Union institutions, bodies, agencies and offices on the basis of other acts provided for in Article 25 of Regulation (EU) 2018/1725 or in accordance with Chapter IX of that Regulation or with the founding acts of other Union institutions, bodies, agencies and offices;
- (b) where the exercise of those rights and obligations could be restricted by competent authorities of Member States on the basis of acts referred to in Article 23 of Regulation (EU) 2016/679 of the European Parliament and of the Council ⁽⁵⁾, or under national measures transposing Articles 13(3), 15(3) or 16(3) of Directive (EU) 2016/680 of the European Parliament and of the Council ⁽⁶⁾;
- (c) where the exercise of those rights and obligations could jeopardise the Agency's cooperation with third countries or international organisations in the conduct of its tasks.

Before applying restrictions in the circumstances referred to in points (a) and (b) of the first subparagraph, the Agency shall consult the relevant Commission services, Union institutions, bodies, agencies, offices or the competent authorities of Member States unless it is clear to the Agency that the application of a restriction is provided for by one of the acts referred to in those points.

3. Any restriction shall be as necessary and proportionate in a democratic society and respect the essence of the fundamental rights and freedoms.

4. A necessity and proportionality test shall be carried out based on the present rules. It shall be documented through an internal assessment note for accountability purposes on a case-by-case basis.

5. Restrictions shall be duly monitored, and a periodical revision shall be done every six months at the latest to assess that the conditions which justify a particular restriction still exist.

6. Restrictions shall be lifted as soon as the conditions that justify them no longer apply, for example where the exercise of the data subjects' rights (e.g. providing information about the data processing and access to the file) would no longer jeopardise the purpose of the concerned investigation or procedure.

Article 4

Information to the Data Protection Officer and review

1. The Controller (on behalf of the Agency) shall, without undue delay, inform the Agency's DPO whenever it restricts the application of data subjects' rights in accordance with this Decision and shall provide access to the records and the documentation of the assessment of the necessity and proportionality of the restriction (including any documents containing underlying factual and legal elements). This requirement applies to any subsequent reviews of the restriction as well.

2. The DPO may request the Controller, in writing, to review the application of the restrictions. The Agency shall inform the DPO, in writing, about the outcome of the requested review.

3. The exchanges of information with the DPO throughout the procedure shall be recorded and documented in writing.

⁽⁵⁾ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

⁽⁶⁾ Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (OJ L 119, 4.5.2016, p. 89).

*Article 5***Restriction of the provision of information to the data subjects**

1. The Agency shall include in the privacy statement related to administrative enquiries and disciplinary procedure and published on its intranet the information relating to the potential restriction of these rights. The information shall cover which rights may be restricted, the reasons for this restriction and the potential duration.
2. Additionally, the Agency shall inform individually data subjects on their rights concerning present or future restrictions, without undue delay and in a written form, and without prejudice to the following paragraphs.
3. Where the Agency restricts, wholly or partly, the provision of information to the data subjects in accordance with this Decision, it shall record the reasons for the restriction, including an assessment of the necessity and proportionality of the restriction. To that end, the record shall state how the provision of the information would jeopardise the purpose of the concerned investigation or procedure, or would adversely affect the rights and freedoms of others. The record and, where applicable, the documents containing underlying factual and legal elements shall be registered. They shall be made available to the European Data Protection Supervisor on request.
4. The restriction referred to in paragraph 3 shall continue to apply as long as the reasons justifying it remain applicable. When the reasons for the restriction no longer apply, the Agency shall provide the information concerned and the reasons for the restriction to the data subject. The data subjects may submit any queries to the DPO.
5. At the same time, the Agency shall inform the data subject of the possibility of lodging a complaint with the European Data Protection Supervisor at any time or of seeking a judicial remedy before the Court of Justice of the European Union.
6. The Agency shall review the application of the restriction every six months from its adoption and at the end of the procedure.

*Article 6***Restriction of right of access by the data subjects**

1. Where data subjects request access to their personal data processed in the context of one or more specific cases or to a particular processing operation, in accordance with Article 17 of Regulation (EU) 2018/1725, the Agency shall limit its assessment of the request to such personal data only.
2. Where the Agency restricts, wholly or partly, the right of access, referred to in Article 17 of Regulation (EU) 2018/1725, it shall take the following steps:
 - (a) it shall inform the data subject concerned, in its reply to the request, of the restriction applied and of the principal reasons thereof to the extent that it would not jeopardise the purpose of the investigation or proceedings concerned, and of the possibility of lodging a complaint with the European Data Protection Supervisor or of seeking a judicial remedy before the Court of Justice of the European Union;
 - (b) it shall record the reasons for the restriction, including an assessment of the necessity and proportionality of the restriction; to that end, the record shall state how providing access would jeopardise the purpose of the concerned investigation or procedure, or would adversely affect the rights and freedoms of others.

The provision of information referred to in point (a) may be deferred, omitted or denied in accordance with Article 25(8) of Regulation (EU) 2018/1725.

3. The record referred to in point (b) of paragraph 2 and, where applicable, the documents containing underlying factual and legal elements shall be registered. They shall be made available to the European Data Protection Supervisor on request. Article 25(7) of Regulation (EU) 2018/1725 shall apply.

*Article 7***Restriction of right of rectification, erasure and restriction of processing**

Where the Agency restricts, wholly or partly, the application of the right to rectification, erasure or restriction of processing, referred to in Articles 18, 19(1), 20(1), and 21 of Regulation (EU) 2018/1725, it shall take the steps set out in Article 6(2) of this Decision and register the record in accordance with Article 6(3) thereof.

*Article 8***Restriction of communication of a personal data breach to the data subjects and confidentiality of electronic communications**

1. Where the Agency restricts the communication of a personal data breach to the data subject, referred to in Article 35 of Regulation (EU) 2018/1725, it shall record and register the reasons for the restriction in accordance with Article 5(3)-(6) of this Decision.
2. Where the Agency restricts the right to the confidentiality of electronic communications of a data subject, referred to in Article 36 of Regulation (EU) 2018/1725, it shall record and register the reasons for the restriction in accordance with Article 5(3)-(6) of this Decision.

*Article 9***Entry into force**

This Decision shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

Done at Amsterdam, 12 June 2019.

Christa WIRTHUMER-HOCHE
Chair of the EMA Management Board

