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Contents

[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.

[1] Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COUNCIL IMPLEMENTING REGULATION (EU) 2021/1241

of 29 July 2021

implementing Article 21(2) of Regulation (EU) 2016/44 concerning restrictive measures in view of the situation in Libya and repealing Regulation (EU) No 204/2011

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Regulation (EU) 2016/44 of 18 January 2016 concerning restrictive measures in view of the situation in Libya and repealing Regulation (EU) No 204/2011 [1], and in particular Article 21(2) thereof,

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

Whereas:

(1) On 18 January 2016 the Council adopted Regulation (EU) 2016/44.

(2) Pursuant to Article 21(6) of Regulation (EU) 2016/44, the Council has reviewed the list of designated persons and entities set out in Annex III to that Regulation.

(3) The Council has concluded that the entry for one person should be deleted, as he is deceased, and that the restrictive measures against all other persons and entities in the list set out in Annex III to Regulation (EU) 2016/44 should be maintained. In addition, the identifying information for one person should be updated.

(4) Regulation (EU) 2016/44 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex III to Regulation (EU) 2016/44 is amended in accordance with the Annex to this Regulation.

Article 2

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

[1] OJ L 12, 19.1.2016, p. 1.

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

Done at Brussels, 29 July 2021.

For the Council
The President
G. DOVŽAN

ANNEX

In Annex III (List of natural and legal persons, entities or bodies referred to in Article 6(2)) to Regulation (EU) 2016/44, Part A (Persons) is amended as follows:

(1) entry 3 (concerning TOHAMI, General Khaled) is deleted;

(2) entry 6 (concerning AL-MAHMOUDI, Baghdadi) is replaced by the following:

'6.	AL-MAHMOUDI, Baghdadi a.k.a. AL-MAHMOUDI Al-Baghdadi, Ali AL-MAHMOUDI AL-BAGHDADI, Ali	Place of birth: Alassa, Libya Nationality: Libya Gender: male Address: Abu Dhabi, United Arab Emirates	Prime Minister of Colonel Qadhafi's Government. Closely associated with the former regime of Muammar Qadhafi.	21.3.2011'

COUNCIL IMPLEMENTING REGULATION (EU) 2021/1242

of 29 July 2021

implementing Regulation (EU) No 267/2012 concerning restrictive measures against Iran

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Regulation (EU) No 267/2012 of 23 March 2012 concerning restrictive measures against Iran and repealing Regulation (EU) No 961/2010 ([1]), and in particular Article 46(2) thereof,

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

Whereas:

(1) On 23 March 2012, the Council adopted Regulation (EU) No 267/2012.

(2) On 18 June 2020, the Council adopted Regulation (EU) 2020/847 ([2]), implementing Regulation (EU) No 267/2012.

(3) Following the judgment of the General Court in Case T-580/19 ([3]), Sayed Shamsuddin Borborudi should be removed from the list of persons and entities subject to restrictive measures set out in Annex IX to Regulation (EU) No 267/2012.

(4) Moreover, on the basis of a review of Annex II to Council Decision 2010/413/CFSP ([4]), the restrictive measures against all persons and entities in the list set out therein should be maintained, in so far as their names are not mentioned in Annex VI to that Decision, and 21 entries included in Annex IX to Regulation (EU) No 267/2012 should be updated.

(5) Regulation (EU) No 267/2012 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex IX to Regulation (EU) No 267/2012 is amended as set out in the Annex to this Regulation.

Article 2

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

([1]) OJ L 88, 24.3.2012, p. 1.
([2]) Council Implementing Regulation (EU) 2020/847 of 18 June 2020 implementing Regulation (EU) No 267/2012 concerning restrictive measures against Iran (OJ L 196, 19.6.2020, p. 1).
([3]) Judgment of the General Court of 9 June 2021, *Sayed Shamsuddin Borborudi* v *Council of the European Union*, T-580/19, ECLI:EU:T:2021:330.
([4]) Council Decision 2010/413/CFSP of 26 July 2010 concerning restrictive measures against Iran and repealing Common Position 2007/140/CFSP (OJ L 195, 27.7.2010, p. 39).

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

Done at Brussels, 29 July 2021.

For the Council
The President
G. DOVŽAN

ANNEX

Annex IX to Regulation (EU) No 267/2012 is amended as follows:

(1) under the heading 'I. Persons and entities involved in nuclear or ballistic missile activities and persons and entities providing support to the Government of Iran.', under the subheading 'A. Persons', the following entry is deleted: '25. Sayed Shamsuddin Borborudi'.

(2) under the heading 'I. Persons and entities involved in nuclear or ballistic missile activities and persons and entities providing support to the Government of Iran.', the following entries replace the corresponding entries in the list set out under the subheading 'A. Persons':

	Name	Identifying information	Reasons	Date of listing
'8.	Ebrahim MAHMUDZADEH		Former Managing Director of Iran Electronic Industries (see Part B, No 20). Director general of the Armed Forces Social Security Organization until September 2020. Iranian Deputy Defense Minister until December 2020.	23.6.2008
13.	Anis NACCACHE		Former administrator of Barzagani Tejarat Tavanmad Saccal companies; his company has attempted to procure sensitive goods for entities designated under Resolution 1737 (2006).	23.6.2008
16.	Rear Admiral Mohammad SHAFI'I RUDSARI (a.k.a. ROODSARI, Mohammad, Hossein, Shafiei; ROODSARI, Mohammad, Shafi'I; ROODSARI, Mohammad, Shafiei; RUDSARI, Mohammad, Hossein, Shafiei; RUDSARI, Mohammad, Shafi'I; RUDSARI, Mohammad, Shafiei)		Former MODAFL Deputy for Coordination (see Part B, n°29).	23.6.2008
17.	Abdollah SOLAT SANA (a.k.a. Solatsana Solat Sanna; Sowlat Senna; Sovlat Thana)		Managing Director of the Uranium Conversion Facility (UCF) in Esfahan. This is the facility that produces the feed material (UF6) for the enrichment facilities at Natanz. On 27 August 2006, Solat Sana received a special award from President Ahmadinejad for his role.	23.4.2007
23.	Davoud BABAEI		The current head of security for the Ministry Of Defence Armed Forces Logistics' research institute the Organisation of Defensive Innovation and Research (SPND), which was run by UN-designated Mohsen Fakhrizadeh-Mahabadi. The IAEA have identified SPND with their concerns over possible military dimensions to Iran's nuclear programme over which Iran refuses to co-operate. As head of security, Babaei is responsible for preventing the disclosure of information, including to the IAEA.	1.12.2011

	Name	Identifying information	Reasons	Date of listing
29.	Milad JAFARI (Milad JAFERI)	DOB: 20.9.1974	An Iranian national supplying goods, mostly metals, to UN designated SHIG front companies. Delivered goods to SHIG between January and November 2010. Payments for some of the goods were made at the central branch of EU-designated Export Development Bank of Iran (EDBI) in Tehran after November 2010.	1.12.2011'

(3) under the heading 'I. Persons and entities involved in nuclear or ballistic missile activities and persons and entities providing support to the Government of Iran.', the following entries replace the corresponding entries in the list set out under the subheading 'B. Entities':

	Name	Identifying information	Reasons	Date of listing
'2.	Armed Forces Geographical Organisation		A subsidiary of MODAFL assessed to provide geospatial data for the Ballistic Missile programme.	23.6.2008
20.	Iran Electronics Industries (including all branches) and subsidiaries:	P. O. Box 18575-365, Tehran, Iran	Wholly-owned subsidiary of MODAFL (and therefore a sister-organisation to AIO, AvIO and DIO). Its role is to manufacture electronic components for Iranian weapons systems.	23.6.2008
	(b) Iran Communications Industries (ICI) (a.k.a. Sanaye Mokhaberat Iran; Iran Communication Industries; Iran Communications Industries Group; Iran Communications Industries Co.)	PO Box 19295-4731, Pasdaran Avenue, Tehran, Iran; Alternative address: PO Box 19575-131, 34 Apadana Avenue, Tehran, Iran; Alternative address: Shahid Langary Street, Nobonyad Square Ave, Pasdaran, Tehran	Iran Communications Industries, a subsidiary of Iran Electronics Industries (listed by the EU), produces various items including communication systems, avionics, optics and electro-optics devices, micro-electronics, information technology, test and measurement, telecommunication security, electronic warfare, radar tube manufacture and refurbishment, and missile launchers.	26.7.2010
28.	Mechanic Industries Group (a.k.a.: Mechanic Industries Organisation; Mechanical Industries Complex; Mechanical Industries Group; Sanaye Mechanic)		Took part in the production of components for the ballistics programme.	23.6.2008
37.	Schiller Novin (a.k.a.: Schiler Novin Co.; Schiller Novin Co.; Shiller Novin)	Gheytariyeh Avenue - no 153 - 3rd Floor - PO BOX 17665/153 6 19389 Tehran	Acting on behalf of Defense Industries Organisation (DIO).	26.7.2010

	Name	Identifying information	Reasons	Date of listing
38.	Shahid Ahmad Kazemi Industrial Group (SAKIG)		Entity subordinate to Iran's Aerospace Industries Organisation (AIO). SAKIG develops and produces surface-to-air missiles systems for Iran's military. It maintains military, missile, and air defense projects and procures goods from Russia, Belarus, and North Korea.	26.7.2010
40.	State Purchasing Organisation (SPO, a.k.a. State Purchasing Office; State Purchasing Organization)		The SPO appears to facilitate the import of whole weapons. It appears to be a subsidiary of MODAFL.	23.6.2008
52.	Raad Iran (a.k.a. Raad Automation Company; Middle East Raad Automation; RAAD Automation Co.; Raad Iran Automation Co.; RAADIRAN, Middle East RAAD Automation Co.; Automasion RAAD Khavar Mianeh; Automation Raad Khavar Mianeh Nabbet Co)	Unit 1, No 35, Bouali Sina Sharghi, Chehel Sotoun Street, Fatemi Square, Tehran	A company involved in procurement of inverters for Iran's proscribed enrichment programme. Raad Iran was established to produce and design controlling systems and provides the sale and installation of inverters and programmable Logic Controllers.	23.5.2011
86.	Karanir (a.k.a Karanir Sanat, Moaser; Tajhiz Sanat)	1139/1 Unit 104 Gol Building, Gol Alley, North Side of Sae, Vali Asr Avenue. PO Box 19395-6439, Tehran	Involved in purchasing equipment and materials, which have direct applications in the Iranian nuclear programme.	1.12.2011
95.	Samen Industries (a.k.a. Khorasan Metallurgy Industries)	2nd km of Khalaj Road End of Seyyedi St., P.O. Box 91735-549, 91735 Mashhad, Iran, Tel.: +98 511 3853008, +98 511 3870225	Shell name for UN-designated Khorasan Metallurgy Industries, subsidiary of Ammunition Industries Group (AMIG).	1.12.2011
99.	TABA (Iran Cutting Tools Manufacturing company - Taba Towlid Abzar Boreshi Iran; a.k.a. Iran Centrifuge Technology Co.; Iran's Centrifuge Technology Company; Sherkate Technology Centrifuge Iran, TESA, TSA)	12 Ferdowsi, Avenue Sakhaee, avenue 30 Tir (sud), nr 66 – Tehran	Owned or controlled by EU-sanctioned TESA, Involved in manufacturing equipment and materials, which have direct applications in the Iranian nuclear programme.	1.12.2011

	Name	Identifying information	Reasons	Date of listing
153.	Organisation of Defensive Innovation and Research (SPND)		The Organisation of Defensive Innovation and Research (SPND) directly supports Iran's proliferation sensitive nuclear activities. The IAEA has identified SPND with their concerns over possible military dimensions (PMD) to Iran's nuclear programme. SPND was run by UN-designated Mohsen Fakhrizadeh-Mahabadi and is part of the Ministry of Defence For Armed Forces Logistics (MODAFL) designated by the EU.	22.12.2012
161.	Sharif University of Technology	Last address known: Azadi Ave/Street, PO Box 11365-11155, Tehran, Iran, Tel. +98 21 66 161 Email: info@sharif.ir	Sharif University of Technology (SUT) has a number of cooperation agreements with Iranian Government organisations which are designated by the UN and/or the EU and which operate in military or military-related fields, particularly in the field of ballistic missile production and procurement. This includes: an agreement with the EU-designated Aerospace Industries Organisation for, inter alia, the production of satellites; cooperating with the Iranian Ministry of Defence and the Iranian Revolutionary Guards Corps (IRGC) on smart boat competitions; a broader agreement with the IRGC Air Force which covers developing and strengthening the University's relations, organisational and strategic cooperation. Taken together, these show a significant record of engagement with the Government of Iran in military or military-related fields that constitutes support to the Government of Iran.	8.11.2014'

(4) under the heading 'II. Iranian Revolutionary Guard Corps.', the following entries replace the corresponding entries in the list set out under the subheading 'A. Persons':

	Name	Identifying information	Reasons	Date of listing
'2.	Rear Admiral Ali FADAVI		Deputy Chief of the Islamic Revolutionary Guard Corps (IRGC). Former Commander of IRGC Navy.	26.7.2010
6.	IRGC Mohammad Ali JAFARI		Former Commander of the IRGC. Currently head of the Hazrat Baqiatollah al-Azam Cultural and Social Headquarters.	23.6.2008'

(5) under the heading 'II. Iranian Revolutionary Guard Corps.', the following entry replaces the corresponding entry in the list set out under the subheading 'B. Entities':

	Name	Identifying information	Reasons	Date of listing
'12.	Etemad Amin Invest Co Mobin (a.k.a.: Etemad Amin Investment Company Mobin; Etemad-e Mobin, Etemad Amin Invest Company Mobin; Etemad Mobin Co.; Etemad Mobin Trust Co.; Etemade Mobin Company; Mobin Trust Consortium; Etemad-e Mobin Consortium)	Pasadaran Av. Tehran, Iran	A company owned or controlled by IRGC that contributes to financing the strategic interests of the regime.	26.7.2010'.

COMMISSION DELEGATED REGULATION (EU) 2021/1243

of 19 April 2021

supplementing Regulation (EU) 2019/2144 of the European Parliament and of the Council by laying down detailed rules concerning the alcohol interlock installation facilitation in motor vehicles and amending Annex II to that Regulation

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/2144 of the European Parliament and of the Council of 27 November 2019 on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users, amending Regulation (EU) 2018/858 of the European Parliament and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No 672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 ([1]), and in particular Article 4(6) and Article 6(6) thereof,

Whereas:

(1) Article 6 of Regulation (EU) 2019/2144 requires motor vehicles of categories M and N to be equipped with certain advanced vehicle systems, including alcohol interlock installation facilitation. It lays down in its Annex II basic requirements for the type-approval of motor vehicles with regard to the alcohol interlock installation facilitation in those vehicles.

(2) The alcohol interlocks enhance traffic safety by preventing persons with alcohol concentrations in their bodies exceeding a set limit value from driving a motor vehicle.

(3) Detailed rules are necessary concerning the specific requirements for the approval of vehicles with regard to alcohol interlock installation facilitation.

(4) The European Standard EN 50436 series specifies test methods and essential performance requirements for alcohol interlocks and gives guidance for authorities, decision makers, purchasers and users. Standards in that series also include specific provisions related to motor vehicles to facilitate the installation of alcohol interlocks.

(5) Alcohol interlocks are mostly intended for aftermarket installation. For this purpose, they are connected to the electric and control circuits of the vehicle. Such installation should not interfere with the proper performance or maintenance of the vehicle, should not impair the safety and security of the vehicle, but should also be as straightforward as possible for specialised and trained installers.

(6) It is therefore necessary to require vehicle manufacturers to make available on their websites a document with clear instructions for installation of the alcohol interlocks ('installation document') in order to allow the technicians to properly install an alcohol interlock in a certain vehicle model.

([1]) OJ L 325, 16.12.2019, p. 1.

(7) As some of the information contained in the installation document may relate to security-related vehicle repair and maintenance information services, it should only be available to the independent operators that are authorised by accredited entities in accordance with Appendix 3 of Annex X to Regulation (EU) 2018/858 of the European Parliament and of the Council ([2]).

(8) The table containing the list of requirements in Annex II to Regulation (EU) 2019/2144 does not contain any reference to regulatory acts as regards alcohol interlock installation facilitation. It is therefore necessary to introduce a reference to this Regulation in that Annex.

(9) Regulation (EU) 2019/2144 should therefore be amended accordingly.

(10) As Regulation (EU) 2019/2144 is to apply from 6 July 2022, this Regulation should apply from the same date,

HAS ADOPTED THIS REGULATION:

Article 1

Requirements for alcohol interlock installation facilitation

The type-approval of motor vehicles with regard to alcohol interlock installation facilitation shall be subject to the requirements set out in Annex I.

Article 2

Amendment to Regulation (EU) 2019/2144

Annex II to Regulation (EU) 2019/2144 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force and application

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

It shall apply from 6 July 2022.

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

Done at Brussels, 19 April 2021.

For the Commission
The President
Ursula VON DER LEYEN

([2]) Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1).

ANNEX I

Technical requirements

1. Alcohol interlock installation facilitation shall allow the fitting or retrofitting of an alcohol interlock complying with European Standards EN 50436-1:2014 or EN 50436-2:2014+A1:2015.

2. The vehicle system as regards alcohol interlock installation facilitation in each motor vehicle of categories M and N shall conform to the relevant vehicle model as laid down in the alcohol interlock installation document ('installation document'), conforming to European Standard EN 50436-7:2016. For this purpose, the installation document shall cover at least one of the options in EN 50436-7:2016 Annex C 3a, 3b or 3c. The vehicle manufacturer may provide the installation document conforming to later revisions of the European Standard, in agreement with the approval authority and the technical service.

3. Installation document

3.1. The installation document shall contain a detailed description, diagrams and images explaining the installation of an alcohol interlock, covering any of the following sets of information:

(a) the information regarding battery feed, ground, vehicle ready and start enabler;

(b) the information regarding battery feed, ground, vehicle ready and start-allowing or start-prohibiting input and output line, and an optional detection of propulsion capability (e.g. engine run) or vehicle moving signal line; or

(c) the information regarding battery feed, ground and a data bus connection.

3.2. Any additional software, hardware or procedures necessary to allow the installation of an alcohol interlock in a standard vehicle shall be identified and indicated in the installation document.

3.3. The alcohol interlock shall be in the blocking state normally. The blocking state of the alcohol interlock shall be achieved by either an open output relay, a corresponding output signal or the corresponding digital bus message. The closure of this relay or the change of the blocking output signal into the non-blocking output signal or the transmission of the corresponding non-blocking data bus message shall occur when an accepted breath sample with an alcohol concentration below the pre-set limit has been delivered.

3.4. An installed alcohol interlock shall only intervene in the engine starting process or in allowing the vehicle to move under its own power upon the activation of the vehicle master control switch and the alcohol interlock shall not influence a running engine or a moving vehicle.

4. Access to alcohol interlock facilitation information

4.1. Vehicle manufacturers shall put in place the necessary arrangements and procedures to ensure that vehicle alcohol interlock facilitation information, in the form of relevant details of the standardised installation document, is accessible in accordance with Annex X of Regulation (EU) 2018/858. As some of the information may relate to security-related vehicle repair and maintenance information services, access to the alcohol interlock facilitation information is restricted to independent operators that comply with the procedure laid down in Appendix 3 of that Annex.

5. The vehicle manufacturer shall annex to the information document a declaration made out using the template set out in the Appendix to this Annex.

Appendix

Manufacturer's declaration

(Manufacturer):

……

(Address of the manufacturer):

……

Certifies that

It provides access to the *alcohol interlock installation document* in compliance with Article 1 of Commission Delegated Regulation (EU) 2021/1243 ([1]) for the following vehicle make and type: …

The principal website address(es), where the alcohol interlock installation document may be accessed, is (are) listed in Annex A to this declaration. The contact details of the responsible manufacturer's representative who has signed this declaration are set out in Annex B to this declaration.

Done at …[Place]

On …[Date]

[Signature] [Position][]

Annex A: website address(es)

Annex B: contact details

([1]) Commission Delegated Regulation (EU) 2021/1243 of 19 April 2021 supplementing Regulation (EU) 2019/2144 of the European Parliament and of the Council by laying down detailed rules concerning the alcohol interlock installation facilitation in motor vehicles and amending Annex II to that Regulation (OJ L 272 p. 11).

ANNEX II

Amendment to Regulation (EU) 2019/2144

In Annex II to Regulation (EU) 2019/2144 the row for requirement E1 is replaced by the following:

'E1 Alcohol interlock installation facilitation	Commission Delegated Regulation (EU) 2021/1243 (*)		B	B	B	B	B	B						

(*) Commission Delegated Regulation (EU) 2021/1243 of 19 April 2021 supplementing Regulation (EU) 2019/2144 of the European Parliament and of the Council by laying down detailed rules concerning the alcohol interlock installation facilitation in motor vehicles and amending Annex II to that Regulation (OJ L 272, p. 11).'

COMMISSION DELEGATED REGULATION (EU) 2021/1244

of 20 May 2021

amending Annex X to Regulation (EU) 2018/858 of the European Parliament and of the Council as regards the standardised access to vehicle on-board diagnostics information and repair and maintenance information, and the requirements and procedures for access to vehicle security information

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC ([1]), and in particular Article 61(11) thereof,

Whereas:

(1) Article 61(2) of Regulation (EU) 2018/858 requires vehicle manufacturers to make vehicle on-board diagnostics (OBD) information and vehicle repair and maintenance information (RMI) available on their own websites. There are, however, no harmonised criteria as to the manner in which that information is to be made available, which requires independent operators to adapt to numerous and different Web services and terminology.

(2) The Report from the Commission to the European Parliament and the Council of 9 December 2016 ([2]) on the operation of the system of access to vehicle repair and maintenance information concluded that by standardising those websites and the corresponding terminology the burden on independent operators could be alleviated.

(3) Since access to vehicle OBD information and vehicle RMI should be possible regardless of the type of powertrain of a vehicle, it is necessary to clarify that such access is not only compulsory for emission related requirements.

(4) On 15 September 2014, the European Committee for Standardisation (CEN) published Parts 1 to 5 of standard EN ISO 18541 'Road vehicles – Standardized access to automotive repair and maintenance information (RMI)'. Those parts aim at facilitating the exchange between manufacturers and independent operators of vehicle OBD information and vehicle RMI by establishing the technical requirements and procedures for facilitating access to that information. It is therefore appropriate to refer in Annex X to Regulation (EU) 2018/858 to the requirements of Parts 1 to 5 of standard EN ISO 18541-2014.

(5) Given that vehicle OBD information and vehicle RMI include information which is important for ensuring the security of the vehicle, access to certain vehicle security features should only be provided to independent operators complying with the requirements laid down in this Annex.

(6) According to the recommendations of the Forum on Access to Vehicle Information, referred to in Article 66(1) of Regulation (EU) 2018/858, those requirements should include the approval of the independent operators concerned and the authorisation of their employees engaged in the relevant activities by accredited entities. It is therefore necessary to lay down the procedure for the approval and authorisation of independent operators to access vehicle security features, which should be based on the 'Scheme for accreditation, approval and authorization to Access Security-related Repair and Maintenance Information (RMI)', which was validated on 19 May 2016 by the European cooperation for Accreditation. It is also necessary to assess whether such operators are not involved in illegitimate business activities.

([1]) OJ L 151, 14.6.2018, p. 1.

([2]) Report from the Commission to the European Parliament and the Council on the operation of the system of access to vehicle repair and maintenance information established by Regulation (EC) No 715/2007 on type approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information, COM(2016) 0782 final.

(7) In addition, it is necessary to lay down the role and responsibilities of the bodies involved in the approval and authorisation of independent operators and their employees to be granted access to security-related vehicle repair and maintenance information.

(8) In order to enable Member States and national authorities as well as economic operators to prepare for the application of the new rules introduced by this Regulation, the date of application should be deferred.

(9) Annex X to Regulation (EU) 2018/858 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex X to Regulation (EU) 2018/858 is amended in accordance with the Annex to this Regulation.

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*.

It shall apply from 30 July 2023.

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

Done at Brussels, 20 May 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annex X to Regulation (EU) 2018/858 is amended as follows:

(1) point 2.1 is replaced by the following:

'2.1. A manufacturer shall put in place the necessary arrangements and procedures, in accordance with Article 61(2), second subparagraph, first sentence, to ensure that vehicle OBD information and vehicle repair and maintenance information is accessible through websites. Compliance with the obligation for manufacturers to provide OBD information and vehicle repair and maintenance information on their websites through a standardised format shall be presumed by conforming to Part 1 'General information and use case definition', Part 2 'Technical requirements', Part 3 'Functional user interface requirements' of standard EN ISO 18541 – 2014, Part 4 'Conformance test' of standard EN ISO 18541 – 2015 and Part 5 'Heavy duty specific provision' 'Road vehicles – Standardized access to automotive repair and maintenance information (RMI)' of standard EN ISO 18541 – 2018. Access to vehicle OBD information and vehicle repair and maintenance information shall be granted in a readily accessible and prompt manner.';

(2) point 2.5.2 is replaced by the following:

'2.5.2. service handbooks, including service and maintenance records, and technical specifications references regarding fluids including on lubricants, brake fluids and cooling liquids;';

(3) in point 2.9, the first paragraph is replaced by the following:

'For the purpose of vehicle OBD, diagnostics, repair and maintenance, monitoring and inspection, the direct vehicle data stream, including fault codes and diagnostic functions, shall be made available through the serial data port on the standardised data link connector specified in paragraph 6.5.1.4 and in accordance with the specifications set out in section 6.5.3 of Appendix 1 of Annex 11 to Regulation No 83 of the Economic Commission for Europe of the United Nations (UN/ECE) (*) and in accordance with paragraph 4.7.3 of Annex 9B and the reference standard documents set out in Appendix 6 to that Annex to Regulation No 49 of the Economic Commission for Europe of the United Nations (UN/ECE) (**).

(*) Regulation No 83 of the Economic Commission for Europe of the United Nations (UN/ECE) – Uniform provisions concerning the approval of vehicles with regard to the emission of pollutants according to engine fuel requirements (OJ L 42, 15.2.2012, p. 1).

(**) Regulation No 49 of the Economic Commission for Europe of the United Nations (UN/ECE) – Uniform provisions concerning the measures to be taken against the emission of gaseous and particulate pollutants from compression-ignition engines for use in vehicles, and the emission of gaseous pollutants from positive-ignition engines fuelled with natural gas or liquefied petroleum gas for use in vehicles (OJ L 180, 8.7.2011, p. 53).';

(4) in point 6.1, the first paragraph is replaced by the following:

'Compliance with the obligation for manufacturers to provide OBD information and vehicle repair and maintenance information on their websites through a standardised format shall be presumed by conforming with the Parts of standard EN ISO 18541 referred to in point 2.1.';

(5) point 6.2 is replaced by the following:

'Access to vehicle security features shall be made available to independent operators under protection of security technology in accordance with the following requirements:';

(6) point 6.3 is amended as follows:

(a) the first sentence is replaced by the following:

'The procedure for the approval and authorisation of independent operators to access vehicle security features as referred to in point 6.2 is set out in Appendix 3. The role and responsibilities of the bodies involved in the accreditation, approval and authorisation of independent operators are detailed through functional requirements consisting of examples and use cases laid down in Commission Notice.';

(b) the following paragraph is added:

'For the purposes of that procedure, operators shall not be considered to pursue a legitimate business activity where they advertise or offer repair or maintenance operations that would negatively impact the emissions performance of the vehicle. This shall include:

(a) deactivating or removing pollution control devices or emission control systems, or degrading their performance or concealing their malfunction;

(b) installing defeat devices (*), or defeat strategies (**);

(c) deactivating, removing or tampering with devices for the monitoring of the consumption of fuel or electric energy, or tampering with odometer readings;

(d) tampering with the engine control unit, including the rated engine power.

_____

(*) As defined in Article 3(10) of Regulation (EC) No 715/2007.
(**) As defined in Article 3(8) of Regulation (EC) No 595/2009.';

(7) the following Appendix 3 is added:

'***Appendix 3***

Procedure for the approval and authorisation of independent operators to access vehicle security features (*)

1. Scope

This Appendix contains the requirements for the purposes of approval and authorisation of independent operators requiring access to security-related vehicle repair and maintenance information (RMI).

It specifies in detail the process and the bodies required to approve and authorise independent operators to be granted access to security-related vehicle repair and maintenance information for light passenger and commercial vehicles and heavy duty vehicles.

2. Definitions and abbreviated terms

2.1. Definitions

For the purposes of this Appendix, the following definitions shall apply:

2.1.1. 'Accreditation'

'accreditation' shall mean accreditation as defined in Article 2, point 10 of Regulation (EC) No 765/2008

2.1.2. 'IO employee'

'IO employee' shall mean the employee of an approved independent operator (IO) who, upon authorisation from his or her conformity assessment body (CAB), will have access to security-related RMI

2.1.3. 'Security-related repair and maintenance information' or 'security-related RMI'

'security-related repair and maintenance information' or 'security-related RMI' shall mean the information, software, functions and services required to repair and maintain the features that are included in a vehicle by the manufacturer to prevent the vehicle from being stolen or driven away and to enable the vehicle to be tracked and recovered.

2.1.4. 'Approval inspection certificate'

'approval inspection certificate' shall mean the certificate issued by the CAB to IOs complying with the approval criteria set out in this Appendix and which confirms that those IOs are approved and that IO employees can request the authorisation to access security-related RMI.

2.1.5. 'Authorisation inspection certificate'

'authorisation inspection certificate' shall mean the certificate issued by the CAB to IO employees complying with the authorisation criteria set out in this Appendix and which confirms that those employees are authorised to access security-related RMI on the website of a vehicle manufacturer.

2.1.6. 'Trust centre' or 'TC'

'trust centre' or 'TC' shall mean the body designated by SERMI and approved by the Commission and that is responsible for:

(a) managing the digital certificates and authorisation status of the IO employees and for providing to the CAB the necessary security tokens and digital certificates for authorised IO employees;

(b) providing a vehicle manufacturer with information regarding the authorisation status of an IO employee.

2.1.7. 'Security token'

'security token' shall mean a device that allows a secure authentication of an IO.

2.1.8. 'Digital certificate'

'digital certificate' shall mean a digital certificate which requires a digital signature of the issuing trust centre to bind a public key to the identity of the IO employee in accordance with the standard ISO 9594.

2.1.9. 'Authorisation database'

'authorisation database' shall mean a database held by the trust centre and which contains the authorisation details of the anonymised authorised IO employees and the registration of approved IOs.

2.1.10. 'Certification database'

'certification database' shall mean a database held by the trust centre to manage the digital certificate validity and the identifiers of authorised IO employees.

2.1.11. 'European cooperation for Accreditation' or 'EA'

'European cooperation for Accreditation' or 'EA' shall mean the body recognised by the Commission in accordance with Article 14 of Regulation (EC) No 765/2008 and which is responsible for the development, maintenance and implementation of accreditation in the Union.

2.1.12. 'Forum for Access to Security-Related Vehicle RMI' or 'SERMI'

The 'Forum for Access to Security-Related Vehicle RMI' or 'SERMI' means the entity that is in charge of coordinating and advising the Commission on the implementation of the procedures of accreditation, approval and authorisation for the purpose of accessing security-related RMI.

2.1.13. 'Relevant authorities'

'relevant authorities' shall mean those public authorities that have a legal mandate to act in the area of vehicle security crime protection, investigation and prosecution.

3. Accreditation of CABs, approval of IOs and authorisation of IO employees

Only CABs that are accredited by the national accreditation body ('NAB'), as defined in Article 2, point 11 of Regulation (EC) No 765/2008, of the Member State in which they are established shall issue approval inspection certificates certifying that an IO has been approved and authorisation inspection certificates certifying that an IO employee is to access security-related RMI.

The approval of the IO and the authorisation of the IO employee shall be granted for a period of 60 months starting from the date of issuance of the relevant inspection certificates.

IOs wishing to receive security-related RMI shall obtain an approval inspection certificate from a CAB accredited by the NAB of the Member State where the IO is established.

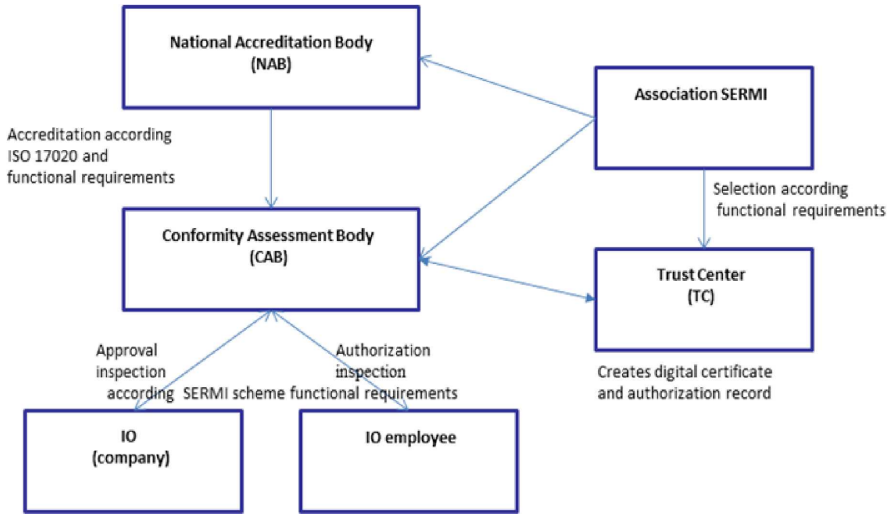
IO employees who are to handle security-related RMI shall obtain an authorisation inspection certificate from a CAB accredited by the NAB of the Member State where the IO employee resides.

CABs shall inform TCs of any approval inspection certificates or authorisation inspection certificates issued, upon which TCs shall create an authorisation record and issue a security token and a digital certificate containing details that allow IO employees to be uniquely identifiable to the vehicle manufacturer RMI website. CABs shall provide individual IO employees with a security token and the digital certificate.

Vehicle manufacturers may demand a fee for the registration of IO employees on those vehicle manufacturers' RMI websites and for access to security-related RMI. Such fee shall be proportionate to the cost for such registration and provision of access. The fees due shall be specified on the vehicle manufacturers' RMI websites. All digital data transfers between IOs, TCs and CABs shall be carried out via business to business (B2B) transactions using secure protocols and in a timely manner.

Figure 1

The bodies involved in the accreditation of CABs, approval of IOs and authorisation of IO employees and their relationship



A declaration that certifies that the IO pursues a legitimate business activity as referred to in point 6.3 of this Annex shall be signed by the IO requesting to be authorised by the CAB. An IO shall only be approved after an inspection by the CAB that shall verify that this declaration has been signed and that shall assess whether the IO and its individual employees comply with the requirements laid down in this Appendix.

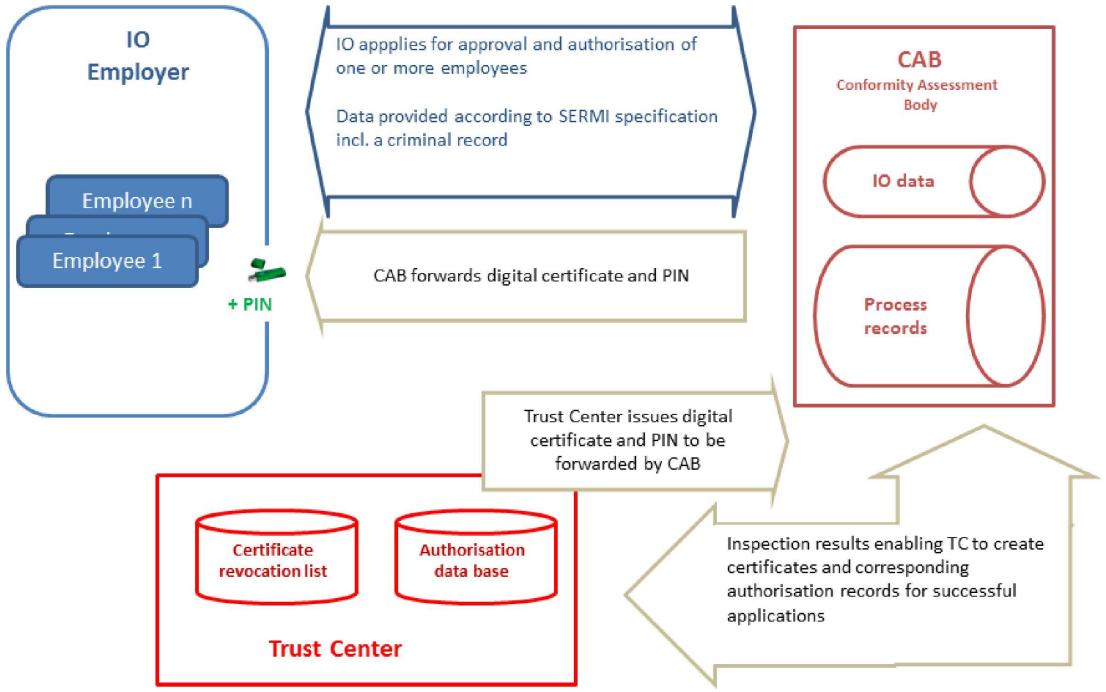
Individual IO employees shall only be authorised after an inspection by a CAB. CABs shall check the documents submitted and shall verify whether the IO employee concerned made a previous request for authorisation that has been rejected by the CAB concerned or any other CAB at Union level.

CABs shall send all data to the TC that are necessary for the TC to produce the digital certificate and the security token, which the CAB shall send to the IO employees..

IO employees that have been authorised shall receive from their CABs the PIN associated with the digital certificate.

Figure 2

IO approval and IO employee authorisation process



3.1. Overview of the access to security-related RMI

Vehicle manufacturers shall provide access to security-related RMI through their RMI website, provided that the IO employees are authorised and are able to produce the authorisation inspection certificate, and that the IO on whose behalf the IO employees are working has an approval inspection certificate.

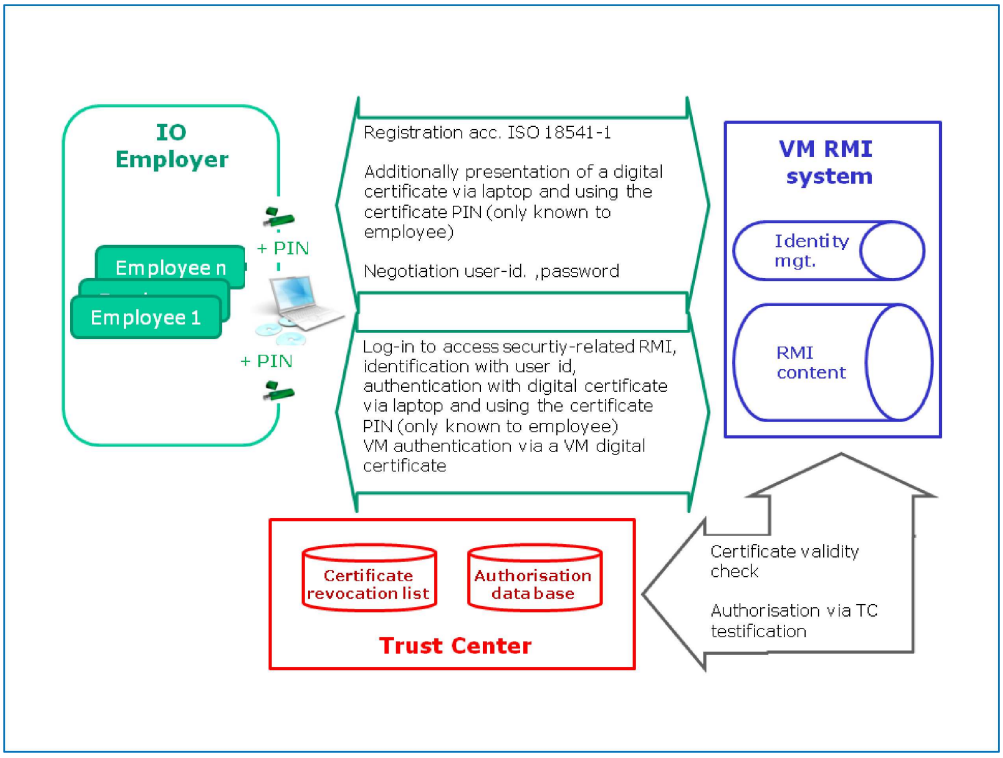
Manufacturers may offer access to an on-line ordering facility for security-related parts using a specialised application linked to the RMI website to authorised IO employees that work for approved IOs.

Upon receipt of a request for access to an RMI website, the vehicle manufacturers' websites shall require identification through the IO employee unique identifier and request authentication. Authentication of IO employees shall be carried out exclusively using digital certificates. Upon receipt of a digital certificate, vehicle manufacturer RMI websites shall verify the IO employee unique identifier and the current status of the digital certificate and authorisation, by communicating with the TC identified in the digital certificate.

All digital data transfers between IOs, vehicle manufacturers, TCs and CABs shall be carried out via business to business (B2B) transactions, using secure protocols and in a timely manner. Once the IO employee unique identifier and authorisation status of the IO employee have been verified, access to the required security-related RMI shall be provided by the vehicle manufacturer through its website.

Figure 3

Access to security-related RMI



4. Detailed rules concerning access to security-related RMI

4.1. The role of SERMI

4.1.1. Responsibilities and obligations

SERMI shall monitor the implementation of the accreditation process across the Member States and inform the Commission accordingly. SERMI shall advise the Commission on requests for changes to the accreditation process.

(a) SERMI shall advise the Commission on requests for changes to the accreditation process. SERMI shall monitor the implementation of the accreditation process across the Member States and inform the Commission accordingly;

(b) SERMI shall consult the Commission on the creation of the TC selection criteria;

(c) SERMI shall advise the Commission on the introduction of technical implementation guidelines for interaction between the entities involved in the process;

(d) SERMI shall follow the EA's rules on scheme ownership;

(e) the members of the SERMI shall be represented by the stakeholders engaged in the process of accreditation, approval and authorisation for the purpose of accessing security-related RMI.

4.1.2. Trust centre selection

The TC shall be selected by SERMI and be notified to the Commission for approval.

Selected TC shall comply with standard ETSI TS 319 411-3, fulfil the requirements on electronic signatures laid down in Regulation (EU) No 910/2014 of the European Parliament and of the Council (**) and the requirements laid down in point 4.6 of this Appendix.

In addition, the TC shall:

— have the technical and managerial competence, and the financial viability and experience relevant to the accreditation process;

— have key personnel that has the skills, experience and availability necessary for the accreditation process;

— be able to operate across Member States;

— have in place a quality assurance process at operational level.

4.2. The role of NABs

The NAB shall be responsible for the accreditation of CABs for the purposes of approving IOs and authorising IO employees for access to security-related RMI.

4.2.1. Responsibilities and requirements

The responsibilities and requirements of the NAB are set out in Articles 8 to 12 of Regulation (EC) No 765/2008.

4.2.2. Criteria for CAB accreditation

CABs shall be accredited as type A inspection bodies in accordance with ISO/IEC 17020:2012. CABs shall comply with the requirements concerning the highest level of independence.

Additionally, the NAB shall assess CABs' capability to comply with the requirements laid down in points 4.3.1 to 4.3.4.

The personnel in charge of IO inspections shall have a level of knowledge in the automotive vehicle repair and maintenance business and of the automotive aftermarket specifics that is appropriate for the tasks they are performing.

4.3. The role of CABs

The CAB shall be responsible for the inspection of IOs and their respective IO employees and for issuing approval and authorisation inspection certificates in accordance with this Appendix, and for revoking such certificates.

4.3.1. Responsibilities and requirements

(a) CABs shall keep the data submitted for the approval of an IO;

(b) CABs shall establish a secure communication channel with the TC and provide the inspection results to the TC in order to issue the security token with a digital certificate;

(c) CABs shall notify IO employees 6 months before their authorisation expires;

(d) CABs shall maintain a database containing data submitted for the authorisation of IO employees;

(e) CABs that refuse to approve an IO or authorise an IO employee shall communicate the inspection results concerning that IO or that employee to the TC;

(f) CABs shall only collect and use data required for the approval or authorisation process;

(g) CABs shall keep all data relating to IO and IO employees confidential and shall ensure that only authorised employees have access to such data;

(h) CABs shall provide once a year statistics on the number of approval and authorisations issued and also on the number of refusals to SERMI and the Commission;

(i) CABs shall retain secure records of approval and authorisation inspections for a period of 5 years;

(j) CABs shall inform all other CABs in the Member State in which it is established about negative inspection results of an IO;

(k) IOs and IO employees that have received a negative inspection result may provide the CAB with additional information correcting minor deficiencies within 15 working days from receiving the negative inspection result. CABs shall accordingly determine whether the inspection result is to be changed;

(l) CABs shall notify IOs 6 months before their approval expires;

(m) CABs shall make random und unannounced on-site inspections of IOs within the 60 months approval validity period, and subject each approved IO to at least one random, on-site inspection over the 60 months approval validity period;

(n) On the basis of a complaint against an approved IO or an authorised IO employee, CABs shall check that the concerned IO or IO employee are in compliance with the criteria against which they were respectively approved or authorised. The CAB shall determine during its investigation whether an on-site inspection is required;

(o) For the purposes of on-site inspections, CABs may request the assistance of market surveillance authorities from the Member State they are established;

(p) CABs shall revoke IO approvals and IO employee authorisations where they no longer comply with the criteria against which they were respectively approved or authorised. CABs shall accordingly request the TC to suspend and repeal digital certificate of the concerned IO employees.

4.3.2. Renewal of the approval

CABs shall, upon request by an IO or 6 months prior to the expiry of validity of the approval, make an on-site inspection, and in case of a positive inspection result, renew the approval.

CABs shall issue a new approval inspection certificate for IO that fulfils the approval criteria.

CABs shall assess applications for renewals of authorisations and issue an authorisation inspection certificate to IO employees fulfilling the authorisation criteria.

4.3.3. Criteria for IO approval by the CAB

Before approving an IO and during any on-site inspection during the approval validity period, CABs shall check the following:

(a) documented ownership of IO, name of managing director;

(b) the list provided by the IO of employees to be authorised;

(c) information about the responsibility and the function of employees referred to in point (a);

(d) whether the IO has a liability insurance with a minimum amount of coverage of 1 million Euro for bodily injury and 0,5 million Euro for property damage;

(e) whether the approval of the IO has been revoked for reasons of misuse;

(f) whether the IO has provided proof of activity in the automotive area;

(g) whether the declaration certifying that the IO pursues a legitimate business activity as referred to in point 6.3 has been signed by the IO and during an on-site inspection whether the IO effectively conducts a legitimate business activity;

(h) whether the IO or the IO employees have a clean criminal record;

(i) whether there is declaration signed by the IO legal representative that compliance with the procedural requirements laid down in point 4.3.4 is ensured for all operations related to vehicle security.

4.3.4. Criteria for IO employee authorisation by the CAB

Before authorising an employee as an IO employee, and during any on-site inspection during the approval validity period, CABs shall verify the following:

(a) that the employee concerned did not have a previous authorisation which has been revoked because of misuse of that authorisation;

(b) that the employee has a clean criminal record;

(c) that there is an employment agreement between the employee concerned and an approved IO;

(d) that the employee concerned has a valid country specific identity card or an equivalent document.

4.4. Role of the IOs

4.4.1. Responsibilities and requirements

(a) IOs shall request an inspection from their CAB to obtain approval;

(b) IOs shall inform their CAB about changes in their contact details;

(c) IOs shall inform their CAB when their business is dissolved;

(d) IOs shall record every security related RMI transaction and operation;

(e) IOs shall inform their CAB of any termination of employment of any of their authorised employees;

(f) IOs shall report to the relevant authorities any offence or misconduct that has been committed by their authorised employees and that concerns security related RMI;

(g) IOs shall ensure that their authorised employees only use their own authorisation inspection certificates;

(h) IOs shall ensure that all fees relating to their IO employee's authorisation have been paid;

(i) IOs shall ensure that their IO employees are trained for repair activities concerning automotive maintenance, reprogramming and security and safety functions;

(j) IO shall request their CAB for an on-site inspection in the six months prior to the expiration of their approval inspection certificate.

4.5. Role of IO employees

4.5.1. Responsibilities and requirements

(a) IO employees shall request their CAB for authorisation;

(b) IO employees shall register themselves on the vehicle manufacturer's RMI system;

(c) IO employees shall access security-related RMI in accordance with EN ISO standard 18541 – 2014;

(d) IO employees shall ensure that all records of security related RMI downloaded from the vehicle manufacturer RMI system shall not be stored any longer than necessary for performing the operation for which the information is needed;

(e) where applicable, IO employees shall notify their IO employer that their digital certificate is no longer required;

(f) IO employee shall not share with any third party the security token, the digital certificate or the PIN;

(g) IO employees shall be responsible for using the personal security token and PIN correctly;

(h) IO employees shall inform their IO and their TC about any loss or misuse of their security token within 24 hours of such loss or misuse;

(i) IO employees shall report to the relevant authorities any request or act from other IO employees relating to security-related RMI that does not constitute a legitimate business activity as referred to in point 6.3 of this Annex.

4.6. Role of the trust centre

TCs shall create and send the digital certificates to the IOs via the respective CABs to the IOs and the IO employees. TCs shall maintain a database of issued authorisation inspection certificates. TCs shall provide vehicle manufacturers access to an interface to verify the status of the digital certificates and the authorisation inspection certificates.

TCs shall keep the information regarding IO employees in the authorisation database for an additional period of maximum 60 months. That period shall not be longer than the remaining validity period of the approval granted to the IO where the IO employee is working.

4.6.1. Responsibilities and requirements

(a) TCs can suspend and repeal digital certificates upon request from the CAB;

(b) TCs shall provide the software to use the digital certificates to the IO and IO employees;

(c) TCs shall operate 24 hours a day, 7 days a week.

4.7. Role of vehicle manufacturers

Vehicle manufacturers shall provide to all approved IOs and authorised IO employees access to security-related repair and maintenance information. Vehicle manufacturers shall communicate with TCs to verify the authorisation and authentication status of IO employees seeking access to such information.

4.7.1. Responsibilities and requirements

(a) vehicle manufacturers shall ensure that their websites are adapted to support the access of IOs to security-related RMI;

(b) vehicle manufacturers shall ensure that they download the technical specifications made available on the SERMI website.

4.7.2. Procedural requirements for vehicle manufacturers

Vehicle manufacturers shall not grant access to security-related RMI, unless all of the following procedural requirements have been complied with:

(1) Procedural requirements for stolen vehicles

Vehicle manufacturers shall keep a record of all vehicles of its brand reported by the authorities as stolen.

Vehicle manufacturers shall put in place a process that provides clear traceability and accountability and enables the relevant authorities to trace the data supplied by the vehicle manufacturer to the IO employee who was granted access to the information related to the stolen vehicle.

(2) Procedural requirements for storing information

Vehicle manufacturers shall store the following information for each access granted to security-related repair and maintenance information:

(a) the Vehicle Identification Number (VIN) of the vehicle for which the information was requested;

(b) the date the request was made;

(c) the vehicle registration number of the vehicle for which the information was requested, where available;

(d) type variant of the vehicle for which the information was requested and the version of that vehicle, where available.

Vehicle manufacturers shall store those data for 5 years..

(*) The requirements set out in this Appendix are based on those laid down in the 'Scheme for accreditation, approval and authorization to Access Security-related Repair and Maintenance Information (RMI)' validated on 19 May 2016 by the European cooperation for Accreditation (https://www.vehiclesermi.eu/).

(**) Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC (OJ L 257, 28.8.2014, p. 73).'

COMMISSION REGULATION (EU) 2021/1245

of 23 July 2021

approving amendments to the specification for a protected designation of origin or a protected geographical indication ('Coteaux du Pont du Gard' (PGI))

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([1]), and in particular Article 99 thereof,

Whereas:

(1) The Commission has examined France's application for the approval of amendments to the specification for the protected geographical indication 'Coteaux du Pont du Gard', submitted pursuant to Article 105 of Regulation (EU) No 1308/2013.

(2) The Commission published the application for the approval of amendments to the specification in the *Official Journal of the European Union* ([2]), as required by Article 97(3) of Regulation (EU) No 1308/2013.

(3) No statement of objection has been received by the Commission under Article 98 of Regulation (EU) No 1308/2013.

(4) The amendments to the specification should therefore be approved in accordance with Article 99 of Regulation (EU) No 1308/2013.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Common Organisation of Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

The amendments to the specification published in the *Official Journal of the European Union* regarding the name 'Coteaux du Pont du Gard' (PGI) are hereby approved.

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 all Member States.

Done at Brussels, 23 July 2021.

For the Commission,
On behalf of the President,
Janusz WOJCIECHOWSKI
Member of the Commission

([1]) OJ L 347, 20.12.2013, p. 671.
([2]) OJ C 112, 30.3.2021, p. 2.

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1246

of 28 July 2021

amending Regulation (EC) No 1484/95 as regards fixing representative prices in the poultrymeat and egg sectors and for egg albumin

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([1]), and in particular Article 183(b) thereof,

Having regard to Regulation (EU) No 510/2014 of the European Parliament and of the Council of 16 April 2014 laying down the trade arrangements applicable to certain goods resulting from the processing of agricultural products and repealing Council Regulations (EC) No 1216/2009 and (EC) No 614/2009 ([2]), and in particular Article 5(6)(a) thereof,

Whereas:

(1) Commission Regulation (EC) No 1484/95 ([3]) lays down detailed rules for implementing the system of additional import duties and fixes representative prices in the poultrymeat and egg sectors and for egg albumin.

(2) Regular monitoring of the data used to determine representative prices for poultrymeat and egg products and for egg albumin shows that the representative import prices for certain products should be amended to take account of variations in price according to origin.

(3) Regulation (EC) No 1484/95 should therefore be amended accordingly.

(4) Given the need to ensure that this measure applies as soon as possible after the updated data have been made available, this Regulation should enter into force on the day of its publication,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 1484/95 is replaced by the text set out in the Annex to this Regulation.

Article 2

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

([1]) OJ L 347, 20.12.2013, p. 671.
([2]) OJ L 150, 20.5.2014, p. 1.
([3]) Commission Regulation (EC) No 1484/95 of 28 June 1995 laying down detailed rules for implementing the system of additional import duties and fixing representative prices in the poultrymeat and egg sectors and for egg albumin, and repealing Regulation No 163/67/EEC (OJ L 145, 29.6.1995, p. 47).

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

Done at Brussels, 28 July 2021.

For the Commission
On behalf of the President,
Wolfgang BURTSCHER
Director-General
Directorate-General for Agriculture and Rural Development

ANNEX

'ANNEX I

CN code	Description of goods	Representative price (EUR/100 kg)	Security under Article 3 (EUR/100 kg)	Origin [1]
0207 14 10	Fowls of the species *Gallus domesticus*, boneless cuts, frozen	140,3 176,2	60 42	BR TH

[1] Nomenclature of countries laid down by Commission Regulation (EU) No 1106/2012 of 27 November 2012 implementing Regulation (EC) No 471/2009 of the European Parliament and of the Council on Community statistics relating to external trade with non-member countries, as regards the update of the nomenclature of countries and territories (OJ L 328, 28.11.2012, p. 7).'

COMMISSION REGULATION (EU) 2021/1247

of 29 July 2021

amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for mandestrobin in grapes and strawberries

(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 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC ([1]), and in particular Article 14(1)(a) thereof,

Whereas:

(1) For mandestrobin, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005.

(2) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application for import tolerance was submitted for mandestrobin used in Canada on strawberries and grapes. The applicant claims that the authorised uses of that substance on such crops in Canada lead to residues exceeding the MRLs contained in Regulation (EC) No 396/2005 and that higher MRLs are necessary to avoid trade barriers for the importation of grapes and strawberries.

(3) In accordance with Article 8 of Regulation (EC) No 396/2005, the application was evaluated by the Member State concerned and the evaluation report was forwarded to the Commission.

(4) The European Food Safety Authority ('the Authority') assessed the application and the evaluation report, examining in particular the risks to the consumer and, where relevant, to animals and gave a reasoned opinion on the proposed MRLs ([2]). It forwarded that opinion to the applicant, the Commission and the Member States and made it available to the public.

(5) The Authority concluded that all requirements with respect to data were met and that the modifications to the MRLs requested by the applicant were acceptable with regard to consumer safety on the basis of a consumer exposure assessment for 27 specific European consumer groups. It took into account the most recent information on the toxicological properties of the substance. The lifetime exposure to the substance via consumption of all food products that may contain it showed that there is no risk that the acceptable daily intake is exceeded. Moreover, the Authority concluded that the establishment of an acute reference dose is not necessary due to the low acute toxicity profile of the substance.

(6) Based on the reasoned opinion of the Authority and taking into account the factors relevant to the matter under consideration, the proposed modifications to the MRLs fulfil the requirements of Article 14(2) of Regulation (EC) No 396/2005.

(7) Regulation (EC) No 396/2005 should therefore be amended accordingly.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([1]) OJ L 70, 16.3.2005, p. 1.

([2]) EFSA scientific reports available online: http://www.efsa.europa.eu Reasoned opinion on the setting of import tolerances for mandestrobin in strawberries and table and wine grapes. *EFSA Journal* 2018;16(8):5395.

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 396/2005 is amended in accordance with the Annex to this Regulation.

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 all Member States.

Done at Brussels, 29 July 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Annex II to Regulation (EC) No 396/2005, the column for mandestrobin is replaced by the following:

'**Pesticide residues and maximum residue levels (mg/kg)**

Code number	Groups and examples of individual products to which the MRLs apply [a]	Mandestrobin
(1)	(2)	(3)
0100000	**FRUITS, FRESH or FROZEN; TREE NUTS**	
0110000	**Citrus fruits**	0,01 (*)
0110010	Grapefruits	
0110020	Oranges	
0110030	Lemons	
0110040	Limes	
0110050	Mandarins	
0110990	Others (2)	
0120000	**Tree nuts**	0,01 (*)
0120010	Almonds	
0120020	Brazil nuts	
0120030	Cashew nuts	
0120040	Chestnuts	
0120050	Coconuts	
0120060	Hazelnuts/cobnuts	
0120070	Macadamias	
0120080	Pecans	
0120090	Pine nut kernels	
0120100	Pistachios	
0120110	Walnuts	
0120990	Others (2)	
0130000	**Pome fruits**	0,01 (*)
0130010	Apples	
0130020	Pears	
0130030	Quinces	
0130040	Medlars	
0130050	Loquats/Japanese medlars	
0130990	Others (2)	
0140000	**Stone fruits**	
0140010	Apricots	2
0140020	Cherries (sweet)	3
0140030	Peaches	2
0140040	Plums	0,5

0140990	Others (2)	0,01 (*)
0150000	**Berries and small fruits**	
0151000	**(a) grapes**	**5**
0151010	Table grapes	
0151020	Wine grapes	
0152000	**(b) strawberries**	**3**
0153000	**(c) cane fruits**	0,01 (*)
0153010	Blackberries	
0153020	Dewberries	
0153030	Raspberries (red and yellow)	
0153990	Others (2)	
0154000	**(d) other small fruits and berries**	0,01 (*)
0154010	Blueberries	
0154020	Cranberries	
0154030	Currants (black, red and white)	
0154040	Gooseberries (green, red and yellow)	
0154050	Rose hips	
0154060	Mulberries (black and white)	
0154070	Azaroles/Mediterranean medlars	
0154080	Elderberries	
0154990	Others (2)	
0160000	**Miscellaneous fruitswith**	0,01 (*)
0161000	**(a) edible peel**	
0161010	Dates	
0161020	Figs	
0161030	Table olives	
0161040	Kumquats	
0161050	Carambolas	
0161060	Kaki/Japanese persimmons	
0161070	Jambuls/jambolans	
0161990	Others (2)	
0162000	**(b) inedible peel, small**	
0162010	Kiwi fruits (green, red, yellow)	
0162020	Litchis/lychees	
0162030	Passionfruits/maracujas	
0162040	Prickly pears/cactus fruits	
0162050	Star apples/cainitos	
0162060	American persimmons/Virginia kaki	
0162990	Others (2)	

0163000	**(c) inedible peel, large**	
0163010	Avocados	
0163020	Bananas	
0163030	Mangoes	
0163040	Papayas	
0163050	Granate apples/pomegranates	
0163060	Cherimoyas	
0163070	Guavas	
0163080	Pineapples	
0163090	Breadfruits	
0163100	Durians	
0163110	Soursops/guanabanas	
0163990	Others (2)	
0200000	**VEGETABLES, FRESH or FROZEN**	0,01 (*)
0210000	**Root and tuber vegetables**	
0211000	**(a) potatoes**	
0212000	**(b) tropical root and tuber vegetables**	
0212010	Cassava roots/manioc	
0212020	Sweet potatoes	
0212030	Yams	
0212040	Arrowroots	
0212990	Others (2)	
0213000	**(c) other root and tuber vegetables except sugar beets**	
0213010	Beetroots	
0213020	Carrots	
0213030	Celeriacs/turnip rooted celeries	
0213040	Horseradishes	
0213050	Jerusalem artichokes	
0213060	Parsnips	
0213070	Parsley roots/Hamburg roots parsley	
0213080	Radishes	
0213090	Salsifies	
0213100	Swedes/rutabagas	
0213110	Turnips	
0213990	Others (2)	
0220000	**Bulb vegetables**	
0220010	Garlic	
0220020	Onions	
0220030	Shallots	

0220040	Spring onions/green onions and Welsh onions	
0220990	Others (2)	
0230000	**Fruiting vegetables**	
0231000	**(a) Solanaceae and Malvaceae**	
0231010	Tomatoes	
0231020	Sweet peppers/bell peppers	
0231030	Aubergines/eggplants	
0231040	Okra/lady's fingers	
0231990	Others (2)	
0232000	**(b) cucurbits with edible peel**	
0232010	Cucumbers	
0232020	Gherkins	
0232030	Courgettes	
0232990	Others (2)	
0233000	**(c) cucurbits with inedible peel**	
0233010	Melons	
0233020	Pumpkins	
0233030	Watermelons	
0233990	Others (2)	
0234000	**(d) sweet corn**	
0239000	**(e) other fruiting vegetables**	
0240000	**Brassica vegetables(excluding brassica roots and brassica baby leaf crops)**	
0241000	**(a) flowering brassica**	
0241010	Broccoli	
0241020	Cauliflowers	
0241990	Others (2)	
0242000	**(b) head brassica**	
0242010	Brussels sprouts	
0242020	Head cabbages	
0242990	Others (2)	
0243000	**(c) leafy brassica**	
0243010	Chinese cabbages/pe-tsai	
0243020	Kales	
0243990	Others (2)	
0244000	**(d) kohlrabies**	
0250000	**Leaf vegetables, herbs and edible flowers**	
0251000	**(a) lettuces and salad plants**	
0251010	Lamb's lettuces/corn salads	
0251020	Lettuces	

0251030	Escaroles/broad-leaved endives	
0251040	Cresses and other sprouts and shoots	
0251050	Land cresses	
0251060	Roman rocket/rucola	
0251070	Red mustards	
0251080	Baby leaf crops (including brassica species)	
0251990	Others (2)	
0252000	**(b) spinaches and similar leaves**	
0252010	Spinaches	
0252020	Purslanes	
0252030	Chards/beet leaves	
0252990	Others (2)	
0253000	**(c) grape leaves and similar species**	
0254000	**(d) watercresses**	
0255000	**(e) witloofs/Belgian endives**	
0256000	**(f) herbs and edible flowers**	
0256010	Chervil	
0256020	Chives	
0256030	Celery leaves	
0256040	Parsley	
0256050	Sage	
0256060	Rosemary	
0256070	Thyme	
0256080	Basil and edible flowers	
0256090	Laurel/bay leaves	
0256100	Tarragon	
0256990	Others (2)	
0260000	**Legume vegetables**	
0260010	Beans (with pods)	
0260020	Beans (without pods)	
0260030	Peas (with pods)	
0260040	Peas (without pods)	
0260050	Lentils	
0260990	Others (2)	
0270000	**Stem vegetables**	
0270010	Asparagus	
0270020	Cardoons	
0270030	Celeries	
0270040	Florence fennels	

0270050	Globe artichokes	
0270060	Leeks	
0270070	Rhubarbs	
0270080	Bamboo shoots	
0270090	Palm hearts	
0270990	Others (2)	
0280000	**Fungi, mosses and lichens**	
0280010	Cultivated fungi	
0280020	Wild fungi	
0280990	Mosses and lichens	
0290000	**Algae and prokaryotes organisms**	
0300000	**PULSES**	0,01 (*)
0300010	Beans	
0300020	Lentils	
0300030	Peas	
0300040	Lupins/lupini beans	
0300990	Others (2)	
0400000	**OILSEEDS AND OIL FRUITS**	0,01 (*)
0401000	**Oilseeds**	
0401010	Linseeds	
0401020	Peanuts/groundnuts	
0401030	Poppy seeds	
0401040	Sesame seeds	
0401050	Sunflower seeds	
0401060	Rapeseeds/canola seeds	
0401070	Soyabeans	
0401080	Mustard seeds	
0401090	Cotton seeds	
0401100	Pumpkin seeds	
0401110	Safflower seeds	
0401120	Borage seeds	
0401130	Gold of pleasure seeds	
0401140	Hemp seeds	
0401150	Castor beans	
0401990	Others (2)	
0402000	**Oil fruits**	
0402010	Olives for oil production	
0402020	Oil palms kernels	
0402030	Oil palms fruits	

0402040	Kapok	
0402990	Others (2)	
0500000	**CEREALS**	0,01 (*)
0500010	Barley	
0500020	Buckwheat and other pseudocereals	
0500030	Maize/corn	
0500040	Common millet/proso millet	
0500050	Oat	
0500060	Rice	
0500070	Rye	
0500080	Sorghum	
0500090	Wheat	
0500990	Others (2)	
0600000	**TEAS, COFFEE, HERBAL INFUSIONS, COCOA AND CAROBS**	0,05 (*)
0610000	**Teas**	
0620000	**Coffee beans**	
0630000	**Herbal infusions from**	
0631000	**(a) flowers**	
0631010	Chamomile	
0631020	Hibiscus/roselle	
0631030	Rose	
0631040	Jasmine	
0631050	Lime/linden	
0631990	Others (2)	
0632000	**(b) leaves and herbs**	
0632010	Strawberry	
0632020	Rooibos	
0632030	Mate/maté	
0632990	Others (2)	
0633000	**(c) roots**	
0633010	Valerian	
0633020	Ginseng	
0633990	Others (2)	
0639000	**(d) any other parts of the plant**	
0640000	**Cocoa beans**	
0650000	**Carobs/Saint John's breads**	
0700000	**HOPS**	0,05 (*)

0800000	**SPICES**	
0810000	**Seed spices**	0,05 (*)
0810010	Anise/aniseed	
0810020	Black caraway/black cumin	
0810030	Celery	
0810040	Coriander	
0810050	Cumin	
0810060	Dill	
0810070	Fennel	
0810080	Fenugreek	
0810090	Nutmeg	
0810990	Others (2)	
0820000	**Fruit spices**	0,05 (*)
0820010	Allspice/pimento	
0820020	Sichuan pepper	
0820030	Caraway	
0820040	Cardamom	
0820050	Juniper berry	
0820060	Peppercorn (black, green and white)	
0820070	Vanilla	
0820080	Tamarind	
0820990	Others (2)	
0830000	**Bark spices**	0,05 (*)
0830010	Cinnamon	
0830990	Others (2)	
0840000	**Root and rhizome spices**	
0840010	Liquorice	0,05 (*)
0840020	Ginger (10)	
0840030	Turmeric/curcuma	0,05 (*)
0840040	Horseradish (11)	
0840990	Others (2)	0,05 (*)
0850000	**Bud spices**	0,05 (*)
0850010	Cloves	
0850020	Capers	
0850990	Others (2)	
0860000	**Flower pistil spices**	0,05 (*)
0860010	Saffron	
0860990	Others (2)	

0870000	**Aril spices**	0,05 (*)
0870010	Mace	
0870990	Others (2)	
0900000	**SUGAR PLANTS**	0,01 (*)
0900010	Sugar beet roots	
0900020	Sugar canes	
0900030	Chicory roots	
0900990	Others (2)	
1000000	**PRODUCTS OF ANIMAL ORIGIN -TERRESTRIAL ANIMALS**	
1010000	**Commodities from**	0,01 (*)
1011000	**(a) swine**	
1011010	Muscle	
1011020	Fat	
1011030	Liver	
1011040	Kidney	
1011050	Edible offals (other than liver and kidney)	
1011990	Others (2)	
1012000	**(b) bovine**	
1012010	Muscle	
1012020	Fat	
1012030	Liver	
1012040	Kidney	
1012050	Edible offals (other than liver and kidney)	
1012990	Others (2)	
1013000	**(c) sheep**	
1013010	Muscle	
1013020	Fat	
1013030	Liver	
1013040	Kidney	
1013050	Edible offals (other than liver and kidney)	
1013990	Others (2)	
1014000	**(d) goat**	
1014010	Muscle	
1014020	Fat	
1014030	Liver	
1014040	Kidney	
1014050	Edible offals (other than liver and kidney)	
1014990	Others (2)	

1015000	**(e) equine**	
1015010	Muscle	
1015020	Fat	
1015030	Liver	
1015040	Kidney	
1015050	Edible offals (other than liver and kidney)	
1015990	Others (2)	
1016000	**(f) poultry**	
1016010	Muscle	
1016020	Fat	
1016030	Liver	
1016040	Kidney	
1016050	Edible offals (other than liver and kidney)	
1016990	Others (2)	
1017000	**(g) other farmed terrestrial animals**	
1017010	Muscle	
1017020	Fat	
1017030	Liver	
1017040	Kidney	
1017050	Edible offals (other than liver and kidney)	
1017990	Others (2)	
1020000	**Milk**	0,01 (*)
1020010	Cattle	
1020020	Sheep	
1020030	Goat	
1020040	Horse	
1020990	Others (2)	
1030000	**Birds eggs**	0,01 (*)
1030010	Chicken	
1030020	Duck	
1030030	Geese	
1030040	Quail	
1030990	Others (2)	
1040000	**Honey and other apiculture products (7)**	0,05 (*)
1050000	**Amphibians and Reptiles**	0,01 (*)

1060000	**Terrestrial invertebrate animals**	0,01 (*)
1070000	**Wild terrestrial vertebrate animals**	0,01 (*)
1100000	**PRODUCTS OF ANIMAL ORIGIN - FISH, FISHPRODUCTS AND ANY OTHER MARINE AND FRESHWATER FOOD PRODUCTS (8)**	
1200000	**PRODUCTS OR PART OF PRODUCTS EXCLUSIVELY USED FOR ANIMAL FEED PRODUCTION (8)**	
1300000	**PROCESSED FOOD PRODUCTS (9)**	

(*) Indicates lower limit of analytical determination
([a]) For the complete list of products of plant and animal origin to which MRL's apply, reference should be made to Annex I'

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1248

of 29 July 2021

as regards measures on good distribution practice for veterinary medicinal products in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC ([1]), and in particular Article 99(6) thereof,

Whereas:

(1) Article 101(5) of Regulation (EU) 2019/6 requires wholesale distributors to comply with good distribution practice for veterinary medicinal products, as adopted by the Commission.

(2) Measures on good distribution practice should ensure the identity, integrity, traceability and quality of veterinary medicinal products across the supply chain. Furthermore, those measures should guarantee that veterinary medicinal products are appropriately stored, transported and handled, as well as ensure that they remain within the legal supply chain during storage and transport.

(3) Several international standards and guidelines on good distribution practice exist for medicinal products for human use ([2]) ([3]) ([4]) ([5]). At Union level, guidelines on good distribution practice have been adopted only in respect of medicinal products for human use ([6]). Corresponding measures in the veterinary domain should take into account the experience gained with the application of the current system under Directive 2001/83/EC of the European Parliament and of the Council ([7]) in light of the similarities and potential differences between the requirements on good distribution practice for medicinal products for human use and for veterinary medicinal products.

(4) Wholesale distributors often deal with both medicinal products for human use and veterinary medicinal products. In addition, good distribution practice inspections for both types of medicinal products are often to be performed by the same competent authority experts. Therefore, in order to avoid unnecessary administrative burden on the industry and the competent authorities, it is practical to apply similar measures to the veterinary domain as in the human domain, unless specific needs dictate otherwise.

(5) In order not to affect negatively the availability of veterinary medicinal products in the Union, the good distribution practice requirements for veterinary medicinal products should not be more stringent than the corresponding ones for medicinal products for human use.

([1]) OJ L 4, 7.1.2019, p. 43.

([2]) Good storage and distribution practices for medical products, In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-fourth report. Geneva: World Health Organization; 2020: Annex 7 (WHO Technical Report Series, No 1025).

([3]) Guide to good storage practices for pharmaceuticals. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-seventh report. Geneva: World Health Organization; 2003: Annex 9 (WHO Technical Report Series, No 908).

([4]) Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: forty-fifth report. Geneva: World Health Organization; 2011: Annex 9 (WHO Technical Report Series, No 961).

([5]) PIC/S Guide to good distribution practice for medicinal products, PIC/S, PE 011-1, 1.6.2014.

([6]) Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (2013/C 343/01) (OJ C 343, 23.11.2013, p. 1).

([7]) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

(6) The measures on good distribution practice for veterinary medicinal products laid down in this Regulation should ensure consistency with and complement the implementing measures on good manufacturing practice for veterinary medicinal products and active substances used as starting materials provided for in Article 93(2) of Regulation (EU) 2019/6 and good distribution practice for active substances used as starting materials in veterinary medicinal products provided for in Article 95(8) of that Regulation.

(7) Any person acting as a wholesale distributor of veterinary medicinal products must hold a wholesale distribution authorisation in accordance with Article 99(1) of Regulation (EU) 2019/6 and comply with good distribution practice for veterinary medicinal products in accordance with Article 101(5) of that Regulation. In accordance with Article 99(5) of that Regulation, a manufacturing authorisation allows for the wholesale distribution of the veterinary medicinal products covered by that manufacturing authorisation. Therefore, manufacturers performing any such distribution activities with their own veterinary medicinal products are also to comply with good distribution practice for veterinary medicinal products.

(8) The definition of wholesale distribution as laid down in Article 4(36) of Regulation (EU) 2019/6 does not exclude wholesale distributors established or operating under specific customs regimes, such as free zones or customs warehouses. Therefore, all obligations related to wholesale distribution activities (such as exporting, holding or supplying) also apply to those wholesale distributors in respect of good distribution practice for veterinary medicinal products.

(9) Relevant sections of good distribution practice for veterinary medicinal products should also be adhered to by third-party actors involved in the wholesale distribution of veterinary medicinal products and should be part of their contractual obligations. A consistent approach by all partners in the supply chain is required in order to be successful in the fight against falsified veterinary medicinal products.

(10) A quality system is required to ensure that the objectives of good distribution practice are achieved and should clearly set out responsibilities, processes and risk management principles in relation to the wholesale distributor's activities. That quality system should be the responsibility of the organisation's management, requires their leadership and active participation, and should be supported by personnel commitment.

(11) The correct distribution of veterinary medicinal products relies significantly on an adequate number of competent personnel to carry out all the tasks for which the wholesale distributor is responsible. Individual responsibilities should be clearly understood by personnel and be recorded.

(12) The persons distributing veterinary medicinal products should have suitable and adequate premises, installations and equipment, in order to ensure proper storage and distribution of veterinary medicinal products.

(13) Good documentation should be an essential part of any quality system. Written documentation should be required in order to prevent errors from oral communication and permit the tracking of relevant operations during the wholesale distribution of veterinary medicinal products. All types of documents should be defined and adhered to.

(14) Procedures should describe all distribution activities that affect the identity, traceability and quality of the veterinary medicinal products.

(15) Records of all significant activities or events should be made and kept to ensure the traceability of the origin and destination of veterinary medicinal products, as well as the identification of all suppliers of, or those supplied with, such veterinary medicinal products. Such records should facilitate the recall of a batch of a veterinary medicinal product, if necessary, as well as the investigation of falsified or suspected falsified veterinary medicinal products.

(16) With regard to the processing of personal data of employees, complainants or any other natural person, Regulation (EU) 2016/679 of the European Parliament and of the Council ([8]) on the protection of natural persons should apply to the processing of personal data and on the free movement of such data.

(17) The quality system should fully describe all key operations in appropriate documentation.

(18) Complaints, returns, suspected falsified veterinary medicinal products and recalls should be recorded and handled carefully in accordance with established procedures. Records should be made available to the competent authorities. An assessment of returned veterinary medicinal products should be performed before any approval for resale.

(19) Any activity covered by good distribution practice for veterinary medicinal products that is outsourced should be defined, agreed and controlled in order to avoid misunderstandings that could affect the integrity of the veterinary medicinal product. A written contract between the contract giver and the contract acceptor should clearly establish the duties of each party.

(20) Regardless of the mode of transport, it should be possible to demonstrate that the veterinary medicinal products have not been exposed to conditions that may compromise their quality and integrity. A risk-based approach should be used when planning transport of and for transporting veterinary medicinal products.

(21) Regular self-inspections are necessary to monitor the implementation of and compliance with good distribution practice for veterinary medicinal products and to propose necessary corrective and preventive measures.

(22) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products referred to in Article 145 of Regulation (EU) 2019/6,

HAS ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter and scope

1. This Regulation lays down the measures on good distribution practice for veterinary medicinal products.

2. This Regulation shall apply to holders of a manufacturing authorisation performing wholesale distribution of the veterinary medicinal products covered by that manufacturing authorisation, and to holders of a wholesale distribution authorisation, including those established or operating under specific customs regimes, such as free zones or customs warehouses.

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(a) 'good distribution practice for veterinary medicinal products' means the part of the quality assurance throughout the supply chain which ensures that the quality of veterinary medicinal products is maintained throughout all stages of the supply chain from the site of their manufacturer to the persons referred to in Article 101(2) of Regulation (EU) 2019/6;

([8]) 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).

(b) 'free zone' means any free zone designated by the Member States in accordance with Article 243 of Regulation (EU) No 952/2013 of the European Parliament and of the Council ([9]);

(c) 'customs warehouse' means any of the warehouses referred to in Article 240(1) of Regulation (EU) No 952/2013;

(d) 'quality system' means the sum of all aspects of a system that implements quality policy and ensures that quality objectives are met;

(e) 'quality risk management' means a systematic process, applied both proactively and retrospectively, for the assessment, control, communication and review of risks to the quality of the veterinary medicinal product across the product's lifecycle;

(f) 'validation' means a documented program that provides a high degree of assurance that a specific process, method, or system will consistently produce a result meeting pre-determined acceptance criteria;

(g) 'procedure' means a documented description of the operations to be performed, the precautions to be taken and measures to be applied directly or indirectly related to the distribution of veterinary medicinal products;

(h) 'documentation' means written procedures, instructions, contracts, records and data, in paper or in electronic form;

(i) 'procuring' means obtaining, acquiring or purchasing veterinary medicinal products from manufacturers, importers or other wholesale distributors;

(j) 'holding' means storing veterinary medicinal products;

(k) 'supplying' means all activities of providing, selling or donating veterinary medicinal products to the persons referred to in Article 101(2) of Regulation (EU) 2019/6;

(l) 'transport' means moving veterinary medicinal products between two locations without storing them for unjustified periods of time;

(m) 'deviation' means departure from approved documentation or an established standard;

(n) 'falsified veterinary medicinal product' means any veterinary medicinal product with a false representation of any of the following:

(i) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;

(ii) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or

(iii) its history, including the records and documents relating to the distribution channels used;

(o) 'contamination' means the undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a veterinary medicinal product during production, sampling, packaging or repackaging, storage or transport;

(p) 'calibration' means the set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a reference standard;

(q) 'qualification' means the action of proving that any equipment works correctly and actually leads to the expected results;

([9]) Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1).

(r) 'signed' means the record of the individual who performed a particular action or review. This record can be initials, a full handwritten signature, a personal seal, or an advanced electronic signature as defined in Article 3(11) of Regulation (EU) No 910/2014 of the European Parliament and of the Council ([10]);

(s) 'batch' means a defined quantity of starting material, packaging material or product processed in a single process or series of processes, so that it is expected to be homogeneous;

(t) 'expiry date' means the date placed on the packaging of a veterinary medicinal product designating the time during which that veterinary medicinal product is expected to remain within established shelf life specifications if stored under defined conditions, and after which it should not be used;

(u) 'batch number' means a distinctive combination of numbers or letters that uniquely identifies a batch.

CHAPTER II

QUALITY MANAGEMENT

Article 3

Development and maintenance of a quality system

1. The persons referred to in Article 1(2) shall develop and maintain a quality system.

2. The quality system shall take into account the size, structure and complexity of the activities of those persons and the changes foreseen for those activities.

3. The persons referred to in Article 1(2) shall ensure that all parts of the quality system are adequately resourced with competent personnel, and suitable and sufficient premises, equipment and facilities.

Article 4

Requirements for the quality system

1. The quality system shall set out responsibilities, processes and quality risk management principles in relation to the activities of the persons referred to in Article 1(2). All wholesale distribution activities shall be clearly defined and systematically reviewed. All critical steps of wholesale distribution activities and significant changes shall be justified and, where relevant, subject to validation.

2. The quality system shall encompass the organisational structure, procedures, processes and resources, as well as activities necessary to ensure that the veterinary medicinal products delivered maintain their quality and integrity and remain within the legal supply chain during storage or transport.

3. The quality system shall be fully documented. Its effectiveness shall be monitored. All quality-system-related activities shall be defined and documented.

4. A quality manual or equivalent documentation approach shall be established and include a description of any differences in the quality system regarding handling of veterinary medicinal products of different types.

5. A change control system shall be established and incorporate the principles of quality risk management and be proportionate and effective.

([10]) Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC (OJ L 257, 28.8.2014, p. 73).

6. The quality system shall ensure that the following obligations are fulfilled:

(a) the procuring, holding, supplying, transport or export of veterinary medicinal products comply with the requirements of good distribution practice for veterinary medicinal products laid down in this Regulation;

(b) management responsibilities are clearly specified;

(c) veterinary medicinal products are delivered to the correct consignees within an appropriate time period;

(d) records are made contemporaneously;

(e) deviations are documented and investigated;

(f) appropriate corrective and preventive actions ('CAPA') are taken in line with the principles of quality risk management;

(g) changes that may affect the storage and distribution of veterinary medicinal products are evaluated.

Article 5

Management of outsourced activities

The quality system shall cover the control and review of any outsourced activities related to the wholesale distribution of veterinary medicinal products. Such control and review shall incorporate quality risk management and shall include:

(a) assessment of the suitability and competence of the contract acceptor to carry out the activity and checking authorisation status, if required;

(b) definition of the responsibilities and communication processes for the quality-related activities of the parties involved;

(c) regular monitoring and review of the performance of the contract acceptor, and the identification and implementation of any required improvements on a regular basis.

Article 6

Management review and monitoring

1. The management of the persons referred to in Article 1(2) shall establish and implement a formal process for reviewing the quality system on a periodic basis.

2. The review shall include the following:

(a) a measurement of achievement of the objectives of the quality system;

(b) an assessment of:

  (i) performance indicators that can be used to monitor the effectiveness of processes within the quality system, such as complaints, deviations, CAPA, changes to processes;

  (ii) feedback on outsourced activities;

  (iii) self-assessment processes including risk assessments and audits; and

  (iv) results of external assessments such as inspections, findings and customer audits;

(c) emerging regulations, guidance and quality issues that can impact the quality system;

(d) innovations that might enhance the quality system;

(e) changes in business environment and objectives.

3. The outcome of each management review of the quality system shall be documented in a timely manner and communicated effectively internally.

Article 7

Quality risk management

1. The persons referred to in Article 1(2) shall apply quality risk management.

2. Quality risk management shall ensure that the evaluation of the risk to quality is based on scientific knowledge, experience with the process and ultimately links to the protection of the treated animal or animal group, the persons responsible for the animal and the treatment, the consumer of a food producing animal and the environment.

3. The level of detail and documentation of the quality risk management process shall be proportionate to the level of risk to quality.

CHAPTER III

PERSONNEL REQUIREMENTS

Article 8

Obligations of persons responsible for wholesale distribution

1. The persons responsible for wholesale distribution referred to in Article 101(3) of Regulation (EU) 2019/6 ('the responsible persons') shall ensure compliance with good distribution practice for veterinary medicinal products. In addition to the requirement laid down in Article 100(2)(a) of that Regulation, the responsible persons shall have appropriate competence and experience as well as knowledge of, and training in, compliance with good distribution practice for veterinary medicinal products.

2. The responsible persons shall be personally responsible for fulfilling their obligations and shall be contactable at any time.

3. The responsible persons may delegate their tasks but not their responsibilities.

4. If the responsible persons are not available, the persons referred to in Article 1(2) shall appoint a substitute for the necessary time period so that continuity of business is ensured.

5. A written job description of the responsible persons shall define their authority to take decisions with regard to their responsibilities. The persons referred to in Article 1(2) shall give the responsible persons the defined authority, resources and responsibility needed to fulfil their duties.

6. The responsible persons shall carry out their tasks in such a way as to ensure that the relevant persons referred to in Article 1(2) can demonstrate compliance with good distribution practice for veterinary medicinal products and that the obligations referred to in Article 101(4) of Regulation (EU) 2019/6 are met.

7. The obligations of the responsible persons shall include:

(a) ensuring that a quality system is implemented and maintained;

(b) focusing on the management of authorised activities and the accuracy and quality of records;

(c) ensuring that initial and continuous training programmes are implemented and maintained;

(d) coordinating and promptly performing any recall operations for veterinary medicinal products;

(e) ensuring that relevant customer complaints are dealt with effectively;

(f) ensuring that suppliers and customers are approved;

(g) approving any subcontracted activities which may impact on good distribution practice for veterinary medicinal products;

(h) ensuring that self-inspections are performed at appropriate regular intervals following a prearranged programme and ensuring that the necessary CAPA are put in place;

(i) keeping appropriate records of any delegated tasks;

(j) deciding on the final disposition of returned, rejected, recalled or falsified veterinary medicinal products;

(k) approving any returns to saleable stock;

(l) ensuring that any additional requirements imposed on certain veterinary medicinal products by national law are adhered to;

(m) documenting deviations and deciding on CAPA to correct deviations and avoid their reoccurrence and monitoring of the effectiveness of those CAPA.

Article 9

Other personnel

1. There shall be an adequate number of competent personnel involved in all stages of the wholesale distribution of veterinary medicinal products. That number shall be proportionate to the volume and scope of activities.

2. The organisational structure of the persons referred to in Article 1(2) shall be set out in an organisation chart. The individual roles, responsibilities, and interrelationships of all members of personnel shall be clearly indicated in that chart. Each member of personnel shall understand their own role and responsibilities.

3. The role and responsibilities of employees working in key positions shall be set out in written job descriptions, along with any arrangements for deputising.

Article 10

Training of personnel

1. All personnel involved in wholesale distribution activities shall be trained in the requirements of good distribution practice for veterinary medicinal products. Furthermore, personnel shall have the appropriate competence and experience prior to commencing their tasks.

2. Personnel shall receive initial and continuing training relevant to their role, based on procedures and in accordance with a written training program. The responsible persons shall maintain their competence in good distribution practice for veterinary medicinal products through regular training.

3. Training shall include identifying and preventing falsified veterinary medicinal products from entering the supply chain.

4. Personnel dealing with veterinary medicinal products requiring more stringent handling conditions, such as hazardous products, products presenting special risks of abuse, including narcotic and psychotropic substances, and temperature-sensitive products, shall receive specific training.

5. The persons referred to in Article 1(2) shall keep a record of all training and periodically assess and document its effectiveness.

Article 11

Hygiene

The persons referred to in Article 1(2) shall establish appropriate procedures relating to personnel hygiene, including personal health and appropriate clothing, relevant to the activities carried out. Personnel shall comply with those procedures.

CHAPTER IV

PREMISES AND EQUIPMENT

Article 12

Premises

1. The premises shall be designed or adapted to ensure that the required storage conditions are maintained. They shall be suitably secure, structurally sound and of sufficient capacity to allow safe storage and handling of the veterinary medicinal products. Storage areas shall be provided with adequate lighting to enable all operations to be carried out accurately and safely. Veterinary medicinal products shall be stored suitably spaced to permit cleaning and inspection. Pallets shall be kept in a good state of cleanliness and repair.

2. Where premises are not directly operated by the persons referred to in Article 1(2), a contract shall be in place. The persons referred to in Article 1(2) may only use contracted premises if those premises are covered by a separate wholesale distribution authorisation.

3. Veterinary medicinal products shall be stored in segregated areas that are clearly marked and have access restricted to authorised personnel.

4. Any system replacing physical segregation, as applicable, such as electronic segregation based on a computerised system, shall provide equivalent security and shall be subject to appropriate validation.

5. Veterinary medicinal products pending a decision as to their disposal, or veterinary medicinal products that have been removed from saleable stock, shall be segregated physically or, if an equivalent electronic system is available, electronically, including returned veterinary medicinal products.

6. Veterinary medicinal products received from a third country but not intended for the Union market shall be segregated physically and electronically, if an electronic system is available.

7. Any expired veterinary medicinal products, recalled veterinary medicinal products and rejected veterinary medicinal products shall immediately be segregated physically and stored in a dedicated area away from all other veterinary medicinal products. The appropriate degree of security shall be applied in those areas to ensure that such items remain separate from saleable stock. Those areas shall be clearly identified.

8. The premises shall be designed or adapted to ensure that veterinary medicinal products subject to specific storage and handling measures, such as narcotics and psychotropic substances, are stored in accordance with written instructions and subject to appropriate security measures.

9. One or more dedicated areas shall be provided and appropriate safety and security measures shall be in place for the storage of hazardous veterinary medicinal products, as well as veterinary medicinal products presenting special safety risks of fire or explosion, such as medicinal gases, combustibles, flammable liquids and solids.

10. Receiving and dispatch bays shall protect veterinary medicinal products from prevailing weather conditions. There shall be adequate separation between the receipt and dispatch and storage areas. Procedures shall be in place to maintain control of inbound and outbound goods. Reception areas where deliveries are examined following receipt shall be designated and suitably equipped.

11. Unauthorised access to all areas of the authorised premises shall be prevented by appropriate devices such as a monitored intruder alarm system and appropriate access control. Visitors shall be accompanied at all times.

12. Premises and storage facilities shall be clean and free from litter and dust. Cleaning programmes, instructions and records shall be in place. Appropriate cleaning equipment and cleaning agents shall be chosen and used so as not to present a source of contamination.

13. The premises shall be dry and maintained within acceptable temperature limits.

14. There shall be appropriate procedures for the clean-up of any spillage to ensure complete removal of any risk of contamination.

15. Vehicles shall be cleaned regularly. Equipment chosen and used for the cleaning of vehicles shall not constitute a source of contamination.

16. Premises shall be designed and equipped in order to afford protection against the entry of insects, rodents or other animals. A preventive pest control programme shall be in place.

17. Rest, wash and refreshment rooms for employees shall be adequately separated from the storage areas. The presence of food, drink, smoking material or medicinal products for personal use shall be prohibited in the storage areas.

Article 13

Temperature and environmental control

1. Suitable equipment and procedures shall be in place to check the environment where veterinary medicinal products are stored. Environmental factors to be considered include temperature, light, humidity and cleanliness of the premises.

2. An initial temperature mapping exercise shall be carried out on the storage area before use, under representative conditions. Temperature monitoring equipment shall be located according to the results of the mapping exercise, ensuring that monitoring devices are positioned in the areas that experience the extremes of fluctuations. The mapping exercise shall be repeated according to the results of a risk assessment exercise or whenever significant modifications are made to the facility or the temperature controlling equipment. For small premises of a few square meters that are at room temperature, an assessment of potential risks, such as heaters, shall be conducted and temperature monitors shall be placed accordingly.

Article 14

Equipment

1. All equipment with an impact on storage and distribution of veterinary medicinal products shall be designed, located and maintained to a standard suitable for its intended purpose. Planned maintenance shall be in place for key equipment vital to the functionality of the operation.

2. Equipment used to control or to monitor the environment where the veterinary medicinal products are stored shall be subject to calibration at defined intervals based on a risk and reliability assessment.

3. Calibration of equipment shall be traceable to a national or international measurement standard. Appropriate alarm systems shall be in place to provide alerts when there are excursions from pre-defined storage conditions. Alarm levels shall be appropriately set and alarms shall be regularly tested to ensure adequate functionality.

4. Equipment repair, maintenance and calibration operations shall be carried out in such a way that the integrity of the veterinary medicinal products is not compromised.

5. Defective vehicles and equipment shall not be used and shall either be labelled as such or removed from service.

6. Equipment not relevant for the wholesale activities shall not be stored in the area where veterinary medicinal products are stored.

7. Adequate records of repair, maintenance and calibration activities for key equipment, such as cold stores, monitored intruder alarm and access control systems, refrigerators, thermohygrometers, or other temperature and humidity recording devices, air handling units and any equipment used in conjunction with the onward supply chain, shall be made and the results shall be retained.

Article 15

Computerised systems

1. Before a computerised system is brought into use, it shall be demonstrated, through appropriate validation or verification studies, that the system is capable of achieving the desired results accurately, consistently and reproducibly.

2. A written, detailed description of the computerised system shall be available, including diagrams where appropriate. That description shall be kept up to date. The document shall describe principles, objectives, security measures, system scope and main features, how the system is used and the way it interacts with other systems.

3. Data shall only be entered into the computerised system or amended by persons authorised to do so.

4. Data shall be secured by physical or electronic means and protected against accidental or unauthorised modifications. Stored data shall be checked periodically for accessibility. Data shall be backed up at regular intervals. Backup data shall be retained at a separate and secure location for at least 5 years or for the period stated in the applicable national law, if that period is longer than 5 years.

5. Procedures to be followed if the system fails or breaks down shall be defined. This shall include systems for the restoration of data.

Article 16

Qualification and validation

1. The persons referred to in Article 1(2) shall identify what key equipment qualification and key process validation is necessary to ensure their correct installation and operation. The scope and extent of such qualification and validation activities such as storage, picking and packing processes, shall be determined using a documented risk assessment approach.

2. Equipment and processes shall be subject to qualification or validation, respectively, before commencing use and after any significant changes, such as repair or maintenance.

3. Qualification and validation reports shall be prepared summarising the results obtained and commenting on any deviations observed. The principles of CAPA shall be applied, where necessary. Evidence of satisfactory validation and acceptance of a process or piece of equipment shall be produced and approved by appropriate personnel.

CHAPTER V

DOCUMENTATION, PROCEDURES AND RECORD-KEEPING

Article 17

Documentation requirements

1. Documentation shall fulfil the following requirements:

(a) be readily available or retrievable;

(b) be sufficiently comprehensive with respect to the scope of the activities of the persons referred to in Article 1(2);

(c) be written in a language understood by personnel;

(d) be written in clear, unambiguous language.

2. Documentation shall be approved, signed and dated by appropriate authorised persons, as required. It shall not be handwritten, unless handwritten records are justified for practical reasons. In that case, sufficient space shall be provided to make those records.

3. When errors in the documentation are identified, they shall be corrected without delay, with clear traceability of who corrected them and when.

4. Any alteration made in the documentation shall be signed and dated. The alteration shall permit the reading of the original information. Where appropriate, the reason for the alteration shall be recorded.

5. Documents shall be retained for at least 5 years or for the period stated in the applicable national law, if that period is longer than 5 years. Personal data shall be deleted as soon as their storage is no longer necessary for the purpose of distribution activities.

6. Each employee shall have ready access to all necessary documentation for the tasks executed.

7. Relationships and control measures for original documents and official copies, data handling and records shall be stated for all paper-based, electronic and hybrid systems.

Article 18

Procedures

1. Procedures shall describe the wholesale distribution activities affecting the quality of veterinary medicinal products. Those activities include:

(a) receipt and checking of deliveries; suppliers and customers control;

(b) storage;

(c) cleaning and maintenance of the premises and equipment, including pest control;

(d) checking and recording of storage conditions;

(e) protection of veterinary medicinal products during transport;

(f) security of stocks on site and of consignments in transit;

(g) withdrawal from saleable stock;

(h) handling of returned veterinary medicinal products;

(i) recall plans;

(j) qualification and validation;

(k) procedures and measures for the disposal of unusable veterinary medicinal products;

(l) procedures for investigating and resolving complaints;

(m) procedures for identifying veterinary medicinal products suspected of falsification.

2. Procedures shall be approved, signed and dated by the responsible persons.

3. Valid and approved procedures shall be used. Documents shall be clear and appropriately detailed. The title, nature and purpose of documents shall be stated. Documents shall be reviewed regularly and kept up to date. Version control shall be applied to procedures. After revision of a document, a system shall exist to prevent inadvertent use of the superseded version. Superseded or obsolete procedures shall be removed from workstations and archived.

Article 19

Records

1. Records shall be kept either in the form of purchase or sales invoices, delivery slips, or in electronic form, for any transaction in veterinary medicinal products received or supplied.

2. In addition to the detailed records referred to in Article 101(7) of Regulation (EU) 2019/6, records shall include any additional requirements specified by national law, as appropriate.

3. Records shall be made at the time each operation is performed. If handwritten, they shall be made in clear, legible and indelible handwriting.

CHAPTER VI

OPERATIONS

Article 20

Requirements for operations

1. The persons referred to in Article 1(2) shall ensure that the identity of the veterinary medicinal product is not lost during wholesale distribution and shall use all means available to minimise the risk of falsified veterinary medicinal products entering the legal supply chain.

2. The persons referred to in Article 1(2) shall ensure that the wholesale distribution of veterinary medicinal products is performed according to the information on the outer packaging.

3. The persons referred to in Article 1(2) shall ensure that all veterinary medicinal products they distribute in the Union are:

(a) covered by a marketing authorisation granted by a competent authority or the Commission, as applicable;

(b) covered by a registration granted by a competent authority;

(c) covered by an exemption, granted by a competent authority, from the requirements for marketing authorisation;

(d) covered by an approval for parallel trade issued by the competent authority of the destination Member State;

(e) covered by a permission to use in accordance with Articles 110(2) and (3) of Regulation (EU) 2019/6; or

(f) in the case of products to be used under Articles 112(2), 113(2) or 114(4) of Regulation (EU) 2019/6, imported by holders of a manufacturing authorisation issued in accordance with Article 90 of that Regulation or in accordance with the procedures referred to in Article 106(3) of that Regulation, as applicable.

4. All key operations of the persons referred to in Article 1(2) shall be fully described in the quality system in appropriate documentation.

Article 21

Verification of eligibility and approval of suppliers

1. Where veterinary medicinal products are obtained from a person referred to in Article 1(2), the receiving wholesale distributor shall verify that the supplier complies with good distribution practice for veterinary medicinal products as laid down in this Regulation and that they hold an authorisation. This information shall be obtained from the national competent authorities or the Union database on manufacturing, import and wholesale distribution referred to in Article 91(1) of Regulation (EU) 2019/6. Appropriate verification of eligibility and approval of suppliers shall be performed prior to any procurement of veterinary medicinal products. This process shall be controlled by a procedure and the results documented and periodically checked based on quality risk management principles.

2. When entering into a contract with new suppliers, the persons referred to in Article 1(2) shall carry out so called due diligence checks in order to assess the suitability, competence and reliability of the other party. The due diligence checks shall consider:

(a) the reputation or reliability of the supplier;

(b) offers of veterinary medicinal products more likely to be falsified;

(c) large offers of veterinary medicinal products which are generally only available in limited quantities;

(d) unusually high diversity of veterinary medicinal products handled by supplier;

(e) abnormally low prices.

Article 22

Verification of eligibility and approval of customers

1. The persons referred to in Article 1(2) shall perform initial and, as appropriate, periodic checks to establish whether their customers meet the requirements laid down in Article 101(2) of Regulation (EU) 2019/6. This may include requesting copies of a customer's authorisations issued in accordance with national law, verifying status on a competent authority website and requesting evidence of qualifications or entitlement in accordance with national law.

2. The persons referred to in Article 1(2) shall monitor their transactions and investigate any irregularity in the sales patterns of narcotics, psychotropic substances or other dangerous substances. Unusual sales patterns that may constitute diversion or misuse of veterinary medicinal products shall be investigated and reported to competent authorities where necessary.

Article 23

Receipt of veterinary medicinal products

1. The persons responsible for receiving veterinary medicinal products shall ensure that the arriving consignment is correct, that the veterinary medicinal products originate from approved suppliers and that they have not been damaged during transport.

2. Veterinary medicinal products requiring special storage or security measures shall be prioritised and, once appropriate checks have been conducted, those products shall immediately be transferred to appropriate storage facilities.

3. Batches of veterinary medicinal products intended for the Union market shall not be transferred to saleable stock before assurance has been obtained in accordance with procedures, that they are authorised for sale. For batches coming from another Member State, prior to their transfer to saleable stock, the control report referred to in Article 97(6) and (9) of Regulation (EU) 2019/6, the results of necessary tests, as applicable, referred to in Article 97(7) of that Regulation or another proof of release to the market in question based on an equivalent system, shall be carefully checked by appropriately trained personnel.

Article 24

Storage

1. Veterinary medicinal products shall be stored separately from other products likely to alter them and shall be protected from the harmful effects of light, temperature, moisture and other external factors. Particular attention shall be paid to veterinary medicinal products requiring special storage conditions.

2. Incoming containers of veterinary medicinal products shall be cleaned, if necessary, before storage. Any activities performed on the incoming goods shall not impact on the quality of the veterinary medicinal products.

3. Warehousing operations shall be performed so as to ensure that appropriate storage conditions are maintained and allow for appropriate security of stocks.

4. Stock shall be rotated according to the 'first expiry, first out' principle. Exceptions shall be documented.

5. Veterinary medicinal products shall be handled and stored in such a manner as to prevent spillage, breakage, contamination and mix-ups. Veterinary medicinal products shall not be stored directly on the floor unless the package is designed to allow for such storage, such as for some medicinal gas cylinders.

6. Veterinary medicinal products that are nearing their expiry date shall immediately be segregated from saleable stock physically or, if an equivalent electronic system is available, electronically.

7. Stock inventories shall be performed regularly taking into account the requirements of national law. Stock irregularities shall be investigated and documented.

Article 25

Destruction of obsolete veterinary medicinal products

1. Veterinary medicinal products intended for destruction shall be appropriately identified, kept separately and handled in accordance with a procedure.

2. Destruction of veterinary medicinal products shall be carried out in accordance with the applicable requirements for handling, transport and disposal of such products.

3. Records of all destroyed veterinary medicinal products shall be retained for a period defined in the quality system referred to in Article 3.

Article 26

Picking

Controls shall be in place to ensure that the correct veterinary medicinal product is picked. The veterinary medicinal product picked shall have an appropriate remaining shelf life and shall not have been damaged during storage.

Article 27

Supply

1. An electronic or physical document shall accompany all supplies and include, in addition to the information referred to in Article 101(7) of Regulation (EU) 2019/6, a unique number to allow identification of the delivery order, the applicable transport and storage conditions and additional requirements specified by national law.

2. Electronic or physical records shall be kept so that the location of the veterinary medicinal product is known.

Article 28

Export

1. When exporting veterinary medicinal products for which neither a national competent authority, nor the Commission, as applicable, has granted a marketing authorisation in accordance with Chapter III of Regulation (EU) 2019/6, wholesale distributors shall take appropriate measures to prevent those veterinary medicinal products reaching the Union market.

2. Where the persons referred to in Article 1(2) supply veterinary medicinal products to persons in third countries, they shall only supply those products to persons who are authorised or entitled to receive veterinary medicinal products for wholesale distribution or for supply to the public in accordance with the applicable legal and administrative provisions of the third country concerned.

CHAPTER VII

COMPLAINTS, RETURNS, SUSPECTED FALSIFIED VETERINARY MEDICINAL PRODUCTS AND RECALLS

Article 29

Complaints

1. Complaints shall be recorded with all the original details. A distinction shall be made between complaints related to the quality of a veterinary medicinal product and those related to wholesale distribution.

In the event of a complaint about the quality of a veterinary medicinal product and a potential product defect, the manufacturer or marketing authorisation holder shall be informed without delay.

Any veterinary medicinal product distribution complaint shall be thoroughly investigated to identify the origin of or the reason for the complaint.

2. A person shall be appointed to handle complaints and sufficient personnel shall be allocated to support that person.

3. If necessary, appropriate follow-up actions (including CAPA) shall be taken after investigation and evaluation of the complaint, including, where required, notification to the national competent authorities.

Article 30

Returns

1. Returned veterinary medicinal products shall be handled according to a written, risk-based process taking into account the nature of the veterinary medicinal product concerned, any special storage conditions it requires and the time elapsed since it was supplied. Returns shall be conducted in accordance with national law and contractual arrangements between the parties.

2. Veterinary medicinal products which have left the care of the persons referred to in Article 1(2) shall only be returned to saleable stock if all of the following conditions are met:

(a) the veterinary medicinal products are in their unopened and undamaged secondary packaging and are in good condition;

(b) the veterinary medicinal products have not expired and have not been recalled;

(c) the veterinary medicinal products returned from a customer not holding a wholesale distribution authorisation or from pharmacies or persons authorised to supply veterinary medicinal products to the public in accordance with national law of the Member State concerned have been returned within a defined acceptable time limit determined by using quality risk management principles;

(d) the veterinary medicinal products have not been returned by the animal owner to the pharmacy or to other persons authorised to supply veterinary medicinal products to the public in accordance with national law of the Member State concerned, unless such return is permitted under national law of that Member State;

(e) it has been demonstrated by the customer that the veterinary medicinal products have been transported, stored and handled in compliance with their specific storage requirements;

(f) the veterinary medicinal products have been examined and assessed by a sufficiently trained and competent person authorised to do so;

(g) the persons referred to in Article 1(2) have reasonable evidence that the veterinary medicinal product was supplied to the customer returning the veterinary medicinal product, as evidenced by copies of the original delivery note or by referencing invoice numbers, batch numbers, expiry date etc., as required by national law, and that there is no reason to believe that the veterinary medicinal product has been falsified.

3. For veterinary medicinal products requiring specific temperature storage conditions such as low temperature, returns to saleable stock shall only be made if there is documented evidence that the product has been stored under the authorised storage conditions throughout the periods in points (a) to (f). If any deviation has occurred, a risk assessment shall be performed, which shall demonstrate the integrity of the veterinary medicinal product. The evidence shall cover all the following steps:

(a) delivery to the customer;

(b) examination of the veterinary medicinal product;

(c) opening of the transport packaging;

(d) return of the veterinary medicinal product to the packaging;

(e) collection and return to the persons referred to in Article 1(2);

(f) return to the wholesale distribution site refrigerator.

4. Products returned to saleable stock shall be placed so that the 'first expiry, first out' system operates effectively.

5. Stolen veterinary medicinal products that have been recovered shall not be returned to saleable stock nor sold to customers.

Article 31

Falsified veterinary medicinal products

1. In addition to the notification referred to in Article 101(6) of Regulation (EU) 2019/6, wholesale distributors shall immediately stop the distribution of any veterinary medicinal products they identify as falsified or suspected to be falsified and act on the instructions as specified by the competent authorities. A procedure shall be in place to this effect. The incident shall be recorded with all the original details and investigated.

2. Any suspected falsified veterinary medicinal products found in the supply chain shall immediately be segregated physically or, if an equivalent electronic system is available, electronically. Any falsified veterinary medicinal products found in the supply chain shall immediately be segregated physically, stored in a dedicated area away from all other veterinary medicinal products and appropriately labelled. All relevant activities in relation to such products shall be documented and records retained.

Article 32

Recalls

1. There shall be documentation and procedures in place to ensure that veterinary medicinal products received and distributed are traceable for the purposes of any product recall.

2. In the event of a veterinary medicinal product recall, the persons referred to in Article 1(2) shall inform, with the appropriate degree of urgency and clear actionable instructions, all affected customers to whom the product has been distributed.

3. The persons referred to in Article 1(2) shall inform the relevant national competent authority of all veterinary medicinal product recalls. If the veterinary medicinal product is exported, the persons referred to in Article 1(2) shall inform the third country clients or the third country competent authorities of the recall as required by national law.

4. The persons referred to in Article 1(2) shall regularly evaluate the effectiveness of the arrangements for veterinary medicinal product recall on the basis of quality risk management principles.

5. The persons referred to in Article 1(2) shall ensure that recall operations can be initiated promptly and at any time.

6. The persons referred to in Article 1(2) shall follow the instructions of a recall message, which shall be approved, if required, by the competent authorities.

7. Any recall operation shall be recorded at the time it is carried out. Records shall be made readily available to the competent authorities.

8. The distribution records shall be readily accessible to the persons responsible for the recall and shall contain sufficient information on distributors and directly supplied customers (with addresses, phone numbers and means of electronic communication inside and outside working hours, batch numbers as required by national law and quantities delivered), including those records for exported veterinary medicinal products and veterinary medicinal product samples.

9. The progress of the recall process shall be recorded in a final report including reconciliation between the delivered and recovered quantities of the recalled veterinary medicinal product.

CHAPTER VIII

OUTSOURCED ACTIVITIES

Article 33

Obligations of contract giver

1. The contract giver shall be responsible for any activities contracted out.

2. The contract giver shall be responsible for assessing the competence of the contract acceptor to successfully carry out the work required and for ensuring by means of the contract and through audits that the principles of good distribution practice for veterinary medicinal products are followed. The contract giver shall perform an audit of the contract acceptor before commencement of the outsourced activities and shall monitor and review the performance of the contract acceptor. The frequency of audit shall be defined based on risk, depending on the nature of the outsourced activities. Where there has been a change to outsourced activities, the contract giver shall apply risk assessment as part of change control to determine if re-audit is required. The contract acceptor shall permit the contract giver to audit the outsourced activities.

3. The contract giver shall provide the contract acceptor with all the information necessary to carry out the contracted operations in accordance with the specific veterinary medicinal product requirements and any other relevant requirements.

Article 34

Obligations of contract acceptor

1. The contract acceptor shall have adequate equipment, procedures, knowledge and experience, competent personnel to carry out the work ordered by the contract giver and if required for the activity, premises.

2. The contract acceptor shall not subcontract out any of the work under the contract to a third party without the contract giver's prior evaluation and approval of the arrangements and an audit of the third party by the contract giver or the contract acceptor. Arrangements made between the contract acceptor and any third party shall provide that the wholesale distribution information is made available in the same way as between the original contract giver and contract acceptor.

3. The contract acceptor shall refrain from any activity that may adversely affect the quality of the veterinary medicinal products handled for the contract giver.

4. The contract acceptor shall forward any information that may influence the quality of the veterinary medicinal products to the contract giver in accordance with the requirements of the contract.

CHAPTER IX

SELF-INSPECTIONS

Article 35

Self-inspection programme

A self-inspection programme shall be implemented covering all aspects of good distribution practice for veterinary medicinal products and compliance with this Regulation and procedures within a defined time frame.

Article 36

Conduct and recording of self-inspections

1. Self-inspections may be divided into several individual self-inspections of limited scope.

2. Self-inspections shall be conducted in an impartial and detailed way by designated competent personnel. Audits by independent external experts may not be used as a substitute for self-inspection.

3. All self-inspections shall be recorded. Reports shall contain all the observations made during the inspection. A copy of the report shall be provided to the management and other relevant persons.

4. In the event that irregularities or deficiencies are observed, their cause shall be determined and the CAPA shall be documented and followed up. The effectiveness of the CAPA shall be reviewed.

CHAPTER X

TRANSPORT

Article 37

Transport requirements

1. The persons referred to in Article 1(2) supplying veterinary medicinal products shall be responsible for protecting those veterinary medicinal products against breakage, adulteration and theft, and for ensuring that temperature conditions are maintained within acceptable limits during transport and shall, whenever possible, monitor such conditions.

2. During transport, the required storage or transport conditions, as appropriate, for veterinary medicinal products shall be maintained within the defined limits as described by the manufacturers and marketing authorisation holders or as stated on the outer packaging.

3. If a deviation such as temperature excursion or veterinary medicinal product damage has occurred during transport, this shall be reported to the persons referred to in Article 1(2) and to the consignee of the affected veterinary medicinal products in order for them to assess the potential impact on the quality of the veterinary medicinal products concerned. A procedure shall be in place for investigating and handling temperature excursions.

4. The persons referred to in Article 1(2) shall ensure that vehicles and equipment used to distribute, store or handle veterinary medicinal products are suitable for their use and appropriately equipped to prevent exposure of the veterinary medicinal products to conditions that could affect their quality and packaging integrity.

5. There shall be procedures in place for the operation and maintenance of all vehicles and equipment involved in the distribution process, including cleaning and safety precautions.

6. Equipment chosen and used for the cleaning of vehicles shall not constitute a source of contamination.

7. Risk assessment of delivery routes shall be used to determine where temperature controls are required. Equipment used for temperature monitoring during transport within vehicles or containers shall be maintained and subject to calibration at regular intervals determined on the basis of quality risk management principles.

8. Dedicated vehicles and equipment shall be used, where possible, when handling both veterinary medicinal products and medicinal products for human use. Where non-dedicated vehicles and equipment are used, procedures shall be in place to ensure that the quality of the veterinary medicinal products will not be compromised.

9. Deliveries shall be made to the address stated on the delivery note and into the care or the premises of the consignee. Veterinary medicinal products shall never be left on alternative premises.

10. For emergency deliveries outside normal business hours, persons shall be designated and procedures shall be available.

11. Where transport is performed by a third party, the contract in place shall encompass the requirements of Articles 33 and 34 and clearly state that third party's obligations for ensuring compliance with good distribution practice for veterinary medicinal products. The persons referred to in Article 1(2) shall make transport providers aware of the relevant transport conditions applicable to the consignment.

12. Where the transport route includes unloading and reloading or transit storage at a transport hub, any intermediate storage facilities shall be clean and secure and shall allow for temperature monitoring, as applicable.

13. Provision shall be made to minimise the duration of temporary storage while awaiting the next stage of the transport route.

Article 38

Containers, packaging and labelling

1. Veterinary medicinal products shall be transported in containers that have no adverse effect on the quality of the veterinary medicinal products and that offer adequate protection from external influences, including contamination.

2. Selection of a container and packaging shall be based on the following:

(a) the storage and transport requirements for the veterinary medicinal products;

(b) the space required for the amount of veterinary medicinal products;

(c) the pharmaceutical forms, also including medicated premixes;

(d) the anticipated external temperature extremes;

(e) the estimated maximum time for transport including transit storage at customs;

(f) the qualification status of the packaging;

(g) the validation status of the shipping containers.

3. Containers shall bear labels providing sufficient information on handling and storage requirements and precautions to ensure that the veterinary medicinal products are properly handled and secured at all times. The containers shall enable identification of the contents of the containers and the source.

Article 39

Products requiring special conditions

1. In relation to deliveries containing veterinary medicinal products requiring special conditions such as narcotics or psychotropic substances, the persons referred to in Article 1(2) shall maintain a safe and secure supply chain for these products in accordance with requirements laid down by the Member States concerned. There shall be additional control systems in place for delivery of these products. There shall be a protocol to address the occurrence of any theft.

2. Veterinary medicinal products comprising highly active materials shall be transported in safe, dedicated and secure containers and vehicles in accordance with the applicable safety measures.

3. For temperature-sensitive veterinary medicinal products, equipment subject to qualification, such as thermal packaging, temperature-controlled containers or temperature-controlled vehicles, shall be used to ensure that correct transport conditions are maintained between the manufacturer, wholesale distributor and customer, unless stability of the product has been demonstrated with other transport conditions.

4. If temperature-controlled vehicles are used, the temperature monitoring equipment used during transport shall be maintained and subject to calibration at regular intervals. Temperature mapping under representative conditions shall be carried out and shall take into account seasonal variations.

5. If requested by customers with adequate justification and in any case in the event of incident, the persons referred to in Article 1(2) shall provide the customers with information to demonstrate that veterinary medicinal products have complied with the temperature storage or transport conditions.

6. If cool-packs are used in insulated boxes, they shall be placed in such a way to ensure the veterinary medicinal product does not come in direct contact with the cool-pack.

7. Personnel shall be trained on the procedures for assembly of insulated boxes, including in function of the season, and on the reuse of cool-packs.

8. The persons referred to in Article 1(2) shall have a system in place to control the re-use of cool-packs to ensure that incompletely cooled packs are not used in error. The persons referred to in Article 1(2) shall ensure that there is adequate physical segregation between frozen and chilled ice packs.

9. The persons referred to in Article 1(2) shall describe the process for delivery of sensitive veterinary medicinal products and control of seasonal temperature variations in a procedure.

CHAPTER XI

FINAL PROVISIONS

Article 40

Entry into force and application

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, 29 July 2021.

For the Commission
The President
Ursula VON DER LEYEN

DECISIONS

COUNCIL DECISION (EU) 2021/1249

of 26 July 2021

on the position to be adopted, on behalf of the European Union, within the EEA Joint Committee concerning an amendment to Protocol 31 on cooperation in specific fields outside of the four freedoms, annexed to the EEA Agreement (Budget line 07 20 03 01 – Social Security)

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 46 and 48 in conjunction with Article 218(9) thereof,

Having regard to Council Regulation (EC) No 2894/94 of 28 November 1994 concerning arrangements for implementing the Agreement on the European Economic Area ([1]), and in particular Article 1(3) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) The Agreement on the European Economic Area ([2]) ('the EEA Agreement') entered into force on 1 January 1994.

(2) Pursuant to Article 98 of the EEA Agreement, the EEA Joint Committee may decide to amend, inter alia, Protocol 31 on cooperation in specific fields outside the four freedoms ('Protocol 31'), annexed to the EEA Agreement.

(3) It is appropriate to continue the cooperation of the Contracting Parties to the EEA Agreement in Union actions funded from the general budget of the Union regarding the free movement of workers, coordination of social security schemes and measures for migrants, including migrants from third countries.

(4) Protocol 31 to the EEA Agreement should therefore be amended in order to allow for such extended cooperation to continue from 1 January 2021.

(5) The position of the Union within the EEA Joint Committee should be based on the draft decision of the EEA Joint Committee,

HAS ADOPTED THIS DECISION:

Article 1

The position to be adopted, on behalf of the Union, within the EEA Joint Committee on the proposed amendment of Protocol 31 on cooperation in specific fields outside the four freedoms, annexed to the EEA Agreement, shall be based on the draft decision of the EEA Joint Committee ([3]).

Article 2

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

([1]) OJ L 305, 30.11.1994, p. 6.
([2]) OJ L 1, 3.1.1994, p. 3.
([3]) See document ST 10507/21 at http://register.consilium.europa.eu.

Done at Brussels, 26 July 2021.

For the Council
The President
G. DOVŽAN

COUNCIL DECISION (EU) 2021/1250

of 26 July 2021

on the position to be adopted on behalf of the European Union, within the EEA Joint Committee concerning an amendment to Protocol 31 on cooperation in specific fields outside the four freedoms, annexed to the EEA Agreement (European Defence Fund)

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 173(3), Article 182(4), Article 183 and the second paragraph of Article 188, in conjunction with Article 218(9) thereof,

Having regard to Council Regulation (EC) No 2894/94 of 28 November 1994 concerning arrangements for implementing the Agreement on the European Economic Area ([1]), and in particular Article 1(3) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) The Agreement on the European Economic Area ([2]) ('the EEA Agreement') entered into force on 1 January 1994.

(2) Pursuant to Article 98 of the EEA Agreement, the EEA Joint Committee may decide to amend, inter alia, Protocol 31 on cooperation in specific fields outside the four freedoms ('Protocol 31'), annexed to the EEA Agreement.

(3) Regulation (EU) 2021/697 of the European Parliament and of the Council ([3]) is to be incorporated into the EEA Agreement.

(4) Protocol 31 to the EEA Agreement should therefore be amended accordingly.

(5) The position of the Union in the EEA Joint Committee should therefore be based on the draft decision of the EEA Joint Committee,

HAS ADOPTED THIS DECISION:

Article 1

The position to be adopted on behalf of the Union within the EEA Joint Committee on the proposed amendment of Protocol 31 on cooperation in specific fields outside the four freedoms, annexed to the EEA Agreement, shall be based on the draft decision of the EEA Joint Committee ([4]).

Article 2

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

([1]) OJ L 305, 30.11.1994, p. 6.
([2]) OJ L 1, 3.1.1994, p. 3.
([3]) Regulation (EU) 2021/697 of the European Parliament and of the Council of 29 April 2021 establishing the European Defence Fund and repealing Regulation (EU) 2018/1092 (OJ L 170, 12.5.2021, p. 149).
([4]) See document ST 10693/21 at http://register.consilium.europa.eu.

Done at Brussels, 26 July 2021.

For the Council
The President
G. DOVŽAN

COUNCIL DECISION (CFSP) 2021/1251

of 29 July 2021

amending Decision (CFSP) 2015/1333 concerning restrictive measures in view of the situation in Libya

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 31 July 2015 the Council adopted Decision (CFSP) 2015/1333 ([1]).

(2) Pursuant to Article 17(2) of Decision (CFSP) 2015/1333, the Council has reviewed the lists of designated persons and entities set out in Annexes II and IV to that Decision.

(3) The Council has concluded that the entries for one person, who is deceased, and another person, with regard to whom restrictive measures applied until 2 April 2021, should be deleted and that restrictive measures against all other persons and entities in the lists set out in Annexes II and IV to Decision (CFSP) 2015/1333 should be maintained. In addition, the identifying information for one person should be updated.

(4) Decision (CFSP) 2015/1333 should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Decision (CFSP) 2015/1333 is amended as follows:

(1) in Article 17, paragraphs 3 and 4 are deleted;

(2) Annexes II and IV are amended in accordance with the Annex to this Decision.

Article 2

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, 29 July 2021.

For the Council
The President
G. DOVŽAN

([1]) Council Decision (CFSP) 2015/1333 of 31 July 2015 concerning restrictive measures in view of the situation in Libya, and repealing Decision 2011/137/CFSP (OJ L 206, 1.8.2015, p. 34).

ANNEX

Decision (CFSP) 2015/1333 is amended as follows:

(1) in Annex II (List of persons and entities referred to in Article 8(2)), Part A (Persons) is amended as follows:

(a) entry 4 (concerning TOHAMI, General Khaled) is deleted;

(b) entry 7 (concerning AL-MAHMOUDI, Baghdadi) is replaced by the following:

'7.	AL-MAHMOUDI, Baghdadi a.k.a. AL-MAHMOUDI Al-Baghdadi, Ali AL-MAHMOUDI AL-BAGHDADI, Ali	Place of birth: Alassa, Libya Nationality: Libya Gender: male Address: Abu Dhabi, United Arab Emirates	Prime Minister of Colonel Qadhafi's Government. Closely associated with the former regime of Muammar Qadhafi.	21.3.2011'

(c) entry 15 (concerning GHWELL, Khalifa) is deleted;

(2) in Annex IV (List of persons and entities referred to in Article 9(2)), Part A (Persons) is amended as follows:

(a) entry 4 (concerning TOHAMI, General Khaled) is deleted;

(b) entry 7 (concerning AL-MAHMOUDI, Baghdadi) is replaced by the following:

'7.	AL-MAHMOUDI, Baghdadi a.k.a. AL-MAHMOUDI Al-Baghdadi, Ali AL-MAHMOUDI AL-BAGHDADI, Ali	Place of birth: Alassa, Libya Nationality: Libya Gender: male Address: Abu Dhabi, United Arab Emirates	Prime Minister of Colonel Qadhafi's Government. Closely associated with the former regime of Muammar Qadhafi.	21.3.2011'

(c) entry 20 (concerning GHWELL, Khalifa) is deleted.

COUNCIL DECISION (CFSP) 2021/1252

of 29 July 2021

amending Decision 2010/413/CFSP concerning restrictive measures against Iran

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 26 July 2010, the Council adopted Decision 2010/413/CFSP ([1]) concerning restrictive measures against Iran.

(2) On 18 June 2020, the Council adopted Decision (CFSP) 2020/849 ([2]), amending Decision 2010/413/CFSP.

(3) Following the judgment of the General Court in Case T-580/19 ([3]), Sayed Shamsuddin Borborudi should be removed from the list of persons and entities subject to restrictive measures set out in Annex II to Decision 2010/413/CFSP.

(4) In accordance with Article 26(3) of Decision 2010/413/CFSP, the Council has also reviewed the list of designated persons and entities set out in Annex II to that Decision.

(5) On the basis of that review, the restrictive measures against all persons and entities in the list set out in Annex II to Decision 2010/413/CFSP should be maintained, in so far as their names are not mentioned in Annex VI to that Decision, and 21 entries included in Annex II should be updated.

(6) Decision 2010/413/CFSP should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Annex II to Decision 2010/413/CFSP is amended as set out in the Annex to this Decision.

Article 2

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, 29 July 2021.

For the Council
The President
G. DOVŽAN

([1]) Council Decision 2010/413/CFSP of 26 July 2010 concerning restrictive measures against Iran and repealing Common Position 2007/140/CFSP (OJ L 195, 27.7.2010, p. 39).

([2]) Council Decision (CFSP) 2020/849 of 18 June 2020 amending Decision 2010/413/CFSP concerning restrictive measures against Iran (OJ L 196, 19.6.2020, p. 8).

([3]) Judgment of the General Court of 9 June 2021, *Sayed Shamsuddin Borborudi* v *Council of the European Union*, T-580/19, ECLI:EU:T:2021:330.

ANNEX

Annex II to Decision 2010/413/CFSP is amended as follows:

(1) under the heading 'I. Persons and entities involved in nuclear or ballistic missile activities and persons and entities providing support to the Government of Iran.', under the subheading 'A. Persons', the following entry is deleted: '25. Sayed Shamsuddin Borborudi'.

(2) under the heading 'I. Persons and entities involved in nuclear or ballistic missile activities and persons and entities providing support to the Government of Iran.', the following entries replace the corresponding entries in the list set out under the subheading 'A. Persons':

	Name	Identifying information	Reasons	Date of listing
'8.	Ebrahim MAHMUDZADEH		Former Managing Director of Iran Electronic Industries (see Part B, No 20). Director general of the Armed Forces Social Security Organization until September 2020. Iranian Deputy Defense Minister until December 2020.	23.6.2008
13.	Anis NACCACHE		Former administrator of Barzagani Tejarat Tavanmad Saccal companies; his company has attempted to procure sensitive goods for entities designated under Resolution 1737 (2006).	23.6.2008
16.	Rear Admiral Mohammad SHAFI'I RUDSARI (a.k.a. ROODSARI, Mohammad, Hossein, Shafiei; ROODSARI, Mohammad, Shafi'I; ROODSARI, Mohammad, Shafiei; RUDSARI, Mohammad, Hossein, Shafiei; RUDSARI, Mohammad, Shafi'I; RUDSARI, Mohammad, Shafiei)		Former MODAFL Deputy for Coordination (see Part B, n°29).	23.6.2008
17.	Abdollah SOLAT SANA (a.k.a. Solatsana Solat Sanna; Sowlat Senna; Sovlat Thana)		Managing Director of the Uranium Conversion Facility (UCF) in Esfahan. This is the facility that produces the feed material (UF6) for the enrichment facilities at Natanz. On 27 August 2006, Solat Sana received a special award from President Ahmadinejad for his role.	23.4.2007
23.	Davoud BABAEI		The current head of security for the Ministry Of Defence Armed Forces Logistics' research institute the Organisation of Defensive Innovation and Research (SPND), which was run by UN-designated Mohsen Fakhrizadeh-Mahabadi. The IAEA have identified SPND with their concerns over possible military dimensions to Iran's nuclear programme over which Iran refuses to co-operate. As head of security, Babaei is responsible for preventing the disclosure of information, including to the IAEA.	1.12.2011

	Name	Identifying information	Reasons	Date of listing
29.	Milad JAFARI (Milad JAFERI)	DOB: 20.9.1974	An Iranian national supplying goods, mostly metals, to UN designated SHIG front companies. Delivered goods to SHIG between January and November 2010. Payments for some of the goods were made at the central branch of EU-designated Export Development Bank of Iran (EDBI) in Tehran after November 2010.	1.12.2011'

(3) under the heading 'I. Persons and entities involved in nuclear or ballistic missile activities and persons and entities providing support to the Government of Iran.', the following entries replace the corresponding entries in the list set out under the subheading 'B. Entities':

	Name	Identifying information	Reasons	Date of listing
'2.	Armed Forces Geographical Organisation		A subsidiary of MODAFL assessed to provide geospatial data for the Ballistic Missile programme.	23.6.2008
20.	Iran Electronics Industries (including all branches) and subsidiaries:	P. O. Box 18575-365, Tehran, Iran	Wholly-owned subsidiary of MODAFL (and therefore a sister-organisation to AIO, AvIO and DIO). Its role is to manufacture electronic components for Iranian weapons systems.	23.6.2008
	(b) Iran Communications Industries (ICI) (a.k.a. Sanaye Mokhaberat Iran; Iran Communication Industries; Iran Communications Industries Group; Iran Communications Industries Co.)	PO Box 19295- 4731, Pasdaran Avenue, Tehran, Iran; Alternative address: PO Box 19575- 131, 34 Apadana Avenue, Tehran, Iran; Alternative address: Shahid Langary Street, Nobonyad Square Ave, Pasdaran, Tehran	Iran Communications Industries, a subsidiary of Iran Electronics Industries (listed by the EU), produces various items including communication systems, avionics, optics and electro-optics devices, micro-electronics, information technology, test and measurement, telecommunication security, electronic warfare, radar tube manufacture and refurbishment, and missile launchers.	26.7.2010
28.	Mechanic Industries Group (a.k.a.: Mechanic Industries Organisation; Mechanical Industries Complex; Mechanical Industries Group; Sanaye Mechanic)		Took part in the production of components for the ballistics programme.	23.6.2008
37.	Schiller Novin (a.k.a.: Schiler Novin Co.; Schiller Novin Co.; Shiller Novin)	Gheytariyeh Avenue - no 153 - 3rd Floor - PO BOX 17665/153 6 19389 Tehran	Acting on behalf of Defense Industries Organisation (DIO).	26.7.2010

	Name	Identifying information	Reasons	Date of listing
38.	Shahid Ahmad Kazemi Industrial Group (SAKIG)		Entity subordinate to Iran's Aerospace Industries Organisation (AIO). SAKIG develops and produces surface-to-air missiles systems for Iran's military. It maintains military, missile, and air defense projects and procures goods from Russia, Belarus, and North Korea.	26.7.2010
40.	State Purchasing Organisation (SPO, a.k.a. State Purchasing Office; State Purchasing Organization)		The SPO appears to facilitate the import of whole weapons. It appears to be a subsidiary of MODAFL.	23.6.2008
52.	Raad Iran (a.k.a. Raad Automation Company; Middle East Raad Automation; RAAD Automation Co.; Raad Iran Automation Co.; RAADIRAN, Middle East RAAD Automation Co.; Automasion RAAD Khavar Mianeh; Automation Raad Khavar Mianeh Nabbet Co)	Unit 1, No 35, Bouali Sina Sharghi, Chehel Sotoun Street, Fatemi Square, Tehran	A company involved in procurement of inverters for Iran's proscribed enrichment programme. Raad Iran was established to produce and design controlling systems and provides the sale and installation of inverters and programmable Logic Controllers.	23.5.2011
86.	Karanir (a.k.a Karanir Sanat, Moaser; Tajhiz Sanat)	1139/1 Unit 104 Gol Building, Gol Alley, North Side of Sae, Vali Asr Avenue. PO Box 19395-6439, Tehran	Involved in purchasing equipment and materials, which have direct applications in the Iranian nuclear programme.	1.12.2011
95.	Samen Industries (a.k.a. Khorasan Metallurgy Industries)	2nd km of Khalaj Road End of Seyyedi St., P.O.Box 91735-549, 91735 Mashhad, Iran, Tel.: +98 511 3853008, +98 511 3870225	Shell name for UN-designated Khorasan Metallurgy Industries, subsidiary of Ammunition Industries Group (AMIG).	1.12.2011
99.	TABA (Iran Cutting Tools Manufacturing company - Taba Towlid Abzar Boreshi Iran; a.k.a. Iran Centrifuge Technology Co.; Iran's Centrifuge Technology Company; Sherkate Technology Centrifuge Iran, TESA, TSA)	12 Ferdowsi, Avenue Sakhaee, avenue 30 Tir (sud), nr 66 – Tehran	Owned or controlled by EU-sanctioned TESA, Involved in manufacturing equipment and materials, which have direct applications in the Iranian nuclear programme.	1.12.2011
153.	Organisation of Defensive Innovation and Research (SPND)		The Organisation of Defensive Innovation and Research (SPND) directly supports Iran's proliferation sensitive nuclear activities. The IAEA has identified SPND with their concerns over possible military dimensions (PMD) to Iran's nuclear programme. SPND was run by UN-designated Mohsen Fakhrizadeh-Mahabadi and is part of the Ministry of Defence For Armed Forces Logistics (MODAFL) designated by the EU.	22.12.2012

	Name	Identifying information	Reasons	Date of listing
161.	Sharif University of Technology	Last address known: Azadi Ave/Street, PO Box 11365-11155, Tehran, Iran, Tel. +98 21 66 161 Email: info@sharif.ir	Sharif University of Technology (SUT) has a number of cooperation agreements with Iranian Government organisations which are designated by the UN and/or the EU and which operate in military or military-related fields, particularly in the field of ballistic missile production and procurement. This includes: an agreement with the EU-designated Aerospace Industries Organisation for, inter alia, the production of satellites; cooperating with the Iranian Ministry of Defence and the Iranian Revolutionary Guards Corps (IRGC) on smart boat competitions; a broader agreement with the IRGC Air Force which covers developing and strengthening the University's relations, organisational and strategic cooperation. Taken together, these show a significant record of engagement with the Government of Iran in military or military-related fields that constitutes support to the Government of Iran.	8.11.2014'

(4) under the heading 'II. Islamic Revolutionary Guard Corps.', the following entries replace the corresponding entries in the list set out under the subheading 'A. Persons':

	Name	Identifying information	Reasons	Date of listing
'2.	Rear Admiral Ali FADAVI		Deputy Chief of the Islamic Revolutionary Guard Corps (IRGC). Former Commander of IRGC Navy.	26.7.2010
6.	IRGC Mohammad Ali JAFARI		Former Commander of the IRGC. Currently head of the Hazrat Baqiatollah al-Azam Cultural and Social Headquarters.	23.6.2008'

(5) under the heading 'II. Islamic Revolutionary Guard Corps.', the following entry replaces the corresponding entry in the list set out under the subheading 'B. Entities':

	Name	Identifying information	Reasons	Date of listing
'12.	Etemad Amin Invest Co Mobin (a.k.a.: Etemad Amin Investment Company Mobin; Etemad-e Mobin, Etemad Amin Invest Company Mobin; Etemad Mobin Co.; Etemad Mobin Trust Co.; Etemade Mobin Company; Mobin Trust Consortium; Etemad-e Mobin Consortium)	Pasadaran Av. Tehran, Iran	A company owned or controlled by IRGC that contributes to financing the strategic interests of the regime.	26.7.2010'.

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