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⁽¹⁾ Text with EEA relevance.

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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.

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II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2021/1340

of 22 April 2021

supplementing Directive 2014/59/EU of the European Parliament and of the Council with regard to regulatory technical standards determining the content of the contractual terms on recognition of resolution stay powers**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2014/59/EU of the European Parliament and of the Council of 15 May 2014 establishing a framework for the recovery and resolution of credit institutions and investment firms and amending Council Directive 82/891/EEC and Directives 2001/24/EC, 2002/47/EC, 2004/25/EC, 2005/56/EC, 2007/36/EC, 2011/35/EU, 2012/30/EU and 2013/36/EU, and Regulations (EU) No 1093/2010 and (EU) No 648/2012 of the European Parliament and of the Council ⁽¹⁾, and in particular Article 71a(5), third subparagraph thereof,

Whereas:

- (1) Directive 2014/59/EU as amended by Directive (EU) 2019/879 of the European Parliament and of the Council ⁽²⁾ introduced certain safeguards to enhance effective resolution execution in relation to financial contracts governed by third-country law.
- (2) In accordance with Article 71a(1) of Directive 2014/59/EU, institutions and entities are required to include terms that recognise the stay powers of resolution authorities in their financial contracts that they enter into and which are governed by third-country law.
- (3) In order to improve the efficiency of resolution, Article 68 of Directive 2014/59/EU lays down that certain crisis prevention measures or crisis management measures should not be deemed to be enforcement events or as insolvency proceedings. Furthermore, that article lays down that such measures should not entitle contracting counterparties in relevant contracts to exercise certain contractual rights solely as a result of the application of such measures. It is therefore necessary to include the parties' acceptance to be bound by these requirements in the content of the contractual terms. In addition, under Articles 33a, 69, 70 and 71 of Directive 2014/59/EU, resolution authorities may, for a limited period of time, suspend contractual payment or delivery obligations due under a contract with an institution or an entity under resolution or in certain circumstances before resolution, restrict the enforcement of security interests and suspend certain rights of counterparties to, for instance, close out, net gross obligations, accelerate future payments or otherwise terminate financial contracts. As these powers of the resolution authorities might not be effective when applied to financial contracts under third-country law, they should be explicitly recognised in the terms of financial contracts.

⁽¹⁾ OJ L 173, 12.6.2014, p. 190.

⁽²⁾ Directive (EU) 2019/879 of the European Parliament and of the Council of 20 May 2019 amending Directive 2014/59/EU as regards the loss-absorbing and recapitalisation capacity of credit institutions and investment firms and Directive 98/26/EC (OJ L 150, 7.6.2019, p. 296).

- (4) In order to ensure the effectiveness of resolution and promote consistency in the approaches adopted by Member States, and in order to ensure that differences in their legal systems or differences arising from a particular contractual form or structure can be taken into account by resolution authorities, institutions and entities, it is appropriate to lay down the mandatory content for the contractual terms. The content of these contractual terms should take into account institutions' and entities' different business models. However, as financial contracts in international transactions generally do not vary in accordance with the institutions' or the entities' business model, it is not necessary to create different content for contractual recognition clauses.
- (5) This Regulation is based on the draft regulatory technical standards submitted to the Commission by the European Banking Authority (EBA).
- (6) The EBA has conducted open public consultations on the draft regulatory technical standards on which this Regulation is based, analysed the potential related costs and benefits and requested the advice of the Banking Stakeholder Group established in accordance with Article 37 of Regulation (EU) No 1093/2010 of the European Parliament and of the Council ⁽³⁾,

HAS ADOPTED THIS REGULATION:

Article 1

Content of the contractual terms

The contractual recognition terms of a relevant financial contract governed by third-country law which an institution or entity, as referred to in Article 1(1), point (b), (c) or (d), of Directive 2014/59/EU enters into, shall include the following:

- (1) the acknowledgement and acceptance by the parties that the contract may be subject to the exercise of powers by a resolution authority to suspend or restrict rights and obligations arising from such a contract under Articles 33a, 69, 70 and 71 of Directive 2014/59/EU as transposed by the applicable national law and that the conditions set out in Article 68 of that Directive as transposed by the applicable national law will apply.
- (2) a description of or a reference to the powers of the resolution authority as set out in Articles 33a, 69, 70 and 71 of Directive 2014/59/EU, as transposed by the applicable national law, and a description of or a reference to the conditions of Article 68 of Directive 2014/59/EU as transposed by the applicable national law.
- (3) the acknowledgement and acceptance by the parties:
 - (a) that they are bound by the effect of an application of the following powers:
 - the suspension of any payment or delivery obligation in accordance with Article 33a of Directive 2014/59/EU as transposed by the applicable national law;
 - the suspension of any payment or delivery obligation in accordance with Article 69 of Directive 2014/59/EU as transposed by the applicable national law;
 - the restriction of enforcement of any security interest in accordance with Article 70 of Directive 2014/59/EU as transposed by the applicable national law;
 - the suspension of any termination right under the contract in accordance with Article 71 of Directive 2014/59/EU as transposed by the applicable national law;
 - (b) that they are bound by the provisions of Article 68 of Directive 2014/59/EU as transposed by the applicable national law;
- (4) the acknowledgement and acceptance by the parties that the contractual recognition terms are exhaustive on the matters described therein to the exclusion of any other agreements, arrangements or understandings between the counterparties relating to the subject matter of the relevant agreement.

⁽³⁾ Regulation (EU) No 1093/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Banking Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/78/EC (OJ L 331, 15.12.2010, p. 12).

*Article 2***Entry into force**

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, 22 April 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION DELEGATED REGULATION (EU) 2021/1341**of 23 April 2021****supplementing Regulation (EU) 2019/2144 of the European Parliament and of the Council by laying down detailed rules concerning the specific test procedures and technical requirements for the type-approval of motor vehicles with regard to their driver drowsiness and attention warning systems 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 point (a) of 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 driver drowsiness and attention warning ('DDAW') systems. It lays down in its Annex II basic requirements for the type-approval of motor vehicles with regard to the driver drowsiness and attention warning systems.
- (2) Detailed rules are necessary concerning the specific test procedures and technical requirements for the type-approval of motor vehicles with regard to driver drowsiness and attention warning systems.
- (3) Fatigue negatively affects driver's physical, cognitive, psychomotor and sensory processing capabilities, which are needed for safe driving. Driver fatigue is a factor in 10-25 % of all road crashes in the Union.
- (4) In accordance with Article 3, point (5), of Regulation (EU) 2019/2144 the DDAW system is a system that assesses the driver's alertness through vehicle systems analysis and warns the driver if needed via the vehicle's human-machine interface.
- (5) DDAW systems are more effective outside the urban zones because the reduced driver alertness due to fatigue mostly occurs in long-distance driving at a constant speed. Moreover, constantly changing driving and steering pattern when driving within urban zones is difficult for assessment with the available technologies. Motor vehicles with a maximum design speed of 70 km/h or below should therefore be exempted from the obligation to be equipped with DDAW systems.
- (6) The DDAW systems assess the human physical state through indirect means, such as system analysis and recognition of driving or steering pattern of a driver exhibiting reduced alertness due to drowsiness, therefore it is not possible to fully test those systems through a set of defined tests or with a programmable machine, which reproduces human behaviour. Instead, the manufacturer should perform validation testing with human participants and present the results to the approval authority together with at least one test protocol for checking the capability of the DDAW systems to produce a warning to the drowsy driver.

⁽¹⁾ OJ L 325, 16.12.2019, p. 1.

- (7) Taking into account the indirect nature of the measurement, the variability in the effects of human drowsiness and the relative immaturity of existing technologies, the performance requirements for DDAW systems should be set at a level that is realistic and attainable. At the same time, those requirements should be technology-neutral, in order to foster development of new technologies, therefore, the assessment of the performance of DDAW systems should be based on a statistical approach, taking into account either the average efficiency among the test subjects or the minimal efficiency for 95 % of them. However, the use of the latter option should be preferred as it provides that the DDAW systems will perform equally effective to all drivers.
- (8) This Regulation should provide a reference scale to be used by manufacturers to measure driver drowsiness in the tests involving human participants. Where manufacturers choose to use an alternative measurement method, it should be duly documented and equivalence to the reference scale in this Regulation should be provided.
- (9) The table in Annex II to Regulation (EU) 2019/2144 containing the list of requirements referred to in Article 4(5) and Article 5(3) of that Regulation does not contain any reference to regulatory acts as regards driver drowsiness and attention warning systems. It is therefore necessary to introduce a reference to this Regulation in that Annex.
- (10) Regulation (EU) 2019/2144 should therefore be amended accordingly.
- (11) As Regulation (EU) 2019/2144 is to apply from 6 July 2022, this Regulation should apply from the same date.
- (12) The provisions of this Regulation are closely linked as they deal with rules concerning the specific test procedures and technical requirements for the type-approval of motor vehicles with regard to their driver drowsiness and attention warning systems. As a result of the rules laid down in this Regulation, it is necessary to add a reference to this Regulation in Annex II to Regulation (EU) 2019/2144. It is therefore appropriate to lay down those provisions in a single Delegated Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

Scope

This Regulation applies to motor vehicles of categories M and N, as defined in points (a) and (b) of Article 4(1) of Regulation (EU) 2018/858 of the European Parliament and of the Council ⁽²⁾, with a maximum design speed above 70 km/h.

Article 2

Technical requirements for the driver drowsiness and attention warning system

Technical requirements for the approval of motor vehicles with regard to the driver drowsiness and attention warning systems are laid down in Part 1 of Annex I.

Article 3

Procedures for validation of driver drowsiness and attention warning systems

Test procedures for validation of driver drowsiness and attention warning systems by the manufacturer are laid down in Part 2 of Annex I.

⁽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).

*Article 4***Procedures for assessment of technical documentation and verification testing**

Procedures for assessment of the technical documentation provided by the manufacturer and for verification testing by the approval authorities and technical services are laid down in Part 3 of Annex I.

*Article 5***Amendment to Regulation (EU) 2019/2144**

Annex II to Regulation (EU) 2019/2144 of the European Parliament and of the Council is amended in accordance with Annex II to this Regulation.

*Article 6***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, 23 April 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

PART 1

Technical requirements for the driver drowsiness and attention warning (DDAW) systems

1. Definitions

For the purposes of this Annex, the following definitions apply:

- 1.1. 'trigger behaviour' means the vehicle action for which the driver drowsiness and attention warning (DDAW) system monitors and provides a warning to the driver once this action happens;
- 1.2. 'drowsiness threshold' is a quantification of the level of driver drowsiness, at or before which the DDAW system shall provide a drowsiness warning to the driver.

2. General technical requirements

- 2.1. A driver drowsiness and attention warning (DDAW) system shall monitor a driver's level of drowsiness and alert the driver through the vehicle human machine interface (HMI).
- 2.2. The DDAW system shall be designed to avoid or minimise the system error rate under real driving conditions.
- 2.3. Privacy and data protection
 - 2.3.1. The DDAW system shall function in normal operation mode without the use of biometric information, including facial recognition, of any vehicle occupants.
 - 2.3.2. The DDAW system shall be designed in such a way that it shall only continuously record and retain data necessary for the system to function and operate within a closed-loop system.
 - 2.3.3. Any processing of personal data shall be carried out in accordance with Union data protection law.

3. Specific technical requirements.

3.1. DDAW system control

- 3.1.1. It shall not be possible for the driver to manually deactivate the DDAW system.

It may however be possible for the driver to manually deactivate the DDAW system HMI warnings. Following manual deactivation of the DDAW System HMI warnings, it shall be possible for the driver to re-activate the system HMI warnings by taking no more than the same number of actions as were required to deactivate it.

- 3.1.2. The DDAW system shall be automatically deactivated in the situations pre-defined by the manufacturer. Such situations include, for instance, the deactivation of the warnings by the driver (point 3.1.1.). The DDAW system shall be automatically reactivated as soon as the conditions that led to its automatic deactivation are no longer present.
- 3.1.3. The DDAW system, including HMI warnings, shall be automatically reinstated to normal operation mode upon each activation of the vehicle master control switch. The vehicle manufacturer can choose to add a condition to such automatic reinstatement: upon the driver's door having been opened or the vehicle being switched off for a maximum period of 15 minutes.
- 3.1.4. The DDAW system shall be automatically activated above the speed of 70 km/h.

- 3.1.5. Once activated, DDAW system shall operate normally within the speed range of 65 km/h to 130 km/h or the vehicle's maximum allowed speed, whichever is lower.

The DDAW system shall not be automatically deactivated at a speed of above 130 km/h (although the system's behaviour can be adapted to the degraded situation).

- 3.1.6. There shall be less than 5-minute delay between the vehicle meeting the activation criteria set out in points 3.1.4., and the DDAW system beginning to actively monitor driver drowsiness.

- 3.1.7. If warning is provided during the learning phase of the DDAW system (allowing for calibration of the system parameters to best fit driver's behaviour and driving pattern), the learning phase is considered over.

The learning phase activation time shall start once all the conditions for the activation of the DDAW system referred to in points 3.1. and 3.2. are met.

3.2. Environmental conditions

- 3.2.1. The DDAW system shall operate effectively during the day and night.

- 3.2.2. The DDAW system shall operate in absence of weather conditions limiting the system's operation.

- 3.2.3. At a minimum, the DDAW system shall work effectively on a multi-lane divided road, with or without a central divide, when lane markings are visible on both sides of the lane.

3.3 Monitoring driver drowsiness

- 3.3.1. The DDAW system shall provide a warning to the driver at a level of drowsiness which is equivalent to or above 8 on the reference sleepiness scale set out in the Appendix (Karolinska Sleepiness Scale, hereinafter referred to as 'KSS').

The DDAW system may provide a warning to the driver at a level of drowsiness which is equivalent to level 7 on KSS.

In addition, manufacturer may implement an information strategy on the HMI prior to the warning.

Detailed requirements for the validation of the DDAW system by the manufacturer are set out in Part 2.

- 3.3.2. The DDAW system shall analyse other vehicle systems for detection of drowsy driving indicators. Such driving indicators may include but are not limited to the following:

- (a) a reduction in the number of micro-corrections within driver steering, paired with an increase in the number of large and fast corrections;
- (b) an increase in the variability of a vehicle's lateral lane position.

It is recommended that the DDAW system analyses other vehicle systems to detect drowsy driving indicators by monitoring lane position, namely the position of the vehicle relative to the lateral lane markings, or a steering input, namely a quantification of the way the driver manipulates the steering wheel, e.g. steering wheel reversal rate, yaw rate, standard deviation of lane position, etc.

An alternative manner of measuring driver performance through vehicle systems analysis ('metrics') may be used, provided that it is an accurate and robust measure of driver drowsiness.

It is possible to use one or more secondary metrics in addition to the recommendation stated in the second subparagraph of point 3.3.2. to aid the reliability and robustness of the system. Examples of such metrics include: additional vehicle metrics, temporal metrics (a temporal measurement directly related to the driver's operation of the vehicle), physiological metrics and vehicle control metrics.

3.4. Human Machine interface requirements

3.4.1. Warning nature

- 3.4.1.1. Visual and acoustic or any other warning used by the DDAW system to alert the driver shall be presented as soon as possible after occurrence of the trigger behaviour and may cascade and intensify until acknowledgement thereof by the driver.

Can be accepted as acknowledgement by the driver: an improvement of the driving behaviour based on the input used for the DDAW system (strategy to be described in the documentation provided by the manufacturer).

3.4.2. Visual Warning

- 3.4.2.1. The visual warning shall be located so as to be readily visible and recognisable in daylight and at night-time by the driver and distinguishable from other alerts.

- 3.4.2.2. The visual warning shall be a steady or flashing indication (e.g. tell-tale, pop-up message, etc.).

- 3.4.2.3. Any new symbols developed for the purpose of a DDAW visual warning are recommended to be constructed using similar elements to and keeping coherence with ISO 2575:2010+A7:2017 K.21 and/or ISO 2575:2010+A7:2017 K.24.

- 3.4.2.4. The contrast of the symbol with the background in sun light, twilight and night conditions are recommended to be in accordance with ISO 15008:2017.

- 3.4.2.5. The following visual alert and background colour combinations should not be used: red/green; yellow/blue; yellow/red; red/violet.

3.4.3. Acoustic warning

- 3.4.3.1. The acoustic warning shall be easily recognised by the driver.

- 3.4.3.2. A majority of the acoustic warning shall fall within the frequency spectrum of 200-8 000 Hz and amplitude range of 50-90 dB.

- 3.4.3.3. If speech alerts are utilised, the vocabulary used shall be consistent with any text used as part of the visual alert.

- 3.4.3.4. The audible portion of the alert shall last for at least the duration that allows the driver to understand it.

3.5. DDAW failure warning

- 3.5.1. A constant visual failure warning signal (e.g. warning reflecting the relevant Diagnostic Trouble Codes (DTC) for the system, tell-tale, pop-up message, etc.) shall be provided when there is a failure detected in the DDAW system as a result of which the DDAW system does not meet the requirements of this Annex.

Temporary visual failure warning signal can be used as complimentary information to the constant optical failure warning signal

- 3.5.2. There shall not be an appreciable time interval between each DDAW self-check, and subsequently there shall not be a delay in displaying the failure warning signal, in the case of an electrically detectable failure.

- 3.5.3. Upon detection of a non-electrical failure condition (e.g. sensor obscuration, excluding temporary obscuration such as caused by sun glare), the failure warning signal as laid down in point 3.5.1. shall be displayed.

- 3.5.4. Failures that activate the warning signal mentioned in point 3.5.1., but which are not detected under static conditions, shall be retained upon detection and continue to be displayed from start-up of the vehicle after each activation of the vehicle master control switch, for as long as the failure or defect persists.
- 3.6. Provisions for periodic roadworthiness tests.
- 3.6.1. For the purpose of periodic roadworthiness tests of vehicles, it shall be possible to verify the following features of the DDAW system:
- (a) Its correct operational status, by visible observation of the failure warning signal status following the activation of the vehicle master control switch and any bulb check. Where the failure warning signal is displayed in a common space (the area on which two or more information functions/symbols may be displayed, but not simultaneously), it must be checked first that the common space is functional prior to the failure warning signal status check;
 - (b) Its correct functionality and the software integrity, by the use of an electronic vehicle interface, such as the one laid down in point I.(14) of Annex III of Directive 2014/45/EU of the European Parliament and of the Council ⁽¹⁾, where the technical characteristics of the vehicle allow for it and the necessary data is made available. Manufacturers shall ensure to make available the technical information for the use of the electronic vehicle interface in accordance with Article 6 of Commission Implementing Regulation (EU) 2019/621 ⁽²⁾.
- 3.6.2. At the time of type-approval, the means to protect against simple unauthorised modification of the operation of the failure warning signal chosen by the manufacturer shall be confidentially outlined in the assessment of the technical documentation under Part 3. Alternatively, this protection requirement is fulfilled when a secondary means of checking the correct operational status of the DDAW system is available.

Appendix to Part 1

Reference sleepiness scale for DDAW system
(Karolinska Sleepiness Scale)

Rating	Verbal Description
1	Extremely alert
2	Very alert
3	Alert
4	Rather Alert
5	Neither alert nor sleepy
6	Some signs of sleepiness
7	Sleepy, no effort to keep awake
8	Sleepy, some effort to keep awake
9	Very sleepy, great effort to keep awake, fighting sleep

⁽¹⁾ Directive 2014/45/EU of the European Parliament and of the Council of 3 April 2014 on periodic roadworthiness tests for motor vehicles and their trailers and repealing Directive 2009/40/EC (OJ L 127, 29.4.2014, p. 51).

⁽²⁾ Commission Implementing Regulation (EU) 2019/621 of 17 April 2019 on the technical information necessary for roadworthiness testing of the items to be tested, on the use of the recommended test methods, and establishing detailed rules concerning the data format and the procedures for accessing the relevant technical information (OJ L 108, 23.4.2019, p. 5).

PART 2

Test procedures for validation of driver drowsiness and attention warning (DDAW) systems

1. Validation testing by the manufacturer
 - 1.1. General requirements
 - 1.1.1. Manufacturers shall carry out validation testing to ensure that DDAW systems are able to monitor driver drowsiness in a manner which is accurate, robust and scientifically valid.
 - 1.1.2. The validation testing of the DDAW shall meet the requirements set out in points 2 to 8. The manufacturer shall document the validation process in the documentation package to be provided by the manufacturer in accordance with Part 3.
 2. Testing requirements
 - 2.1. Validation testing shall take place using human participants. Alternatively the data used for the validation shall derive from behaviour data collected with human participants.
 - 2.2. Any validation testing that includes a human participant operating a motor vehicle in a real-world, non-simulated road environment, shall have a safety backup.

The safety backup shall intervene if the driver becomes drowsy, so that he or she can no longer safely control the motor vehicle.

If the safety backup intervenes, the participant shall not be permitted to drive any further as part of the testing.

If the safety backup is a backup driver, appropriate safety strategy (for example: double pedals) shall be required.

Once the safety backup intervenes, the safety strategy prepared for this test shall apply. For example: another non-drowsy driver takes primary control of the vehicle and the drowsy driver shall not be allowed to continue to drive.
 - 2.3. If validation testing is performed in a simulator, the manufacturer shall document its limitations with regard to real-world open road testing for the purpose of testing the DDAW system. Such documentation will include comparison of primary input data, used for the DDAW system, from the simulator and primary input data from the vehicle in real conditions and analysis of the validity of the simulated validation's results.
3. Test sample
 - 3.1. Each test participant shall generate at least 1 true positive or 1 false negative event as referred to in points 5.1.4. and 5.1.5. The total number, obtained by the sum of true positive events and false negative events, shall be equal to or higher than 10. The minimum sample size of participants shall be 10 participants. It is allowed to run more than one test per participant in order to acquire more data for a given participant.

The sensitivity per participant shall be calculated first for each participant, then the average sensitivity and its standard deviation shall be calculated from the values of sensitivity per participant.

It is explicitly allowed to provide results from a subgroup of participants of a larger test to include only participants fitting the description above.
 - 3.2. All the results from participants fitting the requirements of point 3.1. shall be accounted for the validation. Excluding results from participants with at least 1 true positive or 1 false negative is not allowed.

- 3.3. The participants shall correspond to the targeted demography for the vehicle (for example, participants with a valid license to drive the vehicle on which the DDAW system is installed).
- 3.4. None of the 10 participants of the minimum sample size shall be involved in the development of DDAW system. One of the acceptance criteria, of point 8, shall be met with and without results from the additional participants involved in the DDAW system development.
4. Environmental conditions
 - 4.1. At a minimum, the system shall be tested in the day and night conditions from point 4.1.1. or 4.1.2., and record at least a true positive event in each conditions (overall, not for each participant tested in the condition).

It is not necessary for each participants to test both conditions.

Systems not affected by light do not need to meet the minimum number of true positive event in each conditions indicated above.
 - 4.1.1. For non-simulated road environment testing:
 - (a) Day: testing shall start after sunrise and before sunset;
 - (b) Night: testing shall start after sunset and before sunrise.
 - 4.1.2. For simulated road environment testing:
 - (a) Day: conditions diffuse with ambient light (ISO 15008: 2017);
 - (b) Night: condition of low ambient illumination under which the adaptation level of the driver is mainly influenced by the portion of the road ahead covered by the vehicle's own headlights and surrounding street lights, and display and instrument brightness (ISO 15008: 2017).
5. Measuring drowsiness
 - 5.1. Application of KSS
 - 5.1.1. The participant's level of drowsiness shall be measured using the KSS.
 - 5.1.1.1. Participants shall be trained on the KSS before they apply it as part of the DDAW system validation testing.

The training process shall be the same for all participants.

The training process shall be clearly documented in the evidence dossier supplied to the technical service in accordance with Part 3.
 - 5.1.1.2. The standardised wording in the Appendix to Part 1 shall be used and all levels of the KSS shall be labelled.
 - 5.1.2. Measurements shall be obtained during the testing at intervals of approximately 5 minutes, where each measurement obtained shall be assumed to cover the previous 5 minutes.

The recommended intervals does not apply before the participant provide a first self-assessment rating at level 6 or above on the KSS.
 - 5.1.3. During the validation tests, it is recommended to mute the warning from the DDAW system, to prevent changes of the status of the participant before the next self-assessment. The time at which the warning from the DDAW is provided (muted or not) shall be recorded to clearly establish if it is a true positive event.
 - 5.1.4. Any warning from the DDAW system shall be treated as a true positive event if the participant previous or next rating is at a KSS level of 7 or above.

Once a true positive event occurred, the data points after this event shall be considered irrelevant for this specific test. If the participant restarted the test after a rest, it shall be considered a different dataset (with the same participant).

- 5.1.5. If a participant rating is below the drowsiness threshold referred to in point 3.3.1. of Part 1 and the subsequent rating is above or equal to the drowsiness threshold (e.g. a sequence of rating can be 6-8 or 7-8), either:
- (a) the DDAW system provides a warning and it shall be treated as a true positive and end the specific test as in point 5.1.4.; or
 - (b) the DDAW system does not provide a warning and it shall be treated as a false negative, unless the testing continues for at least an extra testing time interval, and the participant provide either of the following self-assessment:
 - During the extra testing interval, if the participants provide a self-assessment above or equal to the drowsiness threshold again, the reading shall be treated as a false negative (e.g. sequence of rating can be 7-8-8, 7-9-9 or 7-9-8);
 - During the extra testing interval, if the participants provide a self-assessment at the KSS level 7, the data point shall be treated as true negative and marked as an outlier (e.g. sequence can be 6-8-7, 7-8-7 or 7-9-7). All outliers shall be documented in the documentation package;
 - Without prejudice to other situations which can be excluded, during the extra testing interval, if the participants provide a self-assessment below the KSS level of 7, the data points from this specific test shall be excluded from the overall testing data results as the drowsiness ratings of the participant are likely unreliable (e.g. sequence of rating can be 7-8-6 or 6-8-6). It is recommended to provide an additional training session to the participant after such a result.

5.2. Alternative measurement(s)

5.2.1. Manufacturers may use an alternative measurement(s) to validate a DDAW system under the following conditions:

- (a) If the alternative method directly monitors the participants' state, such as Electroencephalogram (EEG) or PERCLOS (percentage of eyelid closure).
- (b) If the alternative method fit the measurement described in the point 5.1. except for the drowsiness scale used and/or the time interval used;
- (c) If the measurement is performed by sleep video analysis performed by at least 3 raters (sleep experts), who do not interact with the participant and each other before the rating process is finalised. The time interval of this method shall not exceed 5 minutes.

5.2.2. Where alternative measurements to KSS are used to determine the participant's level of drowsiness, the manufacturer shall provide evidence that the chosen measurement is a valid and accurate means to assess driver drowsiness, and that the drowsiness threshold used in the validation testing is equivalent to a KSS level referred to in point 3.3.1. of Part 1

For the sleep video analysis, expected evidence concerns the quality of the video used, the visibility of the setup for the participant, the correspondence between the rating scale and KSS, the training of the raters (in addition a minimal performance level of 'concordance rate' superior or equal to 0.70 is required), information of independence of the raters to the DDAW development and description on how the final rating is calculated based on the input from the sleep experts.

'Concordance rate' is a score calculated from the rating of a sleep expert on a facial training video

$$\text{Concordance rate} = \sum_{i=1}^n [1 - (|A_i - B_i|)/D]/n$$

A: 'True' Drowsiness rating value of the training video

B: Evaluated drowsiness level by the sleep expert

D: Maximum of drowsiness level occurring during the training video

n: number of data point to rate during the training video

- 5.2.3. If the alternative measurement uses a different time interval than the one specified in point 5.1.2, point 5.1.5. shall apply, where the intervals of assessment are equal to or shorter than 15 minutes and above or equal to 5 minutes.
- If the time interval is shorter than 5 minutes, the interpretation of point 5.1.5. shall not apply. Instead, a false negative event occurs only if the DDAW does not provide a warning during the 10 minutes following the last rating below the drowsiness threshold. If during 5 minutes or more the ratings are above the drowsiness threshold then it is followed by a rating below the drowsiness threshold, the data point shall be treated as an outlier. All outliers shall be documented in the documentation package;
- 5.2.4. If the time intervals are longer than 15 minutes, the technical services may consider raising the requirements from point 8.1(a) and point 8.1(b) by the amount set out in point 8.1(c) to better allow for a correct assessment of the driver's drowsiness.
- 5.3. Complementary measurements
- Manufacturers may use complementary measurement(s) to KSS or the alternative measurement(s) to validate a DDAW system, which shall be duly documented in the documentation package under Part 3.
- Where sleep expert video analysis are used as a complementary measurement, at a minimum two raters and an inter-rater reliability test shall be conducted, and the results shall be included in the documentation package. The facial cues and body movements/behaviours for each level of drowsiness on the KSS shall be demonstrated (usually it is a confidential document).
6. Alternative drowsiness threshold
- 6.1. If alternative measurements to KSS are used to validate a DDAW system, the manufacture shall state the threshold being used and provide evidence detailing the equivalency between the threshold and a KSS level of 8.
- If the alternative measurement uses a scale which has fewer descriptive levels than the KSS, the equivalence between the alternative scale and the KSS shall refer to the lowest corresponding level when compared to the KSS. The only exception is for the level of the alternative scale that includes the equivalency to a KSS level of 8, in which case it shall refer to the highest corresponding level when compared to the KSS.
- For example, if the alternative scale level '4' corresponds to a range between '6 and 7' on the KSS, a '4' on the alternative scale shall be considered a '6' on the KSS.
- If an alternative scale level 'A' corresponds to a range between '6,5 and 8,5' on the KSS, an 'A' on the alternative scale shall be considered an '8' on the KSS.
- 6.2. If a complementary measurement is used in addition to KSS or to an alternative measurement to validate a DDAW system, the manufacturer shall state the threshold being used and provide evidence detailing the equivalency between the threshold and a KSS level of 8.
7. Test results
- 7.1. Test data shall only be discarded by the manufacturer before any statistical analysis is conducted in any of the following cases:
- (a) there is an error in carrying out the testing procedure;
 - (b) the participant's KSS ratings are deemed unreliable;
 - (c) insufficient data is collected for a participant (e.g. length of trial was too short or participant did not generate at least 1 true positive event or 1 false negative event).
- 7.2. The manufacturer shall document any errors that occur during testing shall be documented as part of the evidence in the documentation package, separate from the test results, along with the erroneous data and, if applicable, the reason for excluding a participants' data from the statistical analysis.

8. Acceptance criteria

8.1 A DDAW system shall be deemed effective by the technical services if the following requirement (a) or (b) is satisfied as modified, if necessary, by requirements (c) for tests using interval time above 15 minutes and (d) for tests performed in a simulated environment:

- (a) the average sensitivity is above 40 % (Sensitivity calculated from the average of the sensitivity of all participants)
- (b) the lower bound from the 90 % confidence interval of the sensitivity results shall be above 20 %. It means that 95 % of the participants statistically have more than 20 % average sensitivity, this is verified by satisfying the equation:

$$Average(Sensitivity) - 1.645 \times \frac{Standard\ Deviation(Sensitivity)}{\sqrt{Number\ of\ participants}} \geq 20\%$$

- (c) the requirement listed in sub-point (a) is increased by 5 % and the requirement listed in sub-point (b) is increased by 2,5 % if the testing method does not use an interval time equal to or shorter than the 15 minutes possible in point 5.2.3 (upper bound possible between the recommended measurement the alternative measurement).
- (d) the requirement listed in sub-point (a) is lowered by 5 % and the requirement listed in sub-point (b) is lowered by 2,5 % if the testing method is performed on an open road.

For example, the average sensitivity required for an open road test using an interval time equal to or shorter than 15 minutes will be $\geq 35\%$ and the average sensitivity required for a simulation test with interval time of more than 15 minutes will be $\geq 45\%$.

Performance metric calculation

The performance metrics shall be calculated as:

Sensitivity value of a participant:

$$Sensitivity = \frac{n(TP)}{n(TP) + n(FN)} \times 100\%$$

Average sensitivity for all participants:

$$Average(Sensitivity) = \frac{\sum Sensitivity}{Number\ of\ participants}$$

Standard Deviation (Sensitivity):

$$Standard\ Deviation(Sensitivity) = \sqrt{\frac{\sum (Sensitivity - Average(Sensitivity))^2}{Number\ of\ participants}}$$

where:

$n(TP)$ is the total number of events in which the system and driver both correctly identify as drowsy;

$n(FN)$ is the total number of events in which the system predicts that the driver is not drowsy, but when the driver is in fact drowsy;

$n(FP)$ is the total number of events in which the system predicts that the driver is drowsy, but the driver is not drowsy;

$n(TN)$ is the total number of events in which the system and driver both correctly identify as not being drowsy;

Σ is the sum over all the participants.

Note: The distribution of the results is approximated by a Gaussian distribution.

- 8.2. If the DDAW system requires a learning phase, the acceptance criteria listed in point 8.1. shall exclude results obtained during the learning phase or for 30 minutes after the condition for activation of the DDAW are fulfilled, whichever is shorter.

PART 3

Procedures for assessment of technical documentation and verification testing by the approval authorities and technical services

1. Documentation package

The manufacturer shall provide to the approval authority and technical service a documentation package containing evidence of the effectiveness of the system. The documentation package shall cover both, the system functionality and the system validation.

1.1. System functionality

The documentation package detailing how the system functions shall include:

- (a) a list of all the system inputs containing the primary and secondary metrics;
- (b) a description of how the metrics function and monitor driving behaviour;
- (c) a description of the trigger behaviour being monitored by the system;
- (d) evidence on the relationship between drowsy driving and/or steering behaviour and the chosen trigger behaviour;
- (e) the system's drowsiness threshold;
- (f) the vehicle speed at which the system is activated;
- (g) an explanation of the systems activation, reactivation and deactivation functions;
- (h) a document detailing the functionality of the system's HMI. This includes evidence of compliance with the DDAW HMI requirements (point 3.4. of Part 1), and justifications if the manufacturer choose not to follow the recommendations listed in the points 3.4.2.3., 3.4.2.4. and 3.4.2.5. of Part 1.
- (i) a document providing at least one test protocol to be tested by the Technical Service, for which the DDAW system shall deliver a warning when performed.

The list of system inputs shall only be provided to the approval authority or the technical service for the purpose of verifying the DDAW system for the type-approval. The list of any secondary metrics will not be passed on from the technical service to the approval authority.

1.2. System validation

Evidence on the effectiveness of the system document shall include:

- (a) the information on the number and demographics of the test participants assessed.
- (b) the description of the test conditions assessed;
- (c) evidence that the system works effectively in weather conditions not limiting the system's operation. The evidence shall indicate the known or logical limitations due to weather conditions, the technical challenge and the strategy for the system behaviour in these given weather conditions (for example strong rain, snow, high temperature etc.).
- (d) a description of full test methodology used to assess the effectiveness of the system and the rationale behind, including any alternative or complementary measurements and alternative drowsiness threshold (referred to in point 5.2., point 5.3. and point 6. of Part 2 respectively);

- (e) a description of the statistical analysis technique used. If a statistical analysis method that differs from that set out in point 8.1. is used, evidence on the statistical analysis technique and level of significance used shall be provided;
- (f) an analysis and description of the results;
- (g) evidence that the system alerts a driver at the time of or before reaching the KSS level set out in point 3.3.1. of Part 1;
- (h) the data of each participant for statistical anomaly assessment.

The information on demographics of the test participants referred to in sub-point (a) shall include:

- (i) inclusionary or exclusionary criteria that were used when selecting participants, and
- (ii) a statement on the adequacy of the participants in respect of the targeted demography for the vehicle set out in point 3.3. of Part 2.

The information on full test methodology referred to in sub-point (d) shall include:

- (i) provide evidence that the complementary measurement(s) or the combination of the primary (KSS or alternative measure) and complementary measurements are a valid and accurate means to assess driver drowsiness;
- (ii) provide information on how the data of the primary and complementary measurements were analysed and collated to assess the effectiveness of the DDAW system;
- (iii) provide evidence that the drowsiness threshold being used in the validation testing is equivalent to a KSS level referred to in point 3.3.1 of Part 1.

- 1.2.1. If the validation was performed on another vehicle, the documentation shall contain information linking the validation process to the type-approval requirements for the vehicle.

e.g. Provide documents demonstrating the technical similarities or the adaptation required to enable the DDAW system to the vehicle presented for type-approval. The requirements on the participants shall also be similar (demography, involvement of professional driver).

- 1.2.2. If the validation was performed as part of a research to establish compliance with the technical requirements for the DDAW system, the documentation shall contain information linking the validation testing to the respective approval requirements for the motor vehicle concerned.

e.g. Provide an additional link between what is enabled in the version of the DDAW system installed in the motor vehicle and a recalculation of the equivalent sensitivity values from the data produced during the research phase.

2. Assessment by the technical service of the DDAW system documentation package and test report

- 2.1 The technical service shall check that the manufacturer has proved on the basis of the tests performed in accordance with this Annex that the DDAW meets the technical criteria laid down in Part 1 and the validation criteria laid down in Part 2. The following actions are expected:

- (a) check that the reported performance levels meet the required minimum thresholds referred to in point 3.3.1. of Part 1;
- (b) review the test report to verify whether the underlying methodology presented in the test report meets the requirements set out in Part 2;
- (c) perform an assessment of the test report from the validation testing carried out by the manufacturer.

The assessment of the test report shall verify whether the underlying evidence on the tests performed correspond with the reported test results to a level of overall effect such that the performance declaration is confirmed as being adequate. This includes assessing the participant data for statistical anomalies such as the number of outliers.

The technical service may use means at its discretion for the assessment of the test report. Such means may include a review of the full raw data sets from a selection of test drives chosen by the technical service (including any data that was excluded from the analysis) and re-running parts of the validation testing based on collected data (may only be possible for limited validation methods, such as sleep video analysis).

- 2.2 The technical service shall, taking into account the information on the system functionality provided under point 1.1, assess the capability of the test protocol, proposed by the manufacturer, to detect a drowsy driving event. The technical service shall also perform the test based on the proposed protocol.
 - 2.2.1. The test shall be accounted as passed as soon as the DDAW system provides a warning for a drowsy driver.
 - 2.2.2. If the test fails to provide a warning for a drowsy driver, the technical service may repeat it up to two times.
 - 2.2.3. The root cause of any failed test run shall be analysed by the technical service and the analysis shall be annexed to the test report. If the root cause cannot be linked to a deviation in the test setup, the technical service may test any variation of parameter within parameter's range defined in the test protocol provided by the manufacturer.
 - 2.2.4. A reference to the code of the respective test protocol, which has been run by the technical service, shall be included in the 'Remarks' section of the Type-Approval Certificate in order to allow competent authorities, when performing for instance market surveillance activities, to request the test protocol from the technical service that carried out the test.
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ANNEX II

Amendment to Regulation (EU) 2019/2144

In Annex II to Regulation (EU) 2019/2144 the row for requirement E2 is replaced by the following:

Subject	Regulatory acts	Additional specific technical provisions	M ₁	M ₂	M ₃	N ₁	N ₂	N ₃	O ₁	O ₂	O ₃	O ₄	STU	Component
E2 Driver drowsiness and attention warning	Commission Delegated Regulation (EU) 2021/1341 (*)		B	B	B	B	B	B						

(*) Commission Delegated Regulation (EU) 2021/1341 of 23 April 2021 supplementing Regulation (EU) 2019/2144 of the European Parliament and of the Council by laying down detailed rules concerning the specific test procedures and technical requirements for the type-approval of motor vehicles with regard to their driver drowsiness and attention warning and amending Annex II to that Regulation (OJ L 292, 16.8.2021, p. 4).'

COMMISSION DELEGATED REGULATION (EU) 2021/1342**of 27 May 2021****supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council with rules on the information to be sent by third countries and by control authorities and control bodies for the purpose of supervision of their recognition under Article 33(2) and (3) of Council Regulation (EC) No 834/2007 for imported organic products and the measures to be taken in the exercise of that supervision****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 ⁽¹⁾, and in particular Articles 48(4) and 57(3) thereof,

Whereas:

- (1) Pursuant to Article 48(1) of Regulation (EU) 2018/848, the recognition of third countries for the purposes of equivalence under Article 33(2) of Council Regulation (EC) No 834/2007 ⁽²⁾ for imports of organic products into the Union will expire on 31 December 2026.
- (2) Pursuant to Article 57(1) of Regulation (EU) 2018/848, the recognition of control authorities and control bodies for the purposes of equivalence under Article 33(3) of Regulation (EC) No 834/2007 for imports of organic products into the Union will expire on 31 December 2024.
- (3) When placed on the Union market until the end of those transitional periods, organic products imported into the Union under those import schemes have to be produced in accordance with the production rules and subject to control arrangements equivalent to those laid down in Regulation (EC) No 834/2007 as well as with the associated implementing rules laid down in Commission Regulations (EC) No 889/2008 ⁽³⁾ and (EC) No 1235/2008 ⁽⁴⁾.
- (4) Therefore, at all stages of production, preparation and distribution in third countries, operators should continue to submit their activities either to a control system of a third country recognised for the purposes of equivalence as referred to in Article 48(1) of Regulation (EU) 2018/848, or to a control authority or control body as referred to in Article 57(1) of that Regulation.
- (5) In order to ensure the appropriate supervision of such third countries or the control authorities and control bodies concerned, it is necessary to lay down rules on the procedures for the regular review of their recognition during the transitional periods. For that purpose, this Regulation should specify, in particular, the information to be provided by the third countries or the control authorities and control bodies to the Commission for the exercise of that supervision, including through on-the-spot examination. In addition, this Regulation should set out the measures to be taken by the Commission in the exercise of that supervision, including suspension or withdrawal of recognised third countries or control authorities and control bodies from the lists established pursuant to Articles 48(3) and 57(2) of Regulation (EU) 2018/848.

⁽¹⁾ OJ L 150, 14.6.2018, p. 1.

⁽²⁾ Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 (OJ L 189, 20.7.2007, p. 1).

⁽³⁾ Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control (OJ L 250, 18.9.2008, p. 1).

⁽⁴⁾ Commission Regulation (EC) No 1235/2008 of 8 December 2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries (OJ L 334, 12.12.2008, p. 25).

- (6) In the interest of clarity and legal certainty, this Regulation should apply from the date of application of Regulation (EU) 2018/848 until the expiry of the recognition of the third countries or control authorities and control bodies,

HAS ADOPTED THIS REGULATION:

Article 1

Supervision of third countries

1. The annual report to be sent to the Commission in accordance with Article 48(2) of Regulation (EU) 2018/848, by 31 March of each year, by a third country referred to in Article 48(1) of that Regulation and included in the list established by an Implementing Regulation to be adopted pursuant to Article 48(3) of Regulation (EU) 2018/848 ('third country') shall include:

- (a) information on the development of organic production in the third country, including the products produced, the area in cultivation, the production regions, the number of producers, and the food processing activities;
- (b) information on the nature of organic agricultural products and foodstuffs exported to the Union;
- (c) a description of the monitoring and supervisory activities carried out by the competent authority of the third country in the previous year, the results obtained and the corrective measures taken;
- (d) any updates on the production standards applied in the third country assessed as equivalent to the production rules referred to in Titles III and IV of Regulation (EC) No 834/2007;
- (e) any updates on the control measures applied in the third country, assessed as having equivalent effectiveness to those referred to in Title V of Regulation (EC) No 834/2007, and confirmation that such control measures have been permanently and effectively applied;
- (f) any other updates on the third country's technical dossier;
- (g) the internet website or other address where the up-to-date list of operators subject to the control system can be found, as well as a contact point where information is readily available on their certification status and the product categories concerned;
- (h) any other information deemed relevant by the third country.

2. The third country shall notify the Commission without delay, via the electronic platform Organic Farming Information System (OFIS), of any changes made to the measures in force in that third country or to their implementation, and in particular to its control system.

3. The third country shall notify the Commission without delay, via OFIS, of any changes made to the administrative data included in the list established by an Implementing Regulation to be adopted pursuant to Article 48(3) of Regulation (EU) 2018/848.

4. The Commission may at any time request any further information from the third country, including the submission of one or more on-the-spot examination reports established by independent experts.

5. The Commission may, based on a risk-assessment or in case of suspected non-compliances, organise an on-the-spot examination in the third country by experts it designates.

6. Where the Commission has received a notification from a Member State informing it of a substantiated suspicion of an irregularity or infringement as regards compliance of imported organic products with the requirements laid down in Regulation (EC) No 834/2007 and production standards and control measures accepted as equivalent on the basis of the assessment made, it shall notify the competent authority of the third country thereof. That competent authority shall investigate the origin of the suspected irregularity or infringement and shall, within 30 calendar days from the Commission's notification, inform the Commission and the Member State concerned of the result of the investigation and of the action taken.

*Article 2***Supervision of control authorities and control bodies**

1. On the basis of annual reports and in the light of any other information received, the Commission shall ensure appropriate supervision of the control authorities and control bodies referred to in Article 57(1) of Regulation (EU) 2018/848 and included in the list established by an Implementing Regulation to be adopted pursuant to Article 57(2) of Regulation (EU) 2018/848 ('control authorities and control bodies') by regularly reviewing their recognition. For this purpose, the Commission may request the assistance of Member States. The nature of the supervision of the control authorities and control bodies shall be determined on the basis of a risk based approach of non-compliance, taking into account in particular the volume of certified products and their exports to the Union and the results of the regular on-the-spot evaluation, surveillance and multiannual re-assessment of their activities by an accreditation body or, as appropriate, by a competent authority.

2. By 28 February of each year, the control authorities and control bodies shall send the Commission an annual report. The annual report shall update the information of the technical dossier included in the initial application for the recognition, as last modified. It shall at least include:

- (a) an overview of the activities of the control authority or control body in the third country or third countries for which it has been recognised, including the number of operators and groups of operators involved and the nature of agricultural products and foodstuffs, sorted by categories and grouped by tariff codes;
- (b) any updates on the production standards applied in the third country or third countries for which the control authority or control body has been recognised, including an assessment of the equivalence of those standards to the production rules referred to in Titles III and IV of Regulation (EC) No 834/2007;
- (c) any updates on the control measures applied in the third country or third countries for which the control authority or control body has been recognised, including an assessment of the equivalence to those referred to in Title V of Regulation (EC) No 834/2007, and confirmation that such control measures have been permanently and effectively applied;
- (d) a description of the control activities carried out by the control authority or control body in the previous year in the third country or third countries for which it has been recognised, the results obtained, the irregularities and infringements observed and the corrective measures taken;
- (e) any other updates on the information of the technical dossier that was sent with the initial application for the recognition and its further updates;
- (f) a copy of the latest assessment report issued by the accreditation body or, where appropriate, by a competent authority, which shall contain the results of the regular on-the-spot evaluation, surveillance and multiannual re-assessment of the activities of the control authority or control body in the third country or third countries for which it has been recognised. That assessment report shall confirm that the control authority or control body has been satisfactorily assessed on its ability to meet the conditions applicable to its recognition by the Commission and that it has effectively implemented its activities according to those conditions. Furthermore, the assessment report shall demonstrate and confirm the equivalence of the production standards and control measures referred to in points (b) and (c);
- (g) the internet website where the list of operators subject to the control system can be found in an official language of the Union, as well as a contact point where information is readily available on their certification status, the product categories concerned, as well as suspended and decertified operators and products;
- (h) any other information deemed relevant by the control authority or control body.

The annual report and any additional information requested by the Commission concerning the annual report shall be provided via OFIS.

3. The Commission may request any additional information concerning the annual report. That additional information shall be provided in electronic form.

*Article 3***Review of the recognition of third countries**

In the framework of its regular review of the recognition of third countries pursuant to Article 48(2) of Regulation (EU) 2018/848, the Commission shall apply the following rules and amend the list of third countries accordingly pursuant to Article 48(3) of that Regulation:

- (a) the Commission may at any time amend the specifications in the list on the basis of the information received;
- (b) the Commission may suspend the entry of a third country from the list either on the basis of the information received, or where a third country has not supplied sufficient information as required or where it has not agreed to an on-the-spot examination;
- (c) the Commission shall suspend the entry of a third country from the list where, after a request from the Commission, the third country fails to take appropriate and timely remedial action within a period to be determined by the Commission according to the severity of the problem, which shall not be less than 30 days;
- (d) the Commission shall withdraw the entry of a third country from the list where:
 - (i) the third country does not send on time the annual report referred to Article 1(1) of this Regulation;
 - (ii) the information included in that annual report is incomplete;
 - (iii) after a request from the Commission within a period to be determined by the Commission according to the severity of the problem, which shall not be less than 30 days, the third country does not keep available the information or does not communicate all information related to its technical dossier or control system; or
 - (iv) after a request from the Commission, the third country does not agree to an on-the-spot examination.

*Article 4***Review of the recognition of control authorities and control bodies**

1. In the framework of its regular review of the recognition of control authorities and control bodies pursuant to Article 2(1) of this Regulation, the Commission shall apply the following rules and amend the list of control authorities and control bodies accordingly pursuant to Article 57(2) of Regulation (EU) 2018/848:

- (a) the Commission may at any time amend the specifications relating to a control authority or control body in the list on the basis of the information received;
- (b) the Commission may suspend the entry of a control authority or control body from the list either on the basis of the information received, or where the control authority or control body has not supplied sufficient information as required or where it has not agreed to an on-the-spot examination;
- (c) the Commission shall suspend the entry of a control authority or control body from the list where, after a request from the Commission, the control authority or control body fails to take appropriate and timely remedial action within a period to be determined by the Commission according to the severity of the problem, which shall not be less than 30 days;
- (d) the Commission shall withdraw the entry of a control authority or control body from the list where:
 - (i) the control authority or control body does not send on time the annual report referred to in Article 2(2) of this Regulation;
 - (ii) the information included in the annual report is incomplete;
 - (iii) the control authority or control body does not keep available or does not communicate all information related to its technical dossier or control system;
 - (iv) the control authority or control body does not keep available information on the investigations of a non-compliance;

- (v) the control authority or control body fails to take adequate corrective measures in response to the non-compliance and infringements observed;
- (vi) the control authority or control body does not agree to an on-the-spot examination required by the Commission, or if an on-the-spot examination comes up with a negative result due to a systematic malfunctioning of the control measures; or
- (vii) in any other situation, there is a risk for the consumer to be misled about the true nature of the products certified by the control authority or control body.

2. Prior to a withdrawal in accordance with point (d) of paragraph 1, the Commission shall request the control authority or control body to remedy the situations referred to in that point within a period to be determined by the Commission according to the severity of the problem, which shall not be less than 30 days.

Article 5

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 1 January 2022.

Articles 1 and 3 shall apply until 31 December 2026.

Articles 2 and 4 shall apply until 31 December 2024.

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

Done at Brussels, 27 May 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1343**of 10 August 2021****approving amendments to the specification for a spirit drink whose name is registered as a geographical indication****[Újfehértói meggypálinka]**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/787 of the European Parliament and of the Council of 17 April 2019 on the definition, description, presentation and labelling of spirit drinks, the use of the names of spirit drinks in the presentation and labelling of other foodstuffs, the protection of geographical indications for spirit drinks, the use of ethyl alcohol and distillates of agricultural origin in alcoholic beverages, and repealing Regulation (EC) No 110/2008 ⁽¹⁾, and in particular Article 30(2) thereof,

Whereas:

- (1) Pursuant to Article 21 in conjunction with Article 17(5) of Regulation (EC) No 110/2008 of the European Parliament and of the Council ⁽²⁾, the Commission has examined Hungary's application of 18 April 2017 for the approval of amendments to the technical file for the geographical indication 'Újfehértói meggypálinka', protected under Regulation (EC) No 110/2008.
- (2) Regulation (EU) 2019/787, which replaces Regulation (EC) No 110/2008, entered into force on 25 May 2019. Under Article 49(1) thereof, Chapter III of Regulation (EC) No 110/2008 on geographical indications is repealed with effect from 8 June 2019. Under Article 22(2) of Regulation (EU) 2019/787, technical files submitted as part of any application before 8 June 2019 under Regulation (EC) No 110/2008 shall be deemed to be product specifications.
- (3) After concluding that the application complied with Regulation (EC) No 110/2008, the Commission published the amendment application in the *Official Journal of the European Union* ⁽³⁾ as required by Article 17(6) of that Regulation, in accordance with the first subparagraph of Article 50(4) of Regulation (EU) 2019/787.
- (4) As no notice of opposition under Article 27(1) of Regulation (EU) 2019/787 has been received by the Commission, the amendments to the specification should be approved pursuant to Article 30(2) of that Regulation, which applies *mutatis mutandis* to product specification amendments,

HAS ADOPTED THIS REGULATION:

Article 1

The amendments to the specification for the name 'Újfehértói meggypálinka', published in the *Official Journal of the European Union*, 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*.

⁽¹⁾ OJ L 130, 17.5.2019, p. 1.

⁽²⁾ Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89 (OJ L 39, 13.2.2008, p. 16).

⁽³⁾ OJ C 147, 26.4.2021, p. 7.

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

Done at Brussels, 10 August 2021.

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

DECISIONS

COMMISSION DECISION (EU) 2021/1344

of 9 August 2021

establishing criteria to define the period of time for which persons posing a threat to security may be banned from the Commission's premises

THE EUROPEAN COMMISSION,

Having regard to Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission ⁽¹⁾, and in particular Article 12(1), point (b) and Article 21 thereof,

Whereas:

- (1) The Commission needs to operate in a safe and secure environment. Accordingly, it needs a coherent, integrated approach as regards its security, providing appropriate levels of protection for persons, assets and information that are commensurate with identified risks, and ensuring the efficient and timely delivery of security. The Commission faces major threats and challenges in the field of security, in particular as regards terrorism, and political and commercial espionage.
- (2) In order to ensure the security of persons, assets and information, the Commission, in particular the Security Directorate of its Directorate General for Human Resources and Security, takes measures pursuant to Decision (EU, Euratom) 2015/443 which apply to all Commission departments and in all Commission premises. Those measures include limited measures concerning persons posing a threat to security, including banning persons from the Commission's premises for a period of time pursuant to Article 12(1), point (b) of that Decision.
- (3) Commission staff duly mandated in accordance with Articles 5 and 12 of Decision (EU, Euratom) 2015/443, should, in deciding on banning a person or persons from Commission premises where, pursuant to Article 12(1), point (b) of that Decision, it is considered that they pose a threat to its security, assess that threat on a case-by-case basis, respecting the relevant individual circumstances.
- (4) The restriction of access may apply to one, several or even all Commission premises.
- (5) The period of the ban should take into account the likelihood, seriousness and duration of the threat.
- (6) This Decision should not apply to a ban to the Commission's premises adopted in the context of suspension proceedings pursuant to Article 23 of Annex IX to the Staff Regulations.
- (7) This Decision should not apply to Commission staff working in Union Delegations, who should be subject to the security rules for the European External Action Service.
- (8) In accordance with the internal rules of procedure, the member of the Commission responsible for security matters has been empowered, by means of Commission Decision C(2016) 2797 ⁽²⁾, to establish implementing rules establishing the criteria necessary for defining the periods of time applicable to a ban on access to the Commission's premises pursuant to Article 12 of Decision (EU, Euratom) 2015/443. That power has been sub-delegated to the Director-General of the Directorate General for Human Resources and Security by means of Commission Decision C(2021) 2684 ⁽³⁾.

⁽¹⁾ OJ L 72, 17.3.2015, p. 41.

⁽²⁾ Commission Decision C(2016) 2797 of 4 May 2016 on an empowerment relating to security.

⁽³⁾ Commission Decision C(2021) 2684 of 13 April 2021 granting a sub-delegation of powers granted in Commission Decision C(2016) 2797 on an empowerment relating to security.

- (9) Security measures pursuant to this Decision should comply with the principles for security in the Commission laid down in Article 3 of Decision (EU, Euratom) 2015/443, in particular respecting the Charter of Fundamental Rights of the European Union,

HAS ADOPTED THIS DECISION:

Article 1

Subject matter and scope

1. This Decision sets out criteria to define the period of time for which persons posing a threat to security may be banned from the Commission's premises pursuant to Article 12(1), point (b) of Decision (EU, Euratom) 2015/443.
2. This Decision shall apply to all Commission departments and in all Commission premises. Commission staff working in Union Delegations shall be subject to the security rules for the European External Action Service ⁽⁴⁾.
3. This Decision shall not apply to suspension proceedings pursuant to Article 23 of Annex IX to the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Economic Community and the European Atomic Energy Community ⁽⁵⁾.

Article 2

Scope of the ban

1. The ban referred to in Article 1(1) may apply to one, several or all Commission premises.
2. Where the Commission shares premises with other EU institutions, agencies and bodies, the Commission shall communicate the decision to ban access to Commission parts of the premises to the latter.

Article 3

Period of ban

1. The period of the ban referred to in Article 1(1) shall be based on the estimated duration, likelihood and seriousness of the threat to security.
2. The criteria for assessing the seriousness of the threat to security shall include:
 - (a) the degree of harm to which it could lead, as regards the life, bodily integrity, well-being or health of persons, and potential damage to assets and information;
 - (b) whether the threat is linked to commitment of a criminal offence;
 - (c) whether the threat is based on negligence, gross negligence or intent;
 - (d) whether the behaviour of the person posing the threat is violent, aggressive or repetitive;
 - (e) the extent of potential financial loss to the Commission;
 - (f) the extent of potential reputational damage to the Commission.

⁽⁴⁾ Decision ADMIN(2017) 10 of the High Representative of the Union for Foreign Affairs and Security Policy of 19 September 2017 on the security rules for the European External Action Service (OJ C 126, 10.4.2018, p. 1).

⁽⁵⁾ Regulation No 31 (EEC), 11 (EAEC) laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Economic Community and the European Atomic Energy Community (OJ P 45, 14.6.1962, p. 1385).

3. Where the duration of the threat cannot be estimated with sufficient certainty and the threat is very serious, the person posing the threat may be banned until further notice. That applies, in particular, where the threat has one of the following characteristics:

- (a) it consists of involvement in terrorist or espionage activities and networks;
- (b) it could lead to loss of life, serious injury or harm, or significant damage to property, compromise sensitive or classified information, or disrupt the Commission's IT systems or essential operational capacities;
- (c) it consists of violent, aggressive or repetitive behaviour, having the effect of seriously disrupting the functioning of Commission services.

Article 4

Review of bans

The Commission shall review any decision taken pursuant to Article 12(1), point (b) of Decision (EU, Euratom) 2015/443 on request of the person concerned, provided the latter demonstrates new substantial elements that allow a re-examination of the ban. The Commission shall base its review on the criteria that led to the initial ban.

Article 5

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

Done at Brussels, 9 August 2021.

For the Commission

Gertrud INGESTAD

Director-General

Directorate-General for Human Resources and Security

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