

Official Journal of the European Union

L 204



English edition

Legislation

Volume 64

10 June 2021

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II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2021/930

of 1 March 2021

supplementing Regulation (EU) No 575/2013 of the European Parliament and of the Council with regard to regulatory technical standards specifying the nature, severity and duration of an economic downturn referred to in Article 181(1), point (b), and Article 182(1), point (b), of 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) No 575/2013 of the European Parliament and of the Council of 26 June 2013 on prudential requirements for credit institutions and investment firms and amending Regulation (EU) No 648/2012 ⁽¹⁾, and in particular the third subparagraph of Article 181(3) and the third subparagraph of Article 182(4) thereof,

Whereas:

- (1) Article 181(1), point (b), of Regulation (EU) No 575/2013 requires institutions, in quantifying the risk parameters to be associated with rating grades or pools, to use own-LGD estimates that are appropriate for an economic downturn if those estimates are more conservative than the long-run average. Similarly, Article 182(1), point (b), of that Regulation requires institutions to use own-conversion factor ('CF') estimates that are appropriate for an economic downturn if those estimates are more conservative than the long-run average.
- (2) Given the specificities of different portfolios, institutions should be required to identify economic downturns separately for each type of exposures, as defined in Article 142(1), point (2), of Regulation (EU) No 575/2013.
- (3) The nature of an economic downturn for a given type of exposures should be specified by reference to the set of economic indicators that are considered to be either explanatory variables for, or indicators of, the economic cycle specific to that type of exposures. The set of economic indicators should include both macro-economic and credit-related indicators. This is to ensure that, for a comparable type of exposures, institutions will, generally speaking, identify the same economic downturn.
- (4) Even though the level of realised LGDs and realised CFs may be substantially above the long-run average as a result of an economic downturn, the conditions characterising an economic downturn should not be considered as the equivalent of the conditions used for stress testing. The conditions used for stress testing may be more severe and potentially use more extreme scenarios that are not necessarily based on historical observations. Regulation (EU) No 575/2013, and the delegated acts that supplement it, adequately provide for the carrying out of stress testing in cases where this is required, and the provisions relating to own-LGD and own-CF estimates do not include any such requirement for stress testing. The specification of an economic downturn for the purposes of own-LGD and own-CF estimates should be based instead on historically observed economic conditions.

⁽¹⁾ OJ L 176, 27.6.2013, p. 1.

- (5) The severity of an economic downturn should be specified by reference to the most severe 12-month values observed over an appropriate historical time-span for the set of economic indicators characterising the nature of a downturn for the particular type of exposures under consideration. For each economic indicator in the set, the most severe 12-month value should be used because it strikes a balance between stability and identification of the most severe conditions observed in an appropriate time-span. This approach was chosen for simplicity of the 12-month view and also because a longer average could potentially dilute adverse conditions observed on an economic indicator. More frequent values, for example quarterly values, could be subject to seasonal influences. On the other hand, less frequent values, for example values representing 36-month averages, could hide severe conditions.
- (6) Even for economic indicators reported annually, the 12 months to which indicators relate are not necessarily the same in all cases. Some indicators relate to calendar years, others to financial years, others to tax years and so on. For the purpose of identifying economic downturns, it should therefore be possible, in the case of both economic indicators reported annually and indicators reported on a more frequent basis, to use 12-month periods that start at any point in time within the year.
- (7) Given that a type of exposures may comprise exposures related to different businesses, sectors or geographical areas, an economic downturn for a type of exposures may comprise either one or several distinct 'downturn periods'. A downturn period should be recognised as a period of specified time in which a relevant economic indicator shows its most severe 12-month value. If the peaks or troughs related to the most severe 12-month value observed for two or more economic indicators are reached simultaneously or shortly after each other, those economic indicators should all be attributed to the same 'downturn period'. The reason for allowing for the possibility of an economic downturn comprising more than one distinct downturn period is to ensure that each relevant economic indicator is taken into account in specifying non-overlapping downturn periods which are to be analysed in the context of a downturn LGD estimation and a downturn CF estimation.
- (8) In order to avoid excessive complexity, it is appropriate to establish a list of economic indicators to be taken into account in all cases. However, given the specificities of particular portfolios, institutions should also be required to take into account additional economic indicators that are explanatory variables for, or indicators of, the economic cycle specific to the particular type of exposures.
- (9) Given the wide geographical and sectoral diversity of portfolios, it is not practicable to prescribe the precise data sources that must be used for each listed indicator in every jurisdiction of the world and every sector. Moreover, institutions are already required under Regulation (EU) No 575/2013 to use reliable data and to have robust systems in place for validating the estimation of all risk parameters. As a result, institutions will in any event be required to demonstrate the accuracy and reliability of the data sources used by them for obtaining indicator values. It is therefore not necessary to lay down specific rules in this Regulation about the precise data sources to be used.
- (10) Institutions should use appropriate reliable data sources, but they should not be required to acquire data for available economic indicators if the costs of doing so are disproportionate, having regard to the type of indicator as well as to the materiality of the type of exposures under consideration relative to the other types of exposures in the portfolio.
- (11) The economic indicators are to be considered in levels or in changes of levels as appropriate, taking into account the way in which the economic indicator is commonly reported and the extent to which it is able to reveal cyclicity.
- (12) An economic indicator should be included in the set of relevant economic indicators once for each jurisdiction, or smaller geographical area where appropriate, that represents a material share of the type of exposures under consideration. This is to ensure that the set of indicators fairly reflects the geographical mix of the exposures in that type of exposures. A similar rule should apply for each industry sector representing a material share of the type of exposures. Only where different jurisdictions or different industry sectors exhibit strong co-movements in realised values of economic indicators institutions should be allowed to group those jurisdictions or sectors for the purposes of identifying an economic downturn.
- (13) The historical time-span over which values for a given economic indicator are to be examined should be specified. A default time-span of 20 years should be set for each economic indicator. This is to ensure that the historical observation period covers at least two economic cycles. However, where those 20 years do not contain sufficiently

severe values, institutions should be required to look further back into the data history. Values should be considered 'not sufficiently severe' if the variability of the economic indicator over that 20-year observation period is not representative of the likely range of variability of that indicator in the future.

- (14) For reasons of simplicity and comparability, a downturn period should have a duration of at least 12 months. In order to ensure greater accuracy in the results, that period of time should be treated as a minimum. Institutions should be required to apply a longer duration where the most severe value(s) for the economic indicator(s) associated with a downturn period imply a longer downturn. The duration of a downturn period should reflect adverse conditions in cyclical behaviours specific to the type of exposures under consideration, rather than structural changes in the economy leading to long-term effects on the values of economic indicators.
- (15) The requirements for estimating LGDs and CFs in Regulation (EU) No 575/2013 require institutions to document the design and operational details of their rating systems, including the design of their processes for identifying economic downturns, and to retain evidence to show compliance with the estimation requirements in that Regulation. Regulation (EU) No 575/2013 further requires institutions to review their LGD and CF estimates and any input data required to make these estimates when new information comes to light and, in any event, at least annually.
- (16) The provisions in this Regulation are closely linked since they deal with the nature, severity and duration of an economic downturn affecting two different risk parameters that are both used for the purposes of applying the Internal Ratings Based (IRB) Approach, namely own-LGD estimates and own-CF estimates. To ensure that the provisions needed for identifying economic downturns for LGD purposes and the provisions needed for identifying economic downturns for CF purposes are consistent and that they enter into force at the same time, and to ensure ready access to those provisions, it is desirable to include the regulatory technical standards required by Article 181(3) and the regulatory technical standards required by Article 182(4) of Regulation (EU) No 575/2013 in a single Regulation.
- (17) Given the interplay with other Union acts relevant for own-LGD and own-CF estimations, the date of application of this Regulation should be deferred until 1 January 2021. In particular, institutions will need to comply with the revised materiality threshold set by competent authorities in accordance with Commission Delegated Regulation (EU) 2018/171 ⁽²⁾.
- (18) This Regulation is based on the draft regulatory technical standards submitted by the European Banking Authority to the Commission.
- (19) The European Banking Authority has conducted open public consultations on the draft regulatory technical standards on which this Regulation is based, analysed the potential related costs and benefits, in accordance with Article 10 of Regulation (EU) No 1093/2010 of the European Parliament and of the Council ⁽³⁾, and requested the opinion of the Banking Stakeholder Group established in accordance with Article 37 of that Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

Specification of the nature, severity and duration of an economic downturn

1. For the purposes of Article 181(1), point (b), or 182(1), point (b) of Regulation (EU) No 575/2013, an economic downturn shall be identified for each type of exposure, as defined in Article 142(1), point (2), of that Regulation.

⁽²⁾ Commission Delegated Regulation (EU) 2018/171 of 19 October 2017 on supplementing Regulation (EU) No 575/2013 of the European Parliament and of the Council with regard to regulatory technical standards for the materiality threshold for credit obligations past due (OJ L 32, 6.2.2018, p. 1).

⁽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).

2. In identifying an economic downturn for a given type of exposures, the following specification rules shall apply:
 - (a) the nature of an economic downturn is characterised by a set of economic indicators that are classified as relevant for exposures within that type of exposures in accordance with the rules laid down in Article 2 ('the relevant indicator set');
 - (b) in terms of severity, an economic downturn is indicated by the most severe value relating to a 12-month period ('the most severe 12-month value') that is observed, for each economic indicator in the relevant indicator set, over a historical time-span determined for that economic indicator in accordance with Article 3 ('the applicable time-span');
 - (c) an economic downturn is comprised of one or more distinct downturn periods covering the peaks and troughs related to the most-severe 12-month values for the economic indicators in the relevant indicator set, each such period being of a duration determined in accordance with Article 4 ('the duration of a downturn period').
3. For the purposes of paragraph 2, point (b), the 12-month periods to which values for an economic indicator relate may start at any point in time within the applicable time-span.
4. For the purposes of paragraph 2, point (c):
 - (a) a downturn period is a period in which an economic indicator reaches its most severe 12-month value;
 - (b) where, for different, significantly correlated economic indicators, the peaks or troughs related to the most severe 12-month values are reached simultaneously or shortly after each other, the downturn periods in which those indicators reach their most severe 12-month value are to be treated as one single downturn period covering the most severe 12-month values for all those indicators.

Article 2

The relevant indicator set

1. The following economic indicators shall be classified as relevant for exposures within a given type of exposures:
 - (a) for all types of exposures:
 - (i) gross domestic product (GDP);
 - (ii) unemployment rate;
 - (iii) externally provided aggregate default rates, where available;
 - (iv) externally provided aggregate credit losses, where available;
 - (b) in addition to the economic indicators listed in point (a):
 - (i) for exposures to corporates or to retail small and medium-sized enterprises (SMEs): sector- or industry-specific indices;
 - (ii) for residential property exposures to corporates or to retail obligors: house prices or house price indices;
 - (iii) for commercial immovable property exposures to corporates or to SME retail obligors: commercial immovable property prices or commercial immovable property price indices, and commercial immovable property rental prices or commercial immovable property rental price indices;
 - (iv) for retail exposures other than those falling within point (i), (ii) or (iii): total household debt and disposable personal income, in each case where available;
 - (v) for specialised lending exposures:
 - in the case of immovable property: immovable property prices or immovable property price indices, immovable property rental prices, or immovable property rental price indices for residential, commercial or industrial property, as applicable,
 - in the case of project finance: prices for the underlying products supplied,

- in the case of object finance: indices for the relevant type or types of collateral,
 - in the case of commodity finance: prices or price indices for the relevant type of commodity;
 - (vi) for exposures to institutions: financial credit indices;
 - (c) in addition to the economic indicators listed in points (a) and (b), any other economic indicators that are explanatory variables for, or indicators of, the economic cycle specific to exposures in the type of exposures under consideration.
2. The economic indicators identified for exposures within a type of exposures in accordance with paragraph 1 shall reflect the geographical distribution and, where applicable, the sectoral distribution of the exposures within that type of exposures.

For that purpose, an economic indicator shall be included in the relevant indicator set as follows:

- (a) once for each jurisdiction or, where appropriate, once for each geographical area within a jurisdiction, covered by a material share of that type of exposures; and
- (b) once for each sector, where applicable, covered by a material share of that type of exposures.

However, where economic indicators to be included in accordance with the second subparagraph show strong co-movement across the different jurisdictions, or where appropriate, different geographical areas within a jurisdiction, or, where applicable, different sectors, a common economic indicator may instead be selected to reflect those jurisdictions, geographical areas or sectors overall.

Article 3

Determining the applicable time-span

For the purposes of Article 1(2), point (b), the historical time-span applicable to an economic indicator shall be the period of 20 years ending at the point in time at which the institution identifies the economic downturn in accordance with this Regulation. However, where the variability of an economic indicator over that 20-year period is not representative of the likely range of variability of that indicator in the future, the historical time-span applicable to that indicator shall be of such longer length as is sufficient to provide values that are representative of that likely range of variability.

Article 4

Duration of a downturn period

For the purposes of Article 1(2), point (c), the duration of a downturn period shall be determined as follows:

- (a) in a case falling within Article 1(4), point (b), the single downturn period shall be such period that is long enough to cover all the peaks or troughs related to the most severe 12-month values observed for the different economic indicators associated with that single downturn period;
- (b) in all cases, whether or not falling within Article 1(4), point (b), where the various 12-month values observed for the economic indicator or indicators in question over the applicable time-span do not significantly deviate from their most severe 12-month value over a specific, continuous period of time within the applicable time-span, the downturn period shall be long enough to reflect the prolonged severity observed for the economic indicator or indicators in question;
- (c) in all cases, whether or not falling within Article 1(4), point (b), where the economic indicator or indicators show adjacent peaks or troughs to those peaks or troughs related to the most severe 12-month values observed for the economic indicator or indicators in question over the applicable time-span and those adjacent peaks and troughs do not significantly deviate from the most severe 12-month value observed for that indicator or those indicators over that time-span and those adjacent peaks and troughs are related to the same overall economic condition, the downturn period shall be long enough to reflect the whole prolonged period over which those adjacent peaks or troughs are observed;
- (d) in a case falling within Article 1(4), point (a), where neither point (b), nor point (c) of this Article applies, the downturn period shall be the 12-month period to which the most severe 12-month value relates.

*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.

This Regulation shall apply from 1 January 2021.

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

Done at Brussels, 1 March 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION DELEGATED REGULATION (EU) 2021/931**of 1 March 2021**

supplementing Regulation (EU) No 575/2013 of the European Parliament and of the Council with regard to regulatory technical standards specifying the method for identifying derivative transactions with one or more than one material risk driver for the purposes of Article 277(5), the formula for calculating the supervisory delta of call and put options mapped to the interest rate risk category and the method for determining whether a transaction is a long or short position in the primary risk driver or in the most material risk driver in the given risk category for the purposes of Article 279a(3)(a) and (b) in the standardised approach for counterparty credit risk

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 575/2013 of the European Parliament and of the Council of 26 June 2013 on prudential requirements for credit institutions and investment firms and amending Regulation (EU) No 648/2012 ⁽¹⁾, and in particular the third subparagraph of Article 277(5) and the third subparagraph of Article 279a(3) thereof,

Whereas:

- (1) Institutions should identify the risk drivers of a derivative transaction by determining the risk factors on which the cash flows of that transaction depend. To ensure that institutions follow a harmonised approach for this identification, they should at least consider the risk factors listed in Section 3, Chapter 1a of Title IV of Part Three of Regulation (EU) No 575/2013.
- (2) The method for identifying derivative transactions with only one material risk driver, for the purpose of mapping those derivative transactions to the relevant risk category, should be simple for all cases where the primary and only material risk driver of the derivative transaction is immediately discernible from the nature and cash flows of that transaction.
- (3) Cross-currency interest rate swaps are used by institutions to hedge the foreign exchange risk arising from funding or investment in foreign currencies. Although such transactions primarily depend on foreign exchange risk drivers, they can depend also on other risk drivers, such as interest rate risk drivers. Nevertheless, as market experience shows that the effect of these other risk drivers is very often immaterial for these particular transaction types, if a transaction falls under this type, this should suffice for identifying such transactions as derivative transactions with only one material risk driver.
- (4) Irrespective of the nature and cash flows of a derivative transaction, the interest rates used to discount the cash flows of the transaction ('the discount rate') should not be considered as a material risk driver. Requiring institutions to take into account the discount rate in the method for identifying derivative transactions with only one material risk driver would be disproportionate and burdensome, as empirical experience shows that that risk driver has usually a more limited effect on the value of derivative transactions than the other risk drivers from which their cash flows are derived.
- (5) For derivative transactions that have more than one risk driver, institutions should take into account the sensitivities and the volatility of the underlying to identify those risk drivers that are material in each risk category and the most material of those risk drivers in each risk category.
- (6) For derivative transactions that have more than one risk driver and where those risk drivers refer to different risk categories, it may not be possible to conclude which of those risk drivers are material, even after taking into account sensitivities and the volatility of the underlying of the transaction. In such cases, institutions should, as a simple, conservative fallback approach, consider all the risk drivers of the transaction material and, consequently, allocate the derivative transaction to the risk categories corresponding to these risk drivers on the basis of the most material risk drivers within each risk category.

⁽¹⁾ OJ L 176, 27.6.2013, p. 1.

- (7) The method for identifying derivative transactions with only one material risk driver should be performed at inception only, where such derivative transactions have been identified at inception as having only one risk driver, because that single risk driver is a basic characteristic of those transactions and is therefore not expected to change. Where, at inception, derivative transactions have been identified as having more than one risk driver, the process for identifying the material and most material of those risk drivers should be undertaken on a quarterly basis so that any changes in those transactions can be appropriately reflected in the mapping of those derivative transaction to the relevant risk categories.
- (8) Article 279a(3), point (a), of Regulation (EU) No 575/2013 requires that the formula to be used for the calculation of the supervisory delta of call and put options, when mapped to the interest rate risk category, that is compatible with market conditions in which interest rates may be negative, is to be specified in accordance with international regulatory developments. On 22 March 2018, the Basel Committee on Banking Supervision (BCBS) ⁽²⁾ published the 'Frequently asked questions on the Basel III standardised approach for measuring counterparty credit risk exposures', explaining that the supervisory delta for interest rate options in the case of a negative interest rate environment should be determined in accordance with a specific formula, in which a lambda (λ) shift is applied to the spot or forward interest rate and to the strike of the option used in that formula to ensure that that spot or forward interest rate and strike of the option are positive.
- (9) In order to render the spot or forward interest rate and the strike of the option positive, the λ shift should be large enough to enable institutions to calculate the supervisory delta of a transaction in accordance with the formula laid down in Article 279a(1) of Regulation (EU) No 575/2013, but at the same time small enough not to introduce unnecessary bias in the outcome of the supervisory delta calculation.
- (10) The supervisory volatility, being one of the parameters for the calculation of the supervisory delta, should be determined in light of the specific formula for the calculation of the supervisory delta for put and call options in the interest rate risk category. In that respect, the value of the supervisory volatility for put and call options in the interest rate risk category as determined in the international standards adopted by the BCBS is deemed suitable for its use under Union law.
- (11) To enable institutions to determine whether a transaction is a long or short position in the primary risk driver, in a material risk driver or in the most material risk driver of a given risk category, it should be laid down which information concerning a transaction institutions should use for making such a determination. To avoid unnecessary burdens for institutions, they should be allowed to use the same information as the information they use for the identification of material risk drivers.
- (12) This Regulation is based on the draft regulatory technical standards submitted by the European Banking Authority to the Commission.
- (13) The European Banking Authority 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 ⁽³⁾,

⁽²⁾ Frequently asked questions on the Basel III standardised approach for measuring counterparty credit risk exposures, 22 March 2018.

⁽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).

HAS ADOPTED THIS REGULATION:

CHAPTER 1

Method for identifying transactions with only one material risk driver, transactions with more than one material risk driver and for identifying the most material of those risk drivers

Article 1

Method for identifying the risk drivers of a derivative transaction

1. For the purpose of identifying transactions with only one material risk driver and transactions with more than one material risk driver, institutions shall, at inception of each transaction, identify all the risk drivers of the transaction by determining the risk factors on which the cash flows of that transaction depend, having regard to at least the risk factors referred to in Articles 325l to 325q of Regulation (EU) No 575/2013. The risk factors identified by the institutions shall be the risk drivers of the transaction.
2. Institutions shall not consider as risk drivers of a transaction the interest rate risk factors used to discount the cash flows of the transaction.

Article 2

Method for identifying transactions with only one material risk driver

1. After the identification of all the risk drivers of a transaction in accordance with Article 1, institutions shall, at inception of each transaction, identify transactions with only one material risk driver by applying the following:
 - (a) where the cash flows of the transaction depend exclusively on one risk driver that belongs to one of the risk categories referred to in Article 277(1) of Regulation (EU) No 575/2013, institutions shall identify that risk driver as the only material risk driver of that transaction;
 - (b) where the cash flows of the transaction depend on more than one risk driver and where institutions have identified only one risk driver of that transaction as material in accordance with either the method laid down in Article 4(3) or the method laid down in Article 4(4), institutions shall identify that risk driver as the only material risk driver of that transaction.
2. By way of derogation from paragraph 1, for cross-currency interest-rate swaps as referred to in point 2(a) of Annex II to Regulation (EU) No 575/2013, institutions may identify the foreign exchange risk driver as the only material risk driver of the transaction.

Article 3

Method for identifying transactions with more than one material risk driver

For the purposes of Article 277(3) of Regulation (EU) No 575/2013, institutions shall identify all transactions other than those referred to in Article 2 as transactions with more than one material risk driver.

Article 4

Method for identifying the material risk drivers and the most material of those risk drivers

1. After identification of all the risk drivers of a transaction in accordance with Article 1 and where the cash flows of the transaction depend on more than one risk driver, institutions shall identify the material risk drivers and the most material of those risk drivers by applying one of the methods laid down in paragraphs 2, 3 and 4, as appropriate.

2. Institutions shall apply the following steps at inception of the transaction:
 - (a) they shall consider all the risk drivers of the transaction identified in accordance with the procedure referred to in Article 1 to be material risk drivers;
 - (b) for each risk category corresponding to those material risk drivers, they shall identify as the most material risk driver the risk driver corresponding to the highest risk category add-on from those referred to in Articles 280a to 280f of Regulation (EU) No 575/2013.
3. Institutions shall apply the following steps at inception of the transaction, and then at least on a quarterly basis:
 - (a) they shall calculate the delta risk sensitivities in accordance with Article 325r of Regulation (EU) No 575/2013 for each risk driver identified in accordance with Article 1 of this Regulation;
 - (b) they shall calculate the weighted sensitivities in accordance with the formula laid down in Article 325f(6) of that Regulation based on the sensitivities calculated in accordance with point (a);
 - (c) for each of the risk categories referred to in Article 277(1) of that Regulation, they shall calculate the risk class specific own funds requirement for market risk in accordance with the formula laid down in Article 325f(8) of that Regulation, based on all the weighted sensitivities referred to in point (b) of risk drivers that have been assigned to that risk category;
 - (d) they shall rank all the risk class specific own funds requirements for market risk referred to in point (c) from the greatest to the smallest in absolute terms, in order to obtain a monotonically decreasing sequence of entries, where the entry a_1 is the greatest absolute term, a_2 is the second greatest term and so on;
 - (e) they shall, for each entry a_i calculated and ranked in accordance with point (d) and in the order resulting from their ranking, verify whether the following condition is met:

$$\frac{\sum_{j=1}^i a_j}{\sum_{k=1}^6 a_k} < Y\%$$

where:

i = the index that denotes the risk categories referred to in Article 277(1) of Regulation (EU) No 575/2013, ranked in accordance with point (d) and in the order resulting from that ranking;

$Y\%$ = 60%;

- (f) they shall consider as material:
 - (i) the risk drivers that correspond to the risk categories for which the condition laid down in point (e) of this paragraph is met;
 - (ii) the risk drivers that correspond to the first risk category for which that condition is not met;
- (g) they shall, for each of the risk categories that correspond to risk drivers that are not material in accordance with point (f), verify whether the following condition is met by the corresponding entry a_i :

$$\frac{a_i}{\sum_{k=1}^6 a_k} \geq Z\%$$

where:

i = the index that denotes the risk categories referred to in Article 277(1) of Regulation (EU) No 575/2013, ranked in accordance with point (d) and in the order resulting from that ranking, and that correspond to risk drivers that are not material in accordance with point (f);

$Z\%$ = 30 %;

- (h) in addition to the material risk drivers identified in accordance with point (f), they shall also consider as material risk drivers those risk drivers that correspond to the risk categories for which the condition laid down in point (g) is met;

- (i) for each of the risk categories referred to in points (f) and (h), they shall consider as the most material risk driver for that risk category the risk driver corresponding to the highest absolute value of the weighted sensitivities referred to in point (b).

4. Institutions that either meet the conditions set out in Article 94(1) of Regulation (EU) No 575/2013, or are exempted from the reporting requirement in accordance with Article 325a(1) of that Regulation, may identify the most material risk driver by applying the following steps at inception of the transaction, and then at least on a quarterly basis:

- (a) they shall calculate the risk category add-ons as referred to in Articles 280a to 280f of Regulation (EU) No 575/2013, as applicable, for each risk driver identified in accordance with Article 1. Where more than one risk driver identified in accordance with Article 1 have been assigned to the same risk category, institutions shall keep for the application of point (b) the risk driver in that risk category corresponding to the highest risk category add-on in that risk category;
- (b) they shall apply the steps laid down in paragraph 3, points (d) to (h), where the entries used in those steps shall be based on the risk category add-ons calculated in accordance with point (a) of this paragraph;
- (c) they shall identify as the most material risk drivers in the relevant risk categories the material risk drivers identified as a result of the method referred to in point (b).

CHAPTER 2

Formula to be used to calculate the supervisory delta of call and put options mapped to the interest rate risk category and supervisory volatility suitable for that formula and method for determining whether a transaction is a long or short position in the primary risk driver or in the most material risk driver in a given risk category

Article 5

Formula to calculate the supervisory delta of call and put options mapped to the interest rate risk category and supervisory volatility suitable for such formula

1. Institutions shall calculate the supervisory delta (δ) of call and put options, when mapped to the interest rate risk category, that is compatible with market conditions in which interest rates may be negative as follows:

$$\delta = \text{sign} \cdot N \left(\text{type} \cdot \frac{\ln \left(\frac{(P + \lambda)}{(K + \lambda)} \right) + 0,5 \cdot \sigma^2 \cdot T}{\sigma \cdot \sqrt{T}} \right)$$

where:

$\text{type} = \begin{cases} -1 & \text{where the transaction is a put option} \\ +1 & \text{where the transaction is a call option} \end{cases}$

$\text{sign} = \begin{cases} -1 & \text{where the transaction is a sold call option or a bought put option} \\ +1 & \text{where the transaction is a sold put option or a bought call option} \end{cases}$

$N(x)$ = the cumulative distribution function for a standard normal random variable which reflects the probability that a normal random variable with mean zero and variance of one is less than or equal to 'x';

P = the spot or forward price of the underlying instrument of the option;

K = the strike price of the option;

T = the expiry date of the option, expressed in years using the relevant business day convention;

λ = the shift adequate to move both P and K into positive territory, determined in accordance with paragraph 2;

σ = the supervisory volatility of the option determined in accordance with paragraph 3.

2. For the purposes of paragraph 1, institutions shall calculate the shift (λ) for any call and put options as follows:

$$\lambda_j = \max(\text{threshold} - \min(P_j, K_j), 0)$$

where:

P_j = the spot or forward price of the underlying instrument of the option j ;

K_j = the strike price of the option j ;

$\text{Threshold} = 0.10 \%$

3. For the purposes of paragraph 1, institutions shall determine the supervisory volatility of the option on the basis of the risk category of the transaction and the nature of the underlying instrument of the option in accordance with the following table:

Table

Risk category	Underlying instrument	Supervisory volatility
Interest rate	All	50 %

Article 6

Methods for determining whether a transaction is a long or short position in the primary risk driver or in the most material risk driver in a given risk category

Institutions shall determine whether a transaction is a long or short position in the primary risk driver or in the most material risk driver in a given risk category by applying either of the following methods:

- they shall calculate the delta risk sensitivities of those risk drivers in accordance with Article 325r of Regulation (EU) No 575/2013 and identify the transaction as a long position in a risk driver where the corresponding delta risk sensitivity is positive or as a short position where the corresponding delta risk sensitivity is negative;
- they shall assess the dependence of the structure of cash flows of the transactions on that risk driver or the hedging purpose of the transaction with respect to that risk driver and identify the transaction as either long or short position on the basis of that assessment.

Article 7

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, 1 March 2021.

For the Commission
The President
 Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2021/932**of 9 June 2021****suspending the authorisation of lasalocid A sodium (Avatec 15 % cc) and lasalocid A sodium (Avatec 150 G) as feed additives for chickens for fattening and chickens reared for laying (holder of authorisation Zoetis Belgium S.A.)****(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 13(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting, denying or suspending such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) Lasalocid A sodium (Avatec 15 % cc) and lasalocid A sodium (Avatec 150 G) were authorised by Commission Regulation (EC) No 1455/2004 ⁽³⁾ for 10 years as feed additives belonging to the category of coccidiostats for use for chickens for fattening and chickens reared for laying. Those feed additives were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the authorisation of lasalocid A sodium (Avatec 150 G) as a feed additive for chickens for fattening and chickens reared for laying, requesting the additive to be classified in the additive category 'coccidiostats and histomonostats'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') stated in its opinions of 16 May 2017 ⁽⁴⁾ and 1 July 2020 ⁽⁵⁾ that the assessment of the particulars and documents submitted by the applicant makes it impossible to conclude on the safety and the efficacy of the feed additive lasalocid A sodium (Avatec 150 G) for chickens for fattening and chickens reared for laying. The Authority indicated that no safe level of the active substance lasalocid A sodium, when added to feed, could be identified for the target species. It also concluded that, due to the insufficient number of studies with positive results, the coccidiostatic efficacy of the feed additive was insufficiently demonstrated at the lowest proposed dose level of 75 mg lasalocid A sodium per kg of complete feed. In addition, the Authority verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) Consequently, it has not been established that the feed additive does not have an adverse effect on animal health and that it has a coccidiostatic effect on the target species, when used under the proposed conditions. This conclusion can be extended to the existing authorisation of the feed additive lasalocid A sodium (Avatec 15 % cc), which contains the same concentration of the active substance lasalocid A sodium.
- (6) The existing authorisation of the feed additives lasalocid A sodium (Avatec 15 % cc) and lasalocid A sodium (Avatec 150 G) for chickens for fattening and chickens reared for laying therefore no longer meets the conditions set out by Article 5 of Regulation (EC) No 1831/2003.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

⁽³⁾ Commission Regulation (EC) No 1455/2004 of 16 August 2004 concerning the authorisation for 10 years of the additive «Avatec 15 %» in feedingstuffs, belonging to the group of coccidiostats and other medicinal substances (OJ L 269, 17.8.2004, p. 14).

⁽⁴⁾ EFSA Journal 2017; 15(8):4857.

⁽⁵⁾ EFSA Journal 2020; 18(8):6202.

- (7) It is possible that supplementary data concerning the safety of use and the efficacy of lasalocid A sodium (Avatec 150 G) for the target species bring new elements that would allow a re-consideration of the assessment carried out for that feed additive. In this respect, the applicant for the authorisation of lasalocid A sodium (Avatec 150 G) argues that additional studies may be performed in order to demonstrate the safety and efficacy of the feed additive for the target species. To this end, the applicant committed itself to produce supplementary data according to a time schedule, listing the studies to be carried out and planning that the outcome thereof will be available by 31 December 2021. Those studies would consist of tolerance and 'floor pen' efficacy studies for chickens for fattening and chickens reared for laying.
- (8) In accordance with Article 13(2) of Regulation (EC) No 1831/2003, the authorisation of the feed additives lasalocid A sodium (Avatec 15 % cc) and lasalocid A sodium (Avatec 150 G) should be suspended, pending the submission and assessment of the supplementary data. The suspension measure should be reviewed after due assessment of those data by the Authority.
- (9) Since further use of the feed additives lasalocid A sodium (Avatec 15 % cc) and lasalocid A sodium (Avatec 150 G) might cause a risk to animal health, the feed additives and feed containing them should be withdrawn from the market as soon as possible. For practical reasons, however, a limited transitional period should be allowed for the withdrawal from the market of the products concerned in order to enable operators to comply properly with the withdrawal obligation.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Suspension of the authorisation

The authorisation of the feed additives lasalocid A sodium (Avatec 15 % cc) and lasalocid A sodium (Avatec 150 G) for use for chickens for fattening and chickens reared for laying shall be suspended.

Article 2

Transitional measures

1. Existing stocks of the feed additives lasalocid A sodium (Avatec 15 % cc) and lasalocid A sodium (Avatec 150 G) for use for chickens for fattening and chickens reared for laying, and of premixtures containing them, may continue to be placed on the market until 30 July 2021 and may be used until 30 August 2021 in accordance with the rules applicable before 30 June 2021.
2. Feed materials and compound feed produced with the feed additives or with premixtures referred to in paragraph 1 may continue to be placed on the market until 30 August 2021 and may be used until 30 September 2021 in accordance with the rules applicable before 30 June 2021.

Article 3

Review

This Regulation shall be reviewed by 31 December 2023, after the adoption by the Authority of a new opinion on the safety and efficacy of the feed additive lasalocid A sodium (Avatec 150 G) for use for chickens for fattening and chickens reared for laying.

*Article 4***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, 9 June 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2021/933**of 9 June 2021****derogating from Implementing Regulation (EU) 2017/39 as regards certain measures to address the crisis caused by the COVID-19 pandemic**

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 25 thereof,

Whereas:

- (1) Article 1(2) of Commission Implementing Regulation (EU) 2017/39 ⁽²⁾ lays down the definition of 'school year' for the purposes of the aid scheme referred to under Article 23 of Regulation (EU) No 1308/2013 (the 'school scheme'). The measures put in place by the Member States to address the COVID-19 pandemic, which include the temporary closure of educational establishments, have disrupted the implementation of the school scheme in the 2020/2021 school year. Those measures have temporarily prevented the distribution of fruit, vegetables and milk in the educational establishments and the carrying out of accompanying educational measures and publicity, monitoring and evaluation activities. It is therefore appropriate to provide for a derogation from Article 1(2) of Implementing Regulation (EU) 2017/39 in order to extend the duration of the 2020/2021 school year, so that Member States may continue carrying out the activities envisaged for that school year until 30 September 2021.
- (2) Article 4(3), (4) and (5) and Article 5(3) of Implementing Regulation (EU) 2017/39 lay down the period that aid applications for the supply and distribution of products and for the accompanying educational measures may cover, and the time limit for the submission of aid applications and for the payment of the aid under the school scheme. In view of the extension of the duration of the 2020/2021 school year, a derogation from Article 4(3), (4) and (5) and Article 5(3) of Implementing Regulation (EU) 2017/39 should be provided for with regard to the aid applications for the school scheme activities taking place after 31 July 2021, so that they may cover periods of less than two weeks and to lay down the time limits for the submission of aid applications and for the payment of the aid.
- (3) Article 7(3) of Implementing Regulation (EU) 2017/39 sets out the rules for the reallocation of unrequested Union aid amongst the Member States participating in the school scheme that have notified their willingness to use more than their indicative allocation. The amount of indicative allocation that may be reallocated to another Member State is to be based on the level of use of the definitive allocation of Union aid by that Member State in the previous school year. The confinement rules put in place by the Member States to address the COVID-19 pandemic, which include the temporary closure of educational establishments, might lead to a lower use of Union aid in the 2020/2021 school year. It is therefore appropriate to provide for a derogation from Article 7(3) of Implementing Regulation (EU) 2017/39, in order not to take into account the level of use of Union aid in the 2020/2021 school year for the reallocation of unrequested Union aid amongst the Member States participating in the school scheme in the 2022/2023 school year.
- (4) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Common Organisation of the Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

1. By way of derogation from Article 1(2) of Implementing Regulation (EU) 2017/39, the duration of the 2020/2021 school year is extended until 30 September 2021.

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

⁽²⁾ Commission Implementing Regulation (EU) 2017/39 of 3 November 2016 on rules for the application of Regulation (EU) No 1308/2013 of the European Parliament and of the Council with regard to Union aid for the supply of fruit and vegetables, bananas and milk in educational establishments (OJ L 5, 10.1.2017, p. 1).

2. By way of derogation from Article 4(3) of Implementing Regulation (EU) 2017/39, aid applications relating to the 2020/2021 school year activities that take place after 31 July 2021 may cover periods of less than 2 weeks.
3. By way of derogations from Article 4(4) and (5) of Implementing Regulation (EU) 2017/39, aid applications relating to the 2020/2021 school year activities that take place after 31 July 2021 shall be submitted by 30 September 2021. If this time limit is exceeded, the aid shall not be paid.
4. By way of derogation from Article 5(3) of Implementing Regulation (EU) 2017/39, the aid for the 2020/2021 school year activities that take place after 31 July 2021 shall be paid by the competent authorities by 15 October 2021.
5. By way of derogation from Article 7(3), first subparagraph, of Implementing Regulation (EU) 2017/39, the calculation laid down in that subparagraph shall not apply for the calculation of the definitive allocation of Union aid for the 2022/2023 school year.

Article 2

This Regulation shall enter into force on the third 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, 9 June 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2021/934**of 9 June 2021****laying down special control measures for classical swine fever****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') ⁽¹⁾, and in particular Article 71(3) thereof,

Whereas:

- (1) Classical swine fever is an infectious viral disease affecting kept and wild porcine animals and can have a severe impact on the concerned animal population and the profitability of farming causing disturbance to movements of consignments of those animals and products thereof within the Union and exports to third countries. The spread of the disease can significantly affect the productivity of the farming sector due to both direct and indirect losses.
- (2) Commission Implementing Decision 2013/764/EU ⁽²⁾ lays down animal health control measures in relation to classical swine fever in the Member States and it has been amended several times to take account mainly of developments in the epidemiological situation in the Union as regards that disease. It applies until 21 April 2021.
- (3) Regulation (EU) 2016/429 establishes a new legislative framework for the prevention and control of diseases, which are transmissible to animals or humans. Classical swine fever is listed under Article 5(1)(a)(ii) of that Regulation, and is subject to the disease prevention and control rules laid down therein. In addition, Annex II to Commission Implementing Regulation (EU) 2018/1882 ⁽³⁾ lists classical swine fever as a Category A, D and E disease affecting Suidae and Tayassuidae, while Commission Delegated Regulation (EU) 2020/687 ⁽⁴⁾ supplements the rules for the control of Category A, B and C diseases laid down in Regulation (EU) 2016/429, including disease control measures for classical swine fever. Those three acts apply from 21 April 2021.
- (4) It is necessary to align the current Union control measures for classical swine fever laid down in Implementing Decision 2013/764/EU with the new legislative framework for animal health established by Regulation (EU) 2016/429. It is also necessary to align Union rules as much as possible with international standards, such as those set out in Chapter 15.2 'Infection with classical swine fever virus' of the Terrestrial Animal Health Code of the World Organization for Animal Health ⁽⁵⁾ (OIE Code).
- (5) The overall situation of classical swine fever in the Member States concerned by that disease, both on an epidemiological and risk management level, poses a persistent risk for its possible further spread in the Union. The general disease control measures laid down in Regulation (EU) 2016/429 and in Delegated Regulation (EU) 2020/687 do not cover all specific details and aspects in relation to the spread and the epidemiological situation of classical swine fever. It is therefore appropriate to lay down special disease control measures for a limited period of time, under conditions appropriate to the situation of classical swine fever in the Union, in order to ensure that the necessary measures are implemented in an uniform manner in the Union whenever there is a risk for the spread of that disease.

⁽¹⁾ OJ L 84, 31.3.2016, p. 1.

⁽²⁾ Commission Implementing Decision 2013/764/EU of 13 December 2013 concerning animal health control measures relating to classical swine fever in certain Member States (OJ L 338, 17.12.2013, p. 102).

⁽³⁾ Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases (OJ L 308, 4.12.2018, p. 21).

⁽⁴⁾ Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases (OJ L 174, 3.6.2020, p. 64).

⁽⁵⁾ OIE Terrestrial Animal Health Code, 28th Edition, 2019.

- (6) Regulation (EU) 2016/429 defines an outbreak as the officially confirmed occurrence of a listed disease or an emerging disease in one or more animals in an establishment or other place where animals are kept or located. The rules laid down in this Regulation should take account of whether or not the outbreak of classical swine fever occurred in wild or kept porcine animals.
- (7) This Regulation should provide for a regionalisation approach, which should apply in addition to the disease control measures laid down in Delegated Regulation (EU) 2020/687. This Regulation should list the restricted zones of the Member States concerned by classical swine fever in order to maintain the regionalisation approach established by Implementing Decision 2013/764/EU.
- (8) As regards risks for the spread of classical swine fever, movements of consignments of porcine animals and different porcine commodities pose different levels of risk. As a general rule, movements of consignments of kept porcine animals, germinal products and animal by-products of porcine origin from restricted zones pose a higher level of risk in terms of exposure and consequences, than movements of consignments of products of animal origin, including in particular fresh meat and meat products. Therefore, movements of consignments of kept porcine animals and various high-risk products of porcine origin from the restricted zones listed in Annex I to this Regulation should be prohibited in a manner proportionate to the risk involved, and taking into account the rules laid down in Delegated Regulation (EU) 2020/687 and in Commission Delegated Regulation (EU) 2020/2154 ⁽⁶⁾.
- (9) The rules laid down in Commission Delegated Regulation (EU) 2020/686 ⁽⁷⁾ supplement Regulation (EU) 2016/429 as regards the approval of germinal product establishments, the registers of germinal product establishments to be kept by the competent authorities, the record-keeping obligations of operators, the traceability and animal health requirements, and animal health certification and notification requirements for movements within the Union of consignments of germinal products of certain kept terrestrial animals in order to prevent the spread of transmissible animal diseases within the Union by those products. Therefore, the rules laid down in this Regulation should refer to Commission Delegated Regulation (EU) 2020/689 ⁽⁸⁾, as regards the information required to be kept by the competent authorities of approved germinal product establishments for porcine animals.
- (10) Regulation (EC) No 1069/2009 of the European Parliament and of the Council ⁽⁹⁾ lays down animal health rules for animal by-products in order to prevent and minimise risks to animal health arising from those by-products. In addition, Commission Regulation (EU) No 142/2011 ⁽¹⁰⁾ lays down certain animal health rules for animal by-products falling within the scope of Regulation (EC) No 1069/2009, including rules regarding the certification requirements for movements of consignments of animal by-products in the Union. Those legal acts do not cover all specific details and aspects in relation to the risk of the spread of classical swine fever through animal by-products obtained from kept and wild porcine animals in the restricted zones listed in Annex I to this Regulation. It is therefore appropriate to lay down in this Regulation special disease control measures for animal by-products and movements of consignments of such by-products from restricted zones listed in Annex I to this Regulation, in order to ensure that the necessary measures are implemented in a uniform manner in the Union whenever there is a risk for the spread of that disease.
- (11) In order to avoid any unnecessary disturbances to trade, it is appropriate to lay down certain conditions and derogations from the prohibitions provided for by this Regulation. The derogations should also take into account the general rules for the prevention and control of animal diseases laid down in Regulation (EU) 2016/429 and Delegated Regulation (EU) 2020/687, and the principles of the OIE Code as regards risk mitigation measures for classical swine fever.

⁽⁶⁾ Commission Delegated Regulation (EU) 2020/2154 of 14 October 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards animal health, certification and notification requirements for movements within the Union of products of animal origin from terrestrial animals (OJ L 431, 21.12.2020, p. 5).

⁽⁷⁾ Commission Delegated Regulation (EU) 2020/686 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the approval of germinal product establishments and the traceability and animal health requirements for movements within the Union of germinal products of certain kept terrestrial animals (OJ L 174, 3.6.2020, p. 1).

⁽⁸⁾ Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases (OJ L 174, 3.6.2020, p. 211).

⁽⁹⁾ Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

⁽¹⁰⁾ Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1).

- (12) Article 143 of Regulation (EU) 2016/429 provides that animal health certificates should accompany the movements of consignments of animals, including kept porcine animals. Where derogations from the prohibition on movements of consignments of kept porcine animals from the restricted zones listed in Annex I to this Regulation are applied to such consignments intended for intra-Union movements, those animal health certificates should include a reference to this Regulation, to ensure that adequate and accurate animal health information is provided in those animal health certificates. It is necessary to mitigate the risks arising from movements of consignments, and movements for private use, of fresh meat, meat products and any other products of animal origin obtained from wild porcine animals, bodies of wild porcine animals, which are intended for human consumption, and wild porcine animals from restricted zones listed in Annex I to this Regulation within the same Member State concerned and to other Member States. Risks for the spread of disease should be reduced by prohibiting movements of those products and movements of wild porcine animals by operators as laid down in Article 101 of Commission Delegated Regulation 2020/688 ⁽¹¹⁾ within and from Member States concerned and to other Member States.
- (13) Article 167(1)(b) of Regulation (EU) 2016/429 provides that animal health certificates issued by the competent authority of the Member State of origin are to accompany consignments of products of animal origin, including those of porcine origin, that are allowed to be moved from a restricted zone established in accordance with Article 71(3) of that Regulation subject to certain disease control measures. Where this Regulation provides for derogations from prohibitions on movements of consignments of products of animal origin from the restricted zones listed in Annex I hereto, the accompanying animal health certificates should include a reference to this Regulation, so as to ensure that adequate and accurate health information is provided in accordance with Delegated Regulation (EU) 2020/2154.
- (14) Movements of consignments of fresh or processed meat and meat products, including casings, obtained from porcine animals kept in the restricted zones listed in Annex I to this Regulation, or kept outside those restricted zones but slaughtered in them, should be subject to less stringent certification requirements in order to avoid any unnecessary and overly burdensome trade restrictions. It should be possible to authorise movements of those consignments within the territory of the same Member State and to other Member States based on the health or identification marks applied in establishments, provided that those establishments are designated in accordance with rules laid down in this Regulation. The competent authorities should only designate establishments if the kept porcine animals and products thereof that are eligible for movements outside such restricted zones are clearly separated from those animals and products that are not eligible for such authorised movements.
- (15) In addition, in specific situations, fresh meat from kept porcine animals should be marked in accordance with the requirements for the marking of fresh meat from protection and surveillance zones set out in Annex IX to Delegated Regulation (EU) 2020/687 or the fresh meat and meat products, including casings, from kept porcine animals should be marked with special marks. These special marks should not be confused with the health mark referred to in Article 48 of Commission Implementing Regulation (EU) 2019/627 ⁽¹²⁾ or the identification mark provided for in Article 5(1), point (b), of Regulation (EC) No 853/2004 of the European Parliament and of the Council ⁽¹³⁾.
- (16) Certain risk mitigation measures and reinforced biosecurity measures are necessary in order to prevent and control classical swine fever in establishments of kept porcine animals. Those measures should be laid down in the Annex II to this Regulation and should cover establishments subject to derogations for movements of consignments of porcine animals kept in the restricted zones listed in Annex I hereto. These measures should address procedures and infrastructures in place in establishments of kept porcine animals; they should also address the risk of animals (other than the kept pigs) roaming in the premises and buildings. This risk is higher when related to wild porcine animals entering the premises and buildings. When other species are involved (pets or pests), acting as fomites, the risk is still present and should be addressed as well.

⁽¹¹⁾ Commission Delegated Regulation (EU) 2020/688 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health requirements for movements within the Union of terrestrial animals and hatching eggs (OJ L 174, 3.6.2020, p. 140).

⁽¹²⁾ Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (OJ L 131, 17.5.2019, p. 51).

⁽¹³⁾ Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

- (17) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (Withdrawal Agreement), and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, Regulation (EU) 2016/429, as well as the Commission acts based on it, apply to and in the United Kingdom in respect of Northern Ireland after the end of the transition period provided for in the Withdrawal Agreement. Therefore, references to Member States in this Regulation should include the United Kingdom in respect of Northern Ireland.
- (18) As Regulation (EU) 2016/429 applies with effect from 21 April 2021, this Regulation should apply from the third day following that of its publication in the *Official Journal of the European Union* in order to apply the measures in a timely manner.
- (19) This Regulation should apply for a period of at least five years taking into account the Union's experience in the fight against classical swine fever and the current epidemiological situation and disease management measures in place for this disease in the Member States concerned by that disease. The duration of these measures and the restricted zones listed in Annex I to this Regulation should be monitored and reviewed when new elements appear.
- (20) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

1. This Regulation lays down:
- (a) special disease control measures regarding classical swine fever to be applied for a limited period of time by the Member States ⁽¹⁴⁾ which have restricted zones listed in Annex I to this Regulation (the Member States concerned).

Those special disease control measures apply to kept and wild porcine animals and to products of animal origin, germinal products and animal by-products obtained from porcine animals, and are in addition to the measures applicable for the protection and surveillance of the restricted and infected zones established by the competent authorities of the Member States concerned in accordance with Article 21(1) and Article 63 of Delegated Regulation (EU) 2020/687.

- (b) special disease control measures regarding classical swine fever to be applied for a limited period of time by all Member States.

2. This Regulation applies to:

- (a) the movements of consignments from the restricted zones listed in Annex I of:
- (i) porcine animals kept in establishments located in restricted zones listed in Annex I;
 - (ii) germinal products, products of animal origin and animal by-products obtained from kept porcine animals referred to in point (a)(i);

⁽¹⁴⁾ In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Regulation references to Member States include the United Kingdom in respect of Northern Ireland.

- (b) the movements of:
 - (i) consignments of wild porcine animals in the Member States concerned;
 - (ii) consignments and movements for private use by hunters of products of animal origin and animal by-products obtained from wild porcine in the restricted zones listed in Annex I or processed in establishments located in those restricted zones;
 - (c) food business operators handling consignments referred to in points (a) and (b).
3. The disease control measures referred to in paragraph 1 cover the following:
- (a) Chapter II lays down special rules for the establishment of restricted zones listed in Annex I in the event of an outbreak of classical swine fever;
 - (b) Chapter III lays down special disease control measures applicable to consignments of porcine animals kept in restricted zones listed in Annex I and products obtained thereof in the Member States concerned;
 - (c) Chapter IV lays down special risk-mitigating measures for food businesses in the Member States concerned;
 - (d) Chapter V lays down special disease control measures applicable to wild porcine animals in the Member States concerned;
 - (e) Chapter VI lays down the final provisions.

Article 2

Definitions

For the purposes of this Regulation, the definitions laid down in Delegated Regulation (EU) 2020/687 shall apply.

In addition, the following definitions shall apply:

- (a) 'porcine animal' means an animal of the species of ungulates of the family *Suidae* listed in Annex III to Regulation (EU) 2016/429;
- (b) 'germinal products' means porcine semen, oocytes and embryos obtained from kept porcine animals for artificial reproduction;
- (c) 'Category 2 materials' means animal by-products referred to in Article 9 of Regulation (EC) 1069/2009 obtained from kept porcine animals;
- (d) 'Category 3 materials' means animal by-products referred to in Article 10 of Regulation (EC) 1069/2009 obtained from kept porcine animals.

CHAPTER II

SPECIAL RULES FOR THE ESTABLISHMENT OF RESTRICTED ZONES IN THE EVENT OF AN OUTBREAK OF CLASSICAL SWINE FEVER AND THE APPLICATION OF SPECIAL DISEASE CONTROL MEASURES IN ALL MEMBER STATES

Article 3

Special rules for the establishment of restricted and infected zones in the event of an outbreak of classical swine fever

In the event of an outbreak of classical swine fever in kept or wild porcine animals, the competent authorities of the Member States shall establish either:

- (a) in the case of an outbreak in kept porcine animals, a restricted zone in accordance with Article 21(1) of Delegated Regulation (EU) 2020/687; or
- (b) in the case of an outbreak in wild porcine animals, an infected zone in accordance with Article 63 of Delegated Regulation (EU) 2020/687.

*Article 4***Special rules for the listing of restricted zones in Annex I in the event of an outbreak of classical swine fever in wild porcine animals in a Member State**

1. Following an outbreak of classical swine fever in wild porcine animals in an area of a Member State, that area shall be listed as a restricted zone in Annex I.
2. The competent authorities of the Member State concerned shall ensure that the boundaries of the infected zone established in accordance with Article 63 of Delegated Regulation (EU) 2020/687 are adjusted without delay to comprise at least the relevant restricted zone listed in Annex I to this Regulation for that Member State.

*Article 5***General application of special disease control measures in restricted zones**

The Member States concerned shall apply the special disease control measures laid down in Articles 3 and 4 of this Regulation in the restricted zones listed in Annex I to this Regulation in addition to the disease control measures to be applied in accordance with Delegated Regulation (EU) 2020/687 in:

- (a) the restricted zones established in accordance with Article 21(1) of Delegated Regulation (EU) 2020/687;
- (b) the infected zones established in accordance with Article 63 of Delegated Regulation (EU) 2020/687.

CHAPTER III

SPECIAL DISEASE CONTROL MEASURES APPLICABLE TO CONSIGNMENTS OF PORCINE ANIMALS KEPT IN RESTRICTED ZONES AND PRODUCTS THEREOF IN THE MEMBER STATES CONCERNED

SECTION 1

*Specific prohibitions on movements of consignments of kept porcine animals and products thereof in the Member States concerned**Article 6***Specific prohibition on movements from the restricted zones of consignments of porcine animals kept in restricted zones**

The competent authorities of the Member States concerned shall prohibit movements from the restricted zones listed in Annex I of consignments of porcine animals kept in those restricted zones.

*Article 7***Specific prohibition on movements from the restricted zones of consignments of germinal products obtained from porcine animals kept in restricted zones**

The competent authorities of the Member States concerned shall prohibit movements from the restricted zones listed in Annex I of consignments of germinal products obtained from porcine animals kept in those restricted zones.

*Article 8***Specific prohibition on movements from the restricted zones of consignments of animal by-products obtained from porcine animals kept in restricted zones**

The competent authorities of the Member States concerned shall prohibit movements from the restricted zones listed in Annex I of consignments of animal by-products obtained from porcine animals kept in those restricted zones.

*Article 9***Specific prohibition on movements from the restricted zones of consignments of fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zones**

1. The competent authorities of the Member States concerned shall prohibit movements from the restricted zones listed in Annex I of consignments of fresh meat and meat products, including casings, obtained from porcine animals kept in those restricted zones.
2. The competent authorities of the Member States concerned may decide that the prohibition provided for in paragraph 1 of this Article shall not apply to consignments of meat products, including casings, obtained from porcine animals kept in restricted zones listed in Annex I to this Regulation, which have undergone the relevant risk-mitigating treatment as regards classical swine fever in accordance with Annex VII to Delegated Regulation (EU) 2020/687, in establishments designated in accordance with Article 23(1) of this Regulation.

*SECTION 2****General conditions for derogations authorising movements from restricted zones of consignments of porcine animals kept in restricted zones****Article 10***General conditions for derogations from the specific prohibition in relation to movements from the restricted zones of consignments of porcine animals kept in restricted zones**

1. By way of derogation from the specific prohibition provided for in Article 6, the competent authorities of the Member States concerned may authorise movements from the restricted zones listed in Annex I of consignments of porcine animals kept in those restricted zones in the cases covered by Articles 18 to 22, subject to compliance with the specific conditions laid down in those Articles, and with the following conditions:
 - (a) the general conditions laid down Article 28(2) to (7) of Delegated Regulation (EU) 2020/687; and
 - (b) the additional general conditions concerning:
 - (i) movements of consignments of kept porcine from the restricted zones listed in Annex I, laid down in Article 11;
 - (ii) establishments for kept porcine animals located in restricted zones listed in Annex I, laid down in Article 12;
 - (iii) the means of transport used for the transportation of kept porcine animals from restricted zones listed in Annex I, laid down in Article 13.
2. Prior to granting authorisations provided for in Articles 18 to 22, the competent authorities of the Member States concerned shall assess the risks deriving from such authorisations and that assessment must demonstrate that the risk of the spread of classical swine fever is negligible.

*Article 11***Additional general conditions for movements from the restricted zones of consignments of porcine animals kept in restricted zones**

1. The competent authorities of the Member States concerned shall only authorise movements from the restricted zones listed in Annex I of porcine animals kept in those restricted zones in the cases covered by Articles 18 to 22, subject to compliance with the specific conditions laid down in those Articles and provided that:

- (a) the porcine animals have been kept in and have not been moved from their establishment of dispatch for a period of at least 90 days prior to the date of movement, or since birth, if they are younger than 90 days of age, and during the 30-day period immediately prior to the date of dispatch no other kept porcine animals have been introduced into that establishment from the restricted zones listed in Annex I into either:
 - (i) that establishment of dispatch; or
 - (ii) the epidemiological unit of that establishment of dispatch where the porcine animals to be moved were kept completely separated. The competent authority shall determine, after carrying out a risk assessment, the boundaries of such epidemiological unit confirming that the structure, size and distance between the different epidemiological units and the operations being carried out ensure separate facilities for the housing, keeping and feeding of kept porcine animals so that the classical swine fever virus cannot spread from one epidemiological unit to another;
- (b) a clinical examination has been carried out on the porcine animals kept in the establishment of dispatch, including those animals to be moved, with favourable results concerning classical swine fever:
 - (i) by an official veterinarian;
 - (ii) within the 24-hour period prior to the time of movement of the consignment; and
 - (iii) in accordance with Article 3(1) and (2) of Delegated Regulation (EU) 2020/687 and point A.1 of Annex I thereto;
- (c) if necessary, following the instructions of the competent authority, pathogen identification tests or antibody detection tests have been carried out prior to the date of the movement of the consignment from the establishment of dispatch:
 - (i) following the clinical examination referred to in point (b) for porcine animals kept in the establishment, including those animals to be moved; and
 - (ii) in accordance with point A.2 of Annex I to Delegated Regulation (EU) 2020/687.

2. The competent authorities of the Member States concerned shall obtain, where relevant, negative results of pathogen identification tests referred to in point (1)(c) before authorising the movement of consignment.

*Article 12***Additional general conditions for establishments of kept porcine animals located in restricted zones**

The competent authorities of the Member States concerned shall only authorise movements from the restricted zones listed in Annex I of porcine animals kept in establishments located in those restricted zones outside those zones in the cases covered by Articles 18 to 22, subject to compliance with the specific conditions laid down in those Articles and provided that:

- (a) the establishment of dispatch has been visited by an official veterinarian at least once following the listing of the restricted zones in Annex I to this Regulation, and is subject to regular visits by official veterinarians as provided for in Article 26(2) of Delegated Regulation (EU) 2020/687 at least twice a year, with an interval of at least four months between such visits;
- (b) the establishment of dispatch implements biosecurity requirements for classical swine fever:
 - (i) in accordance with the reinforced biosecurity measures for establishments of kept porcine animals located in restricted zones listed set out in Annex II; and
 - (ii) as established by the Member State concerned;

- (c) continuous surveillance by means of testing with pathogen identification tests and antibody detection tests for classical swine fever is carried out in the establishment of dispatch:
 - (i) in accordance with Article 3(2) of Delegated Regulation (EU) 2020/687 and Annex I thereto;
 - (ii) with negative results, each week, on at least the first two dead kept porcine animals over the age of 60 days or, in the absence of such dead animals over the age of 60 days, on any dead kept porcine animals after weaning, in each epidemiological unit;
 - (iii) at least during the monitoring period for classical swine fever set out in Annex II to Delegated Regulation (EU) 2020/687 before the movement of the consignment from the establishment of dispatch.

Article 13

Additional general conditions for the means of transport used for the transportation from the restricted zones of porcine animals kept in restricted zones

The competent authorities of the Member States concerned shall only authorise movements from the restricted zones listed in Annex I of consignments of porcine animals kept in those restricted zones if the means of transport used for the transportation of those consignments:

- (a) comply with the requirements laid down in Article 24(1) of Delegated Regulation (EU) 2020/687; and
- (b) are cleaned and disinfected in accordance with Article 24(2) of Delegated Regulation (EU) 2020/687 under the control or supervision of the competent authorities of the Member States.

SECTION 3

Obligations on operators with regard to animal health certificates

Article 14

Operators' obligations with regard to animal health certificates for movements from the restricted zones of consignments of porcine animals kept in restricted zones

Operators shall only move consignments of porcine animals kept in the restricted zones listed in Annex I to this Regulation, from those restricted zones to another Member State in the cases covered by Article 18 of this Regulation, if those consignments are accompanied by an animal health certificate, as provided for in Article 143(1) of Regulation (EU) 2016/429, that contains the following attestation of compliance with the requirements laid down in this Regulation:

'Porcine animals kept in restricted zone in compliance with the special control measures relating to classical swine fever laid down in Commission Implementing Regulation (EU) 2021/934.'

Article 15

Operators' obligations with regard to animal health certificates for movements from the restricted zones of consignments of fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zones

1. Operators shall only move consignments of fresh meat and meat products, including casings, obtained from porcine animals kept in the restricted zones listed in Annex I to this Regulation, from those restricted zones to another Member State in the cases covered by Article 22 of this Regulation, if those consignments are accompanied by an animal health certificate as provided for in Article 167(1) of Regulation (EU) 2016/429 that contains:

- (a) the information required in accordance with Article 3 of Delegated Regulation (EU) 2020/2154; and

- (b) the following attestation of compliance with the requirements laid down in this Regulation:

‘Fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zone in compliance with the special control measures relating to classical swine fever laid down in Commission Implementing Regulation (EU) 2021/934’.

2. Operators shall only move consignments of processed meat products, including casings, obtained from porcine animals kept in the restricted zones listed in Annex I, from those restricted zones to another Member State, subject to compliance with the following conditions:

- (a) the processed meat products, including casings, have undergone the relevant risk-mitigating treatment set out in Annex VII to Delegated Regulation (EU) 2020/687;
- (b) those consignments are accompanied by an animal health certificate as provided for in Article 167(1) of Regulation (EU) 2016/429 that contains:

(i) the information required in accordance with Article 3 of Delegated Regulation (EU) 2020/2154; and

(ii) the following attestation of compliance with the requirements laid down in this Regulation:

‘Processed meat products, including casings, obtained from porcine animals kept in restricted zones in compliance with the special control measures relating to classical swine fever laid down in Commission Implementing Regulation (EU) 2021/934’.

3. Operators shall only move consignments of fresh meat and meat products, including casings, obtained from porcine animals kept in areas outside the restricted zones listed in Annex I and slaughtered in slaughterhouses located in those restricted zones, from such restricted zones to another Member State, if those consignments are accompanied by:

- (a) an animal health certificate as provided for in Article 167(1) of Regulation (EU) 2016/429 that contains the information required in accordance with Article 3 of Delegated Regulation (EU) 2020/2154; and

- (b) the following attestation of compliance with the requirements laid down in this Regulation:

‘Fresh meat and meat products, including casings, obtained from porcine animals kept in areas outside restricted zones and slaughtered in restricted zones in compliance with the special control measures relating to classical swine fever laid down in Commission Implementing Regulation (EU) 2021/934’.

4. Operators shall only move consignments of processed meat products, including casings, obtained from porcine animals kept in areas outside the restricted zones listed in Annex I, and processed in those restricted zones, from such restricted zones to another Member State, subject to compliance with the following conditions:

- (a) the processed meat products, including casings, have undergone the relevant risk-mitigating treatment set out in Annex VII to Delegated Regulation (EU) 2020/687;

- (b) those consignments are accompanied by an animal health certificate as provided for in Article 167(1) of Regulation (EU) 2016/429 that contains:

(i) the information required in accordance with Article 3 of Delegated Regulation (EU) 2020/2154; and

(ii) the following attestation of compliance with the requirements laid down in this Regulation:

‘Processed meat products, including casings, obtained from porcine animals kept in areas outside restricted zones and processed in restricted zones in compliance with the special control measures relating to classical swine fever laid down in Commission Implementing Regulation (EU) 2021/934’.

5. The competent authorities of the Member States concerned may decide that a health mark or, where relevant, an identification mark provided for in Article 5(1), point (b) of Regulation (EC) No 853/2004 applied on the fresh or processed meat and meat products, including casings, in establishments designated in accordance with Article 23(1) of this Regulation may be substituted for the animal health certificate for movements from the restricted zones listed in Annex I for the following consignments of:

- (a) fresh meat and meat products, including casings, obtained from porcine animals kept in the restricted zones, listed in Annex I, to another Member State, as laid down in paragraph 1;
- (b) processed meat products, including casings, obtained from porcine animals kept in the restricted zones, listed in Annex I, to another Member State, as laid down in paragraph 2;
- (c) fresh meat and meat products, including casings, obtained from porcine animals kept in areas outside the restricted zones, listed in Annex I, and slaughtered in slaughterhouses located in those restricted zones to another Member State, as laid down in paragraph 3;
- (d) processed meat products, including casings, obtained from porcine animals kept in areas outside the restricted zones, listed in Annex I, and processed in those restricted zones to another Member State, as laid down in paragraph 4.

Article 16

Operators' obligations with regard to animal health certificates for movements from the restricted zones of consignments of germinal products obtained from porcine animals kept in establishments located in restricted zones

Operators shall only move consignments of germinal products obtained from porcine animals kept in the restricted zones listed in Annex I, from those restricted zones to another Member State in the cases covered by Article 19 of this Regulation if those consignments are accompanied by an animal health certificate as referred to in Article 161(4) of Regulation (EU) 2016/429. That animal health certificate shall contain the following attestation of compliance with the requirements laid down in this Regulation:

'Germinal products obtained from porcine animals kept in restricted zone in compliance with the special control measures relating to classical swine fever laid down in Commission Implementing Regulation (EU) 2021/934'.

Article 17

Operators' obligations with regard to animal health certificates for movements from the restricted zones of consignments of Category 2 and 3 material obtained from porcine animals kept in restricted zones

Operators shall only move consignments of Category 2 and 3 material obtained from porcine animals kept in the restricted zones listed in Annex I, from those restricted zones to another Member State in the cases covered by Articles 20 and 21, if those consignments are accompanied by:

- (a) the commercial document referred to in Chapter III of Annex VIII to Regulation (EU) No 142/2011; and
- (b) an animal health certificate referred to in Article 22(5) of Delegated Regulation (EU) 2020/687.

SECTION 4

Specific conditions for derogations authorising movements from the restricted zones of consignments of kept porcine animals and products thereof in the Member States concerned

Article 18

Specific conditions for derogations authorising movements from the restricted zones of consignments of porcine animals kept in restricted zones to other Member States and to third countries

1. By way of derogation from the prohibition provided for in Article 6, the competent authorities of the Member States concerned may authorise movements from the restricted zones listed in Annex I of consignments of porcine animals kept in those restricted zones to an establishment located in the territory of other Member States and to third countries provided that:

- (a) no evidence of classical swine fever has been recorded in the previous 12 months in the establishment of dispatch and that establishment is located outside a protection zone or a surveillance zone established in accordance with Article 21 of Delegated Regulation (EU) 2020/687;
- (b) the general conditions laid down in Article 28(2) to (7) of Delegated Regulation (EU) 2020/687 are met;
- (c) the additional general conditions laid down in Articles 10 to 13 are met.

2. The competent authorities of all Member States shall ensure that consignments of porcine animals subject to an authorised movement referred to in paragraph 1 of this Article remain in the establishment of destination for at least the duration of the monitoring period required for classical swine fever set out in Annex II to Delegated Regulation (EU) 2020/687 or are sent for immediate slaughter.

Article 19

Specific conditions for derogations authorising movements from the restricted zones of consignments of germinal products obtained from germinal product establishments located in restricted zones to other Member States and to third countries

By way of derogation from the prohibition provided for in Article 7, the competent authorities of the Member States concerned may authorise movements from the restricted zones listed in Annex I of consignments of germinal products from germinal product establishments located in those restricted zones to other Member States and to third countries provided that:

- (a) the germinal products were collected or produced, processed and stored in establishments and were obtained from kept porcine animals that comply with conditions laid down in Article 11(1)(b) and (c), Article 11(2) and Article 12;
- (b) the donor males and donor females of the porcine animals were kept at germinal product establishments:
 - (i) for a period of at least 90 days prior to the date of the collection or production of the germinal products;
 - (ii) where no other kept porcine animals were introduced from the restricted zones listed in Annex I for a period of at least 90 days prior to the date of the collection or production of the germinal products.

*Article 20***Specific conditions for derogations authorising movements from the restricted zones of consignments of Category 2 materials obtained from porcine animals kept in restricted zones for the purpose of disposal in another Member State or third country**

1. By way of derogation from the prohibition provided for in Article 8 of this Regulation, the competent authorities of the Member States concerned may authorise movements from the restricted zones listed in Annex I to this Regulation of consignments of animal by-products of Category 2 materials obtained from porcine animals kept in those restricted zones to a processing plant to be processed by methods 1 to 5, as set out in Chapter III of Annex IV to Regulation (EU) No 142/2011, or to an incineration or co-incineration plant, as referred to in Article 24(1)(a), (b) and (c) of Regulation (EC) No 1069/2009, located in another Member State or to a third country, provided that:

- (a) the general conditions laid down in Article 28(2) to (7) of Delegated Regulation (EU) 2020/687 are met;
- (b) the additional general conditions laid down in Article 10(2) are met;
- (c) the means of transport is equipped with a satellite navigation system to determine, transmit and record its real time location.

2. The transport operator responsible for movements of consignments of Category 2 materials shall:

- (a) enable the competent authority to control, by means of a satellite navigation system, the real time movement of the means of transport; and
- (b) keep the electronic records of that movement for a period of at least two months from the date of movement.

3. The competent authorities of both the Member States of dispatch and of destination of the consignment of Category 2 materials shall ensure the controls of dispatch of that consignment in accordance with Article 48(1) and (3) of Regulation (EC) No 1069/2009.

*Article 21***Specific conditions for derogations authorising movements from the restricted zones of consignments of Category 3 materials obtained from porcine animals kept in restricted zones to another Member State or third country for further processing or transformation**

1. By way of derogation from the prohibition provided for in Article 8 of this Regulation, the competent authorities of the Member States concerned may authorise movements from the restricted zones listed in Annex I of consignments of Category 3 materials obtained from porcine animals kept in those restricted zones to a plant or establishment approved by the competent authority for the processing of Category 3 material into processed feed, processed pet food, derived products intended for use outside the feed chain, or the transformation of Category 3 materials into biogas or compost as referred to in Article 24(1)(a), (e) and (g) of Regulation (EC) No 1069/2009, located in another Member State or to a third country, provided that:

- (a) the general conditions laid down in Article 28(2) to (7) of Delegated Regulation (EU) 2020/687 are met;
- (b) the additional general conditions laid down in Article 10(2) are met;
- (c) the Category 3 materials originate from kept porcine animals and establishments that comply with the general conditions laid down in Articles 11 and 12;
- (d) the means of transport is equipped with a satellite navigation system to determine, transmit and record its real time location;
- (e) the animal by-products are moved directly from the slaughterhouse designated in accordance with Article 23(1) to:
 - (i) a processing plant for the processing of derived products referred to in Annexes X and XIII to Regulation (EU) No 142/2011;

- (ii) a pet food plant approved for the production of processed pet food referred to in Chapter II, point 3(b)(i), (ii) and (iii), of Annex XIII to Regulation (EU) No 142/2011;
 - (iii) a biogas or a compost plant approved for transformation of animal by-products into compost or biogas in accordance with the standard transformation parameters referred to in Chapter III, Section I, of Annex V to Regulation (EU) No 142/2011.
2. The transport operator responsible for the movements of consignments of Category 3 materials shall:
- (a) enable the competent authority to control, by means of a satellite navigation system, the real time movement of the means of transport; and
 - (b) keep the electronic records of the movement for a period of at least two months from the date of movement.

Article 22

Specific conditions for derogations authorising movements from the restricted zones of consignments of fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zones to other Member States and to third countries

By way of derogation from the prohibition provided for in Article 9, the competent authorities of the Member States concerned may authorise movements from the restricted zones listed in Annex I of consignments of fresh meat and meat products, including casings, obtained from porcine animals kept in those restricted zones to other Member States and to third countries, provided that:

- (a) the porcine animals were kept in an establishment where there was no evidence of classical swine fever in the 12 months preceding the date of movement and that establishment is located outside a protection zone or a surveillance zone established in accordance with Article 21 of Delegated Regulation (EU) 2020/687;
- (b) the general conditions laid down in Article 28(2) to (7) of Delegated Regulation (EU) 2020/687 are met;
- (c) the additional general conditions laid down in Articles 10(2) are met;
- (d) the fresh meat and meat products, including casings, are obtained from porcine animals kept in establishments that comply with the general conditions laid down in Articles 11 and 12;
- (e) the fresh meat and meat products, including casings, have been produced in establishments designated in accordance with Article 23(1).

CHAPTER IV

SPECIAL RISK-MITIGATING MEASURES CONCERNING CLASSICAL SWINE FEVER FOR FOOD BUSINESSES IN THE MEMBER STATES CONCERNED

Article 23

Special designation of slaughterhouses, cutting plants, cold stores, meat processing and game handling establishments

1. Subject to the authorised movement requirements laid down in Article 22, the competent authorities of the Member States concerned shall, following an application by a food business operator, designate establishments for the slaughtering, cutting, processing and storage of the fresh meat and meat products, including casings, from porcine animals kept in the restricted zones listed in Annex I and from wild porcine animals in those restricted zones.
2. The competent authorities of the Member States concerned may decide that the designation referred to in paragraph 1 shall not be required for establishments slaughtering, processing, cutting and storing fresh meat and meat products, including casings, obtained from porcine animals kept in the restricted zones listed in Annex I and from wild porcine animals in those restricted zones provided that:

- (a) the meat and meat products, including casings, of porcine origin are marked with a special health mark referred to in Article 25;
 - (b) the fresh meat and meat products, including casings, of porcine origin from those establishment are only intended for within the same Member State concerned;
 - (c) animal by-products of porcine origin from those establishments are only processed or disposed of within the same Member State.
3. The competent authorities of the Member States concerned shall:
- (a) provide the Commission and the other Member States with a link to the website of their competent authority with a list of designated establishments and their activities referred to in paragraph 1;
 - (b) keep the list provided for in point (a) updated.

Article 24

Special conditions for the designation of establishments for slaughtering, cutting, processing and storing of the fresh meat and meat products, including casings, obtained from porcine animals kept in the restricted zones listed in Annex I

The competent authorities of the Member States concerned shall only designate establishments for the slaughtering, cutting, processing and storing of the fresh meat and meat products, including casings, obtained from porcine animals kept in the restricted zones listed in Annex I and from wild porcine animals in those restricted zones subject to the authorised movement requirements laid down in Article 22, provided that:

- (a) the cutting, processing and storing of the fresh meat and meat products, including casings, obtained from porcine animals kept in the restricted zones listed in Annex I are carried out separately from fresh meat and meat products, including casings, obtained from porcine animals kept in the restricted zones listed in Annex I that do not comply with:
 - (i) the additional general conditions laid down in Articles 11, 12 and 13; and
 - (ii) the specific conditions laid down in Article 22;
- (b) the operator of the establishment has in place documented instructions or procedures approved by the competent authorities of the Member States concerned to ensure that the conditions laid down in point (a) are met.

Article 25

Special health marks

The competent authorities of the Member States concerned shall ensure that the following products of animal origin are marked with a special health mark or, where relevant, an identification mark that is not oval and cannot be confused with the health mark or identification mark provided for in Article 5 of Regulation (EC) No 853/2004:

- (a) the fresh meat and meat products, including casings, obtained from porcine animals kept in the restricted zones listed in Annex I, unless specific conditions apply for movements from those restricted zones of consignments of porcine animals kept in such restricted zones, as laid down in Article 22; and
- (b) the fresh meat and meat products from wild porcine animals obtained in the restricted zones listed in Annex I and moved from an establishment designated in accordance with Article 23(1).

CHAPTER V

SPECIAL DISEASE CONTROL MEASURES APPLICABLE TO WILD PORCINE ANIMALS IN THE MEMBER STATES CONCERNED*Article 26***Specific prohibitions in relation to the movements of wild porcine animals**

The competent authorities of the Member States concerned shall prohibit movements of wild porcine animals by operators as provided for in Article 101 of Commission Delegated Regulation (EU) 2020/688:

- (a) within the whole territory of the Member State concerned;
- (b) from the whole territory of the Member State concerned to:
 - (i) other Member States; and
 - (ii) third countries.

*Article 27***Specific prohibitions in relation to movements of fresh meat, meat products and any other products of animal origin obtained from wild porcine animals within and from the restricted zones listed in Annex I**

1. The competent authorities of the Member States concerned shall prohibit movements of consignments of fresh meat, meat products and any other products of animal origin obtained from wild porcine animals within and from the restricted zones listed in Annex I.
2. The competent authorities of the Member States concerned shall prohibit movements of fresh meat, meat products and any other products of animal origin obtained from wild porcine animals within and from the restricted zones listed in Annex I for either:
 - (a) private domestic use;
 - (b) linked to the activities of hunters who supply small quantities of wild porcine game or wild game meat of porcine origin directly to the final consumer or to local retail establishments directly supplying the final consumer, as provided for in Article 1(3)(e) of Regulation (EU) 853/2004.

*Article 28***Specific conditions for derogations authorising movements of consignments of fresh meat, processed meat products and any other products of animal origin obtained from wild porcine animals within the restricted zones listed in Annex I**

By way of derogation from the prohibitions provided for in Article 27, the competent authorities of the Member States concerned may authorise movements of items referred to in Article 27 from an establishment located in restricted zones listed in Annex I within such restricted zones provided that:

- (a) pathogen identification tests and antibody detection tests for classical swine fever have been carried out for each wild porcine animal used for the production and processing of meat products in those restricted zones;
- (b) the competent authority obtained negative results for the tests referred to in point (a) before the treatment referred to in point (c);
- (c) the meat products from wild porcine animals were produced, processed and stored in establishments designated in accordance with Article 23(1).

*Article 29***Specific conditions for derogations authorising movements of consignments of processed meat products and any other products of animal origin obtained from wild porcine animals from the restricted zones listed in Annex I**

By way of derogation from the prohibitions provided for in Article 27, the competent authorities of the Member States concerned may authorise movements of consignments of items referred to in Article 27 from an establishment located in restricted zones listed in Annex I to other Member States and to third countries provided that:

- (a) pathogen identification tests and antibody detection tests for classical swine fever have been carried out for each wild porcine animal used for the production and processing of meat products in those restricted zones;
- (b) the competent authority obtained negative results for the tests referred to in point (a) before the treatment referred to in points (c) and (d);
- (c) the meat products from wild porcine animals were produced, processed and stored in establishments designated in accordance with Article 23(1);
- (d) the meat products from wild porcine animals have undergone the relevant risk-mitigating treatment for products of animal origin from restricted zones in accordance with Annex VII to Delegated Regulation (EU) 2020/687, as regards classical swine fever.

*Article 30***Operators' obligations with regard to animal health certificates for movements from the restricted zones of consignments of processed meat products and any other products of animal origin obtained from wild porcine animals from those restricted zones**

Operators shall only move consignments of processed meat products and any other products of animal origin obtained from wild porcine animals from the restricted zones listed in Annex I to this Regulation to another Member State and to third countries in the cases covered by Article 29 of this Regulation, if those consignments are accompanied by an animal health certificate as provided for in Article 167(1) of Regulation (EU) 2016/429 that contains:

- (a) the information required in accordance with Article 3 of Delegated Regulation (EU) 2020/2154; and
- (b) the following attestation of compliance with the requirements laid down in this Regulation:

'Processed meat products, obtained from wild porcine animals in compliance with the special control measures relating to classical swine fever laid down in Commission Implementing Regulation (EU) 2021/934.'

CHAPTER VI

FINAL PROVISIONS

*Article 31***Entry into force and application**

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

It shall apply from third day following that of its publication to 13 June 2026.

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

Done at Brussels, 9 June 2021.

For the Commission
The President
Ursula VON DER LEYEN

*ANNEX I***RESTRICTED ZONES****1. Bulgaria**

The whole territory of Bulgaria.

2. Romania

The whole territory of Romania.

ANNEX II

REINFORCED BIOSECURITY MEASURES FOR ESTABLISHMENTS OF KEPT PORCINE ANIMALS LOCATED IN RESTRICTED ZONES LISTED IN ANNEX I

(as referred to in Article 12, point (b)(i))

1. The following reinforced biosecurity measures, as referred to in Article 12, point (b)(i), shall apply to establishments of kept porcine animals located in restricted zones listed in Annex I, in the case of authorised movements of consignments of:
 - (a) porcine animals kept in restricted zones listed in Annex I, as provided for in Article 18;
 - (b) germinal products obtained from porcine animals kept in restricted zones listed in Annex I, as provided for in Article 19;
 - (c) animal by-products obtained from porcine animals kept in restricted zones listed in Annex I, as provided for in Article 21;
 - (d) fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zones listed in Annex I, as provided for in Article 22.
2. The operators of establishments of porcine animals kept in restricted zones listed in Annex I situated in the Member States concerned, in the case of authorised movements outside those restricted zones shall ensure that the following reinforced biosecurity measures are applied in those establishments of kept porcine animals:
 - (a) there must be no direct or indirect contact between the kept porcine animals and at least:
 - (i) other kept porcine animals from other establishments;
 - (ii) wild porcine animals;
 - (b) appropriate hygienic measures must be taken by persons entering and leaving the premises where porcine animals are kept, such as a change of clothes and footwear;
 - (c) persons entering the premises where porcine animals are kept must wash and disinfect their hands at the entrance;
 - (d) persons entering into contact with kept porcine animals on the establishment must not have engaged in any hunting activity related to wild porcine animals or have had any other contact with wild porcine animals for a period of at least 48 hours before entering into the establishment;
 - (e) a prohibition on unauthorised persons or means of transport entering the establishment, including the premises where porcine animals are kept;
 - (f) adequate record-keeping of persons and means of transport accessing the establishment where the porcine animals are kept;
 - (g) the premises and buildings of the establishment where porcine animals are kept must:
 - (i) be built in such a way that no other animals can enter the premises and buildings or have contact with the kept porcine animals or their feed and bedding material;
 - (ii) allow for the washing and disinfection of hands;
 - (iii) allow for the cleaning and disinfection of the premises;
 - (iv) have appropriate changing facilities for footwear and clothes at the entrance to the premises where porcine animals are kept;
 - (h) have stock-proof fencing of at least the premises where the porcine animals are kept and buildings where their feed and bedding are kept;
 - (i) a biosecurity plan approved by the competent authority of the Member State concerned, taking account of the profile of the establishment and national legislation, must be in place; that biosecurity plan shall at least include:
 - (i) the establishment of the 'clean' and 'dirty' areas for personnel appropriate to the farm typology, such as changing rooms, a shower, a dining room;

- (ii) the setting up and the review, when applicable, of the logistical arrangements for the entry of new kept porcine animals into the establishment;
 - (iii) the procedures for the cleaning and disinfection of the facilities, transport, equipment and personnel hygiene;
 - (iv) rules on food for personnel on-site and a prohibition on the keeping of porcine animals by the personnel, where relevant and if applicable;
 - (v) a dedicated recurrent awareness programme for personnel on the establishment;
 - (vi) the setting up and the review, when applicable, of logistical arrangements in order to ensure a proper separation between different epidemiological units and to avoid porcine animals being in contact, directly or indirectly, with animal by-products and other units;
 - (vii) the procedures and instructions for the enforcement of biosecurity requirements during the construction or repair of the premises or buildings;
 - (viii) internal audit or self-evaluation for enforcing the biosecurity measures.
-

DECISIONS

COUNCIL DECISION (EU) 2021/935

of 3 June 2021

on the position to be taken on behalf of the European Union at the 13th meeting of the Committee of Technical Experts of the Intergovernmental Organisation for International Carriage by Rail regarding the adoption of amendments to the uniform technical prescriptions concerning locomotives and passenger rolling stock, freight wagons, accessibility of the rail system for persons with disabilities and persons with reduced mobility, the adoption of the uniform technical prescriptions applicable to train composition and route compatibility checks and to the subsystem infrastructure, the updating of references to the technical documents referred to in Appendix I of the uniform technical prescription concerning telematic applications for freight, and regarding the revision of ATMF with regard to entities in charge of maintenance

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 91 in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The Union acceded to the Convention concerning International Carriage by Rail of 9 May 1980, as amended by the Vilnius Protocol of 3 June 1999 ('COTIF'), in accordance with Council Decision 2013/103/EU ⁽¹⁾.
- (2) All Member States, with the exception of Cyprus and Malta, are parties to the COTIF.
- (3) Pursuant to point (f) of Article 13 § 1 of the COTIF, the Committee of Technical Experts ('CTE') of the Intergovernmental Organisation for International Carriage by Rail ('OTIF') was set up.
- (4) Pursuant to point (b) of Article 20 § 1 of the COTIF, and in accordance with Article 6 of Appendix F ('APTU'), the CTE is competent to adopt or to amend, inter alia, the uniform technical prescriptions ('UTP') concerning locomotives and passengers rolling stock ('UTP LOC PAS'), freight wagons ('UTP WAG'), accessibility of the rail system for persons with disabilities and persons with reduced mobility ('UTP PRM'), the technical documents of technical specification for interoperability relating to the telematic applications for freight ('TAF TSI') referred to in Appendix I of UTP concerning telematic applications for freight ('UTP TAF'), UTP applicable to train composition and route compatibility checks ('UTP TCRC') and UTP applicable to the subsystem infrastructure ('UTP INF').
- (5) Finally, in accordance with Article 15 § 2 of Appendix G ('ATMF'), the CTE is competent to propose the revision of ATMF with regard to entities in charge of maintenance ('ECM').
- (6) The CTE has included in the agenda of its 13th session that will take place on 22 June 2021, proposals for decisions to amend UTP LOC PAS, UTP WAG and UTP PRM, for the adoption of UTP TCRC and UTP INF, for the updating of the references to the technical documents of TAF TSI listed in Appendix I of UTP TAF and for the revision of ATMF with regard to ECM.

⁽¹⁾ Council Decision 2013/103/EU of 16 June 2011 on the signing and conclusion of the Agreement between the European Union and the Intergovernmental Organisation for International Carriage by Rail on the Accession of the European Union to the Convention concerning International Carriage by Rail (COTIF) of 9 May 1980, as amended by the Vilnius Protocol of 3 June 1999 (OJ L 51, 23.2.2013, p. 1).

- (7) It is appropriate to establish the position to be taken on the Union's behalf in the CTE and, as regards the revision of ATMF, the Revision Committee of OTIF, as the proposed decisions will be binding on the Union.
- (8) The objectives of the proposed decisions are to align UTP LOC PAS, UTP WAG and UTP PRM with Commission Implementing Regulation (EU) 2020/387 ⁽²⁾ and Commission Implementing Regulation (EU) 2019/772 ⁽³⁾ respectively, to adopt new UTP TCRC and UTP INF in line with Commission Implementing Regulation (EU) 2019/773 ⁽⁴⁾ and Commission Regulation (EU) No 1299/2014 ⁽⁵⁾ as amended by Commission Implementing Regulation (EU) 2019/776 ⁽⁶⁾ and to propose to the Revision Committee of OTIF a revision of ATMF with regard to ECM to align it with Directive (EU) 2016/798 ⁽⁷⁾.
- (9) The proposed decisions are in line with the law and the strategic objectives of the Union by contributing to the alignment of OTIF legislation with the equivalent provisions of Union law and should therefore be supported by the Union,

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken on the Union's behalf at the 13th session of the Committee of Technical Experts of the Convention concerning International Carriage by Rail of 9 May 1980 as regards the adoption of amendments to the uniform technical prescriptions concerning locomotives and passengers rolling stock, freight wagons, accessibility of the rail system for persons with disabilities and persons with reduced mobility, as regards the adoption of the uniform technical prescriptions applicable to train composition and route compatibility checks and applicable to the subsystem infrastructure, as regards the update of references to the technical documents of technical specification for interoperability relating to the telematic applications for freight listed in Appendix I of the uniform technical prescription concerning the telematic applications for freight, and on the revision of ATMF with regard to entities in charge of maintenance shall be the following:

- (1) to vote in favour of the CTE proposed amendments to UTP concerning locomotives and passenger rolling stock, as set out in the CTE Working Document TECH-20041-CTE13-UTP LOC PAS annex and TECH-20041 LOC PAS decision;
- (2) to vote in favour of the CTE proposed amendments to UTP concerning rolling stock – freight wagons, as set out in the CTE Working Document TECH-20042-CTE13 WAG draft amendments and TECH-20042 WAG decision;
- (3) to vote in favour of the CTE proposed amendments to UTP concerning accessibility of the rail system for persons with disabilities and persons with reduced mobility, as set out in the CTE Working Document TECH-20043-CTE UTP PRM draft amendments and TECH-20043 PRM decision;
- (4) to vote in favour of the CTE proposed adoption of the UTP applicable to train composition and route compatibility checks, as set out in the CTE Working Document TECH-20039 UTP TCRC and TECH-20039 TCRC decision;

⁽²⁾ Commission Implementing Regulation (EU) 2020/387 of 9 March 2020 amending Regulations (EU) No 321/2013, (EU) No 1302/2014 and (EU) 2016/919 as regards the extension of the area of use and transition phases (OJ L 73, 10.3.2020, p. 6).

⁽³⁾ Commission Implementing Regulation (EU) 2019/772 of 16 May 2019 amending Regulation (EU) No 1300/2014 as regards inventory of assets with a view to identifying barriers to accessibility, providing information to users and monitoring and evaluating progress on accessibility (OJ L 139 I, 27.5.2019, p. 1).

⁽⁴⁾ Commission Implementing Regulation (EU) 2019/773 of 16 May 2019 on the technical specification for interoperability relating to the operation and traffic management subsystem of the rail system within the European Union and repealing Decision 2012/757/EU (OJ L 139 I, 27.5.2019, p. 5).

⁽⁵⁾ Commission Regulation (EU) No 1299/2014 of 18 November 2014 on the technical specifications for interoperability relating to the 'infrastructure' subsystem of the rail system in the European Union (OJ L 356, 12.12.2014, p. 1).

⁽⁶⁾ Commission Implementing Regulation (EU) 2019/776 of 16 May 2019 amending Commission Regulations (EU) No 321/2013, (EU) No 1299/2014, (EU) No 1301/2014, (EU) No 1302/2014, (EU) No 1303/2014 and (EU) 2016/919 and Commission Implementing Decision 2011/665/EU as regards the alignment with Directive (EU) 2016/797 of the European Parliament and of the Council and the implementation of specific objectives set out in Commission Delegated Decision (EU) 2017/1474 (OJ L 139 I, 27.5.2019, p. 108).

⁽⁷⁾ Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety (OJ L 138, 26.5.2016, p. 102).

- (5) to vote in favour of the CTE proposed adoption of the UTP applicable to the subsystem infrastructure, as set out in the CTE Working Document TECH-20040-UTP INF draft and TECH-20040 INF decision;
- (6) to vote in favour of the CTE proposal to update the references to the technical documents of TAF TSI listed in Appendix I of UTP TAF, as set out in the CTE Working Document TECH-21009-CTE UTP TAF decision;
- (7) to vote in favour of the revision of ATMF with regard to entities in charge of maintenance, as set out in the CTE Working Document TECH-20045 ATMF Decision.

Article 2

Once adopted, the decisions of the CTE shall be published in the *Official Journal of the European Union*, indicating the date of their entry into force.

Article 3

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

Done at Luxembourg, 3 June 2021.

For the Council
The President
P. N. SANTOS

COMMISSION IMPLEMENTING DECISION (EU) 2021/936**of 3 June 2021****on the harmonised standards for household washing machines and household washer-dryers drafted in support of Regulation (EU) 2019/2023 and Delegated Regulation (EU) 2019/2014**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council ⁽¹⁾, and in particular Article 10(6) thereof,

Whereas:

- (1) In accordance with Article 9(2) of Directive 2009/125/EC of the European Parliament and of the Council ⁽²⁾, Member States are to regard a product for which harmonised standards have been applied, the reference numbers of which have been published in the *Official Journal of the European Union*, as conforming to all the relevant requirements of the applicable implementing measure to which such standards relate. Article 4 of Commission Regulation (EU) 2019/2023 ⁽³⁾ and Annex III thereto lay down the relevant measurement and calculation requirements for household washing machines and household washer-dryers.
- (2) In accordance with Article 13 of Regulation (EU) 2017/1369 of the European Parliament and of the Council ⁽⁴⁾, after the adoption of a delegated act pursuant to Article 16 of that Regulation setting specific labelling requirements, the Commission is to publish references to the harmonised standards that satisfy the relevant measurement and calculation requirements of the delegated act in the *Official Journal of the European Union*. Where such harmonised standards are applied during the conformity assessment of a product, the model is to be presumed to be in conformity with the relevant measurement and calculation requirements of the delegated act. Article 3 of Commission Delegated Regulation (EU) 2019/2014 ⁽⁵⁾ and Annex IV thereto lay down measurement and calculation requirements for household washing machines and household washer-dryers.
- (3) By Implementing Decision C(2020)4329 ⁽⁶⁾, the Commission made a request to the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (Cenelec) and the European Telecommunications Standards Institute (ETSI) to revise existing harmonised standards on household dishwashers, household washing machines and household washer-dryers in support of Regulations (EU) 2019/2022 and (EU) 2019/2023 and Delegated Regulations (EU) 2019/2017 and (EU) 2019/2014.

⁽¹⁾ OJ L 316, 14.11.2012, p. 12.

⁽²⁾ Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products (OJ L 285, 31.10.2009, p. 10).

⁽³⁾ Commission Regulation (EU) 2019/2023 of 1 October 2019 laying down ecodesign requirements for household washing machines and household washer-dryers pursuant to Directive 2009/125/EC of the European Parliament and of the Council, amending Commission Regulation (EC) No 1275/2008 and repealing Commission Regulation (EU) No 1015/2010 (OJ L 315, 5.12.2019, p. 285).

⁽⁴⁾ Regulation (EU) 2017/1369 of the European Parliament and of the Council of 4 July 2017 setting a framework for energy labelling and repealing Directive 2010/30/EU (OJ L 198, 28.7.2017, p. 1).

⁽⁵⁾ Commission Delegated Regulation (EU) 2019/2014 of 11 March 2019 supplementing Regulation (EU) 2017/1369 of the European Parliament and of the Council with regard to energy labelling of household washing machines and household washer-dryers and repealing Commission Delegated Regulation (EU) No 1061/2010 and Commission Directive 96/60/EC (OJ L 315, 5.12.2019, p. 29).

⁽⁶⁾ Commission Implementing Decision C(2020)4329 of 1 July 2020 on a standardisation request to the European Committee for Standardisation, the European Committee for Electrotechnical Standardisation and the European Telecommunications Standards Institute as regards ecodesign and energy labelling requirements for household dishwashers, household washing machines and household washer-dryers in support of Commission Regulations (EU) 2019/2022 and (EU) 2019/2023 and Commission Delegated Regulations (EU) 2019/2017 and (EU) 2019/2014.

- (4) On the basis of the request set out in Implementing Decision C(2020)4329, Cenelec revised the harmonised standards EN 60456:2016 and EN 50229:2015 in order to take account of the technical and scientific progress. This resulted in the adoption of the amendment EN 60456:2016/A11:2020 and of a new harmonised standard EN IEC 62512:2020, as amended by EN IEC 62512:2020/A11:2020.
- (5) The Commission together with Cenelec, has assessed whether the harmonised standards EN 60456:2016, as amended by EN 60456:2016/A11:2020, and EN IEC 62512:2020, as amended by EN IEC 62512:2020/A11:2020, comply with the request set out in Implementing Decision C(2020) 4329.
- (6) The harmonised standards EN 60456:2016, as amended by EN 60456:2016/A11:2020, and EN IEC 62512:2020, as amended by EN IEC 62512:2020/A11:2020, satisfy the requirements which they aim to cover and which are set out in Regulation (EU) 2019/2023 and Delegated Regulation (EU) 2019/2014.
- (7) Points ZA.4.9 and ZA.4.10 of harmonised standards EN 60456:2016 and EN IEC 62512:2020 should be excluded from publication given that those points make a reference to the application of European standardisation deliverables CLC/TS 50577 and CLC/TS 50707:2019. Reference to European standardisation deliverables in a harmonised standard is incompatible with the nature of harmonised standards. The European standardisation deliverables and harmonised standards, as defined in Article 2(1) and (2) of Regulation (EU) No 1025/2012, are two different instruments serving different purposes. Such reference is also contrary to the request set out in Implementing Decision C(2020)4329 which covers only harmonised standards.
- (8) The column 'Remarks/Notes*' of Table ZZA.1 in harmonised standards EN 60456:2016 and EN IEC 62512:2020 for the purposes of Delegated Regulation (EU) 2019/2014 and the column 'Remarks/Notes*' of Table ZZB.1 in those standards for the purposes of Regulation (EU) 2019/2023 should be excluded from publication due to inconsistency of those columns with requirements in the main normative body of the standards and due to legal uncertainty resulting from the interpretation of the legal effect of presumption of conformity included in the footnote to those columns.
- (9) It is therefore appropriate to publish the reference of harmonised standards EN 60456:2016, as amended by EN 60456:2016/A11:2020, and EN IEC 62512:2020, as amended by EN IEC 62512:2020/A11:2020, in the *Official Journal of the European Union* with restriction.
- (10) Harmonised standard EN 60456:2016, as amended by EN 60456:2016/A11:2020, replaces harmonised standards EN 60456:2016 and EN 60704-2-4:2012, published by Commission communication 2016/C 416/01 ⁽⁷⁾. Harmonised standard EN IEC 62512:2020, as amended by EN IEC 62512:2020/A11:2020, replaces harmonised standard EN 50229:2015, as corrected by EN 50229:2015/AC:2016, published by Commission communication 2016/C 416/02 ⁽⁸⁾. It is therefore appropriate to repeal those communications.
- (11) Compliance with a harmonised standard confers a presumption of conformity with the corresponding requirements set out in Union harmonisation legislation from the date of publication of the reference of such standard in the *Official Journal of the European Union*. This Decision should therefore enter into force on the date of its publication,

HAS ADOPTED THIS DECISION:

Article 1

The references to harmonised standards for household washing machines and household washer-dryers drafted in support of Delegated Regulation (EU) 2019/2014 and listed in Annex I to this Decision are hereby published in the *Official Journal of the European Union* with restriction.

The references to harmonised standards on household washing machines and household washer-dryers drafted in support of Regulation (EU) 2019/2023 and listed in Annex II to this Decision are hereby published in the *Official Journal of the European Union* with restriction.

⁽⁷⁾ Commission communication in the framework of the implementation of the Commission Regulation (EU) No 1015/2010 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for household washing machines and of Commission Delegated Regulation (EU) No 1061/2010 supplementing Directive 2010/30/EU of the European Parliament and of the Council with regard to energy labelling of household washing machines (Publication of titles and references of harmonised standards under Union harmonisation legislation) (OJ C 416, 11.11.2016, p. 1).

⁽⁸⁾ Commission communication in the framework of the implementation of the Commission Directive 96/60/EC implementing Council Directive 92/75/EEC with regard to energy labelling of household combined washer-driers (Publication of titles and references of harmonised standards under Union harmonisation legislation) (OJ C 416, 11.11.2016, p. 3).

Article 2

Communications 2016/C 416/01 and 2016/C 416/02 are repealed.

Article 3

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

Done at Brussels, 3 June 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Harmonised standards drafted in support of Delegated Regulation (EU) 2019/2014

No	Reference of the standard
1.	EN 60456:2016 Clothes washing machines for household use – Methods for measuring the performance EN 60456:2016/A11:2020 Restriction: this publication does not cover the following parts of the standard: (a) points ZA 4.9 and ZA.4.10; (b) column 'Remarks/Notes*' to Table ZZA.1.
2.	EN IEC 62512:2020 Electric clothes washer-dryers for household use – Methods for measuring the performance EN IEC 62512:2020/A11:2020 Restriction: this publication does not cover the following parts of the standard: (a) points ZA 4.9 and ZA.4.10; (b) column 'Remarks/Notes*' to Table ZZA.1.

ANNEX II

Harmonised standards drafted in support of Regulation (EU) 2019/2023

No	Reference of the standard
1.	EN 60456:2016 Clothes washing machines for household use – Methods for measuring the performance EN 60456:2016/A11:2020 Restriction: this publication does not cover the following parts of the standard: (a) points ZA.4.9 and ZA.4.10; (b) column 'Remarks/Notes*' of Table ZZB.1.
2.	EN IEC 62512:2020 Electric clothes washer-dryers for household use – Methods for measuring the performance EN IEC 62512:2020/A11:2020 Restriction: this publication does not cover the following parts of the standard: (a) points ZA.4.9 and ZA.4.10; (b) column 'Remarks/Notes*' of Table ZZB.1.

CORRIGENDA

Corrigendum 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*(Official Journal of the European Union L 150 of 14 June 2018)*

1. On page 47, the title of Article 41:

for: 'Additional rules on actions in case of non-compliance',

read: 'Additional rules on actions in the event of suspected and established non-compliance, and common catalogue of measures'.

2. On page 47, the title of Article 42:

for: 'Additional rules on measures in the event of non-compliance',

read: 'Additional rules on measures in the event of non-compliance affecting integrity'.

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)



Publications Office
of the European Union
L-2985 Luxembourg
LUXEMBOURG

EN