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Contents

[1] Text with EEA relevance.

EN

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

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

Corrigenda

[1] Text with EEA relevance.

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

COUNCIL DECISION (EU) 2021/524

of 22 March 2021

on the signing, on behalf of the Union, of the Agreement in the form of an Exchange of Letters between the European Union and the Islamic Republic of Pakistan pursuant to Article XXVIII of the General Agreement on Tariffs and Trade (GATT) 1994 relating to the modification of concessions on all the tariff-rate quotas included in the EU Schedule CLXXV as a consequence of the United Kingdom's withdrawal from the European Union

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular the first subparagraph of Article 207(4), in conjunction with Article 218(5) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) On 15 June 2018 the Council authorised the Commission to open negotiations pursuant to Article XXVIII of the General Agreement on Tariffs and Trade (GATT) 1994 on the apportionment of the tariff-rate quotas included in the EU Schedule CLXXV as a consequence of the United Kingdom's withdrawal from the Union.

(2) Negotiations with Pakistan have been concluded and an Agreement in the form of an Exchange of Letters between the European Union and the Islamic Republic of Pakistan pursuant to Article XXVIII of the General Agreement on Tariffs and Trade (GATT) 1994 relating to the modification of concessions on all the tariff-rate quotas included in the EU Schedule CLXXV as a consequence of the United Kingdom`s withdrawal from the European Union (the 'Agreement') was initialled on 25 January 2021.

(3) The Agreement should be signed,

HAS ADOPTED THIS DECISION:

Article 1

The signing on behalf of the Union of the Agreement in the form of an Exchange of Letters between the European Union and the Islamic Republic of Pakistan pursuant to Article XXVIII of the General Agreement on Tariffs and Trade (GATT) 1994 relating to the modification of concessions on all the tariff-rate quotas included in the EU Schedule CLXXV as a consequence of the United Kingdom's withdrawal from the European Union is hereby authorised, subject to the conclusion of the said Agreement [1].

[1] The text of the Agreement will be published together with the decision on its conclusion.

Article 2

The President of the Council is hereby authorised to designate the person(s) empowered to sign the Agreement on behalf of the Union.

Article 3

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

Done at Brussels, 22 March 2021.

For the Council
The President
J. BORRELL FONTELLES

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2021/525

of 19 October 2020

amending Annexes II and III to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products

(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 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]) and in particular Article 85 thereof,

Whereas:

(1) Annexes II and III to Regulation (EU) No 528/2012 set out the information requirements for respectively active substances and biocidal products, which an application for approval of an active substance and an application for authorisation of a biocidal product need to fulfil.

(2) It is necessary to modify the information requirements concerning active substances and biocidal products in order to take into account new methods for generating better information on toxicological properties (such as irritation, neurotoxicity, genotoxicity, etc.), new testing strategies favouring *in vitro* tests over *in vivo* tests in order to reduce testing on vertebrate animals and a testing strategy and methods for the determination of endocrine disrupting properties of substances in accordance with the criteria laid down in Commission Delegated Regulation (EU) 2017/2100 ([2]).

(3) A dossier should be considered as complete if it complies with the requirements of Article 6(1) and Article 20(1), and in particular with the information requirements of Annexes II and III to Regulation (EU) No 528/2012. Pre-submission consultations between the applicant for the approval of an active substance or for the authorisation of a biocidal product and the evaluating competent authority contribute to the quality of the dossier and the progress of the evaluation process. The text of paragraphs 5 and 7, respectively, of points 2 of the introductory parts of Annexes II and III should be modified to ensure that the applicants include the conclusions of such consultation in the application to ensure the smooth operation of the evaluation procedure.

(4) In accordance with Annexes II and III to Regulation (EU) No 528/2012, tests submitted for the purpose of the approval of an active substance or the authorisation of a biocidal product, respectively, are to be conducted in accordance with the methods described in Commission Regulation (EC) No 440/2008 ([3]). As there may be a period between the validation of an internationally recognised test method and its inclusion in Regulation (EC) No 440/2008, point 5 of the introductory parts of Annexes II and III to Regulation (EU) No 528/2012 should be amended to allow applicants to apply the most updated version of test methods.

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1).

([3]) Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 142, 31.5.2008, p. 1).

(5) Specific rules for the adaptation of the information requirements listed in the first column of the tables in Titles 1 and 2 of Annexes II and III to Regulation (EU) No 528/2012 are limited to concerns related to the recourse to testing on vertebrates. As some requirements listed in that first column do not include testing on vertebrates, the scope of adaptations listed in the third column of the tables listed in Titles 1 and 2 of Annexes II and III should be extended to cover cases where no testing on vertebrates is involved.

(6) Point 2 of Title 1 of Annex II sets out the information requirements for the identification of the active substance. Those requirements need to be adapted in order to allow identification of active substances generated *in situ*.

(7) Point 6 of Title 1 of Annexes II and III set out the requirements for the assessment of the effectiveness of an active substance or a biocidal product, respectively, against target organisms. Such effectiveness should also be demonstrated for the activity of an active substance in the absence of other substances that may affect the effectiveness. For treated articles, the effectiveness of the biocidal properties conferred to the article should be demonstrated. Moreover, the current provisions on unintended side-effects in point 6 do not specify on which type of organisms or objects information should be provided. Therefore, it should be clarified that any observation on undesirable or unintended side effects is to be limited to non-target organisms or objects and material to be protected by the active substance or biocidal product.

(8) Article 62 of Regulation (EU) No 528/2012 requires that testing on vertebrate animals be undertaken only as a last resort. In setting data requirements for the approval of active substances and the authorisation of biocidal products, priority should be given to reliable *in vitro* methods as a substitute to *in vivo* methods requiring the use of vertebrate animals. The testing strategies included in Annexes II and III to Regulation (EU) No 528/2012 therefore need to be adapted to recently validated *in vitro* test guidelines of the Organisation for Economic Cooperation and Development (OECD) and other international standards.

(9) The first mandatory requirement for following up on a positive *in vitro* gene mutation test is currently the *in vivo* unscheduled DNA synthesis (UDS) test, which has inherent limitations and low sensitivity. The Scientific Committee of the European Food Safety Authority ([4]) concluded in an opinion published in November 2017 that negative UDS results are not a proof that a substance does not induce gene mutation. The reference to the UDS test should, therefore, be removed and replaced by a reference to an appropriate *in vivo* somatic cell genotoxicity study.

(10) The current data requirements in Annex II to Regulation (EU) No 528/2012 require a two-generation reproductive toxicity study (TGRTS) to be used to investigate the reproductive toxicity of a substance. That Annex furthermore stipulates that the extended one-generation reproductive toxicity study (EOGRTS) can be considered as an alternative approach to the TGRTS. The EOGRTS offers a number of advantages in comparison to the TGRTS as it assesses in addition to effects on the male and female reproductive system more toxicological effects linked to endocrine-disrupting mode of actions. Therefore, if there is no TGRTS available, an EOGRTS should be performed instead.

(11) Exposure to neurotoxicants *in utero* or during childhood can contribute to a variety of neurodevelopmental and neurological disorders that manifest themselves only as a person ages, and may contribute to neurodegenerative diseases such as Parkinson's or Alzheimer's diseases. To address this concern, test guidelines to adequately screen and characterise active substances potentially toxic for the developing brain should be included in Annex II to Regulation (EU) No 528/2012.

(12) The current structure of the information requirements relating to health data and medical treatment in points 8.12.1 to 8.12.8 of Title 1 of Annex II to Regulation (EU) No 528/2012 may lead to submission of overlapping information under a number of those points. The data requirements should therefore be streamlined to reduce compliance costs and unnecessary delays in the evaluation of applications.

([4]) Scientific Opinion on the clarification of some aspects related to genotoxicity assessment. *EFSA Journal* 2017;15(12):5113, 25 pp. https://doi. org/10.2903/j.efsa.2017.5113

(13) An evaluation of the potential for unintended effects of substances on the immune system should be conducted. However, as no specific developmental immunotoxicity study is available in an OECD test guideline, relevant data should be required to be provided as additional data set.

(14) Point 8.18 of Title 1 of Annex II to Regulation (EU) No 528/2012 duplicates the content of point 13 of that Title and should therefore be deleted.

(15) Point 9.1.1 of Title 1 of Annex II to Regulation (EU) No 528/2012 should be amended in order to clarify when long-term toxicity testing on fish is to be carried out. The list of OECD test methods in point 9.1.6.1 should be replaced in order to take into account on-going developments as regards the information requirements on long-term toxicity studies on fish.

(16) Several information requirements for microorganisms included in Title 2 of Annexes II and III to Regulation (EU) No 528/2012 are either overlapping with other provisions in the Annexes or are irrelevant for microorganisms. Title 2 of Annexes II and III to Regulation (EU) No 528/2012 should therefore be amended in order to eliminate such overlaps and irrelevant information requirements.

(17) The fourth paragraph of point 2 of the introductory part of Annex III to Regulation (EU) No 528/2012 provides that for non-active substances, the applicants are to use the information provided to them in the context of Title IV of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([5]). That paragraph should be amended in order to clarify that applicants may need to provide additional information on substances of concern included in biocidal products in particular in order to submit a data set that enables the identification of their endocrine disrupting properties.

(18) In order to avoid imposing a disproportionate burden on economic operators, certain tests required by Annex II or Annex III to Regulation (EU) No 528/2012 that were already initiated or carried out before the date of application of this Regulation should be considered appropriate to address the information requirements.

(19) A reasonable period should be allowed to elapse before the data requirements, as modified by this Delegated Regulation become applicable so that the applicants can make the necessary arrangements to meet those requirements. However, in the interests of the protection of human and animal health and of the environment, the applicants should be allowed to apply the changes introduced by this Regulation before its date of application on a voluntary basis.

(20) Regulation (EU) No 528/2012 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EU) No 528/2012 is amended in accordance with Annex I to this Regulation.

Annex III to Regulation (EU) No 528/2012 is amended in accordance with Annex II to this Regulation.

Article 2

Notwithstanding the date of application of this Regulation laid down in Article 3, applications for approval of an active substance and applications for authorisation of a biocidal product submitted before 15 April 2022 shall be evaluated based on information requirements applicable on the day of submission of such applications.

([5]) Regulation (EC) No 1907/2006 of 18 December 2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), stablishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

Article 3

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

It shall apply from 15 April 2022.

By way of derogation, applicants may choose to apply the data requirements as set out in the Annexes I and II to this Regulation from 15 April 2021.

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

Done at Brussels, 19 October 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Annex II to Regulation (EU) No 528/2012 is amended as follows:

(1) the introductory part is amended as follows:

(a) the fifth paragraph of point 2 is replaced by the following:

'The applicant shall initiate a pre-submission consultation with the prospective evaluating body. In addition to the obligation set out in Article 62(2), applicant may also consult with the competent authority that will evaluate the dossier with regard to the proposed information requirements and in particular the testing on vertebrates that the applicant proposes to carry out. The applicant shall document such pre-submission consultations and their outcomes and shall include the relevant documents in the application.';

(b) point 5 is replaced by the following:

'5. Tests submitted for the purpose of the approval of an active substance shall be conducted in accordance with the methods described in Commission Regulation (EC) No 440/2008 (*), or any revised version of these methods not yet included in that Regulation.

However, if a method is inappropriate or not described in Commission Regulation (EC) No 440/2008, other methods shall be used which are scientifically appropriate and their appropriateness shall be justified in the application.

When test methods are applied to nano-materials, an explanation shall be provided of their scientific appropriateness for nanomaterials, and where applicable, of the technical adaptations or adjustments that have been made in order to respond to the specific characteristics of these materials.

_____

(*) Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 142, 31.5.2008, p. 1).';

(2) the table in Title 1 is amended as follows:

(a) the heading of the third column is replaced by the following:

		'Column 3 Specific rules for adaptation from column 1'

(b) row 2 is replaced by the following:

'2	IDENTITY OF THE ACTIVE SUBSTANCE (AND ITS PRECURSOR(S) IF THE ACTIVE SUBSTANCE IS GENERATED *IN SITU*) For the active substance and, if applicable, its precursors, the information given in this Section shall be sufficient to enable the active substance to be identified. If it is not technically possible or if it does not appear scientifically necessary to give information on one or more of the items listed in this Section, the reasons shall be clearly stated'		

(c) row 2.5 is replaced by the following:

'2.5	Molecular and structural formula (including SMILES notation, if available and appropriate). For precursor(s) and for active substances generated *in situ*, information about all generated chemical substances (intended and unintended)		In case it is not possible to exactly define the molecular structure of the precursor(s) and/or active substance, the molecular and structural formulas do not need to be provided'

(d) row 2.8 is replaced by the following:

'2.8	Method of manufacture (syntheses pathways) of active substance including information on starting materials and solvents including suppliers, specifications and commercial availability. For active substances generated *in situ*, a description of the reaction schemes including all intermediate reactions and their associated chemical substances (intended and unintended) shall be provided'		

(e) the following row 2.11.1 is inserted:

'2.11.1	Analytical profile of at least five representative samples taken from the *in situ* generated substance(s), providing information on the content of the active substance(s) and any other constituent above 0,1 % w/w, including residues of precursor(s)'		

(f) row 6.6 is replaced by the following:

'6.6	Efficacy data to support: — the innate activity of the active substance for the intended use(s), and — any claims made on treated articles regarding the biocidal properties conferred to the article. Efficacy data shall include any available standard protocols, laboratory tests or field trials and performance standards where appropriate, or data similar to those available for suitable reference products'		

(g) row 6.7.2 is replaced by the following:

'6.7.2	Observations on undesirable or unintended side effects on non-target organisms or on objects and material to be protected'		

(h) rows 8.1, 8.2 and 8.3 are replaced by the following:

'8.1	Skin corrosion or irritation The assessment shall comprise the following tiers: (a) assessment of the available human, animal and non-animal data; (b) skin corrosion, *in vitro* testing; (c) skin irritation, *in vitro* testing; (d) skin corrosion or irritation, *in vivo* testing		The study/ies in column 1 do(es) not need to be conducted if: — the available information indicates that the substance meets the criteria for classification for skin corrosion or irritation, — the substance is a strong acid (pH≤ 2,0) or base (pH≥ 11,5), — the substance is spontaneously flammable in air or in contact with water or moisture at room temperature, — the substance meets the classification criteria for acute toxicity (Category 1) by the dermal route, or — an acute toxicity study by the dermal route provides conclusive evidence on skin corrosion or irritation adequate for classification. If results from one of the two studies listed in point (b) or point (c) in column 1 of this row already allow conclusive decision on the classification of a substance or on the absence of skin irritation potential, the second study does not need to be conducted An *in vivo* study for skin corrosion or irritation shall be considered only if the *in vitro* studies listed in points (b) and (c) in column 1 of this row are not applicable, or the results of these studies are not adequate for classification and risk assessment

			In vivo studies for skin corrosion or irritation that were carried out or initiated before 15 April 2022 shall be considered appropriate to address this information requirement
8.2	Serious eye damage or eye irritation The assessment shall comprise the following tiers: (a) assessment of the available human, animal and non-animal data; (b) serious eye damage or eye irritation, *in vitro* testing; (c) serious eye damage or eye irritation, *in vivo* testing		The study/ies in column 1 do(es) not need to be conducted if: — the available information indicates that the substance meets the criteria for classification for eye irritation or causing serious damage to eyes, — the substance is a strong acid (pH≤ 2,0) or base (pH≥ 11,5), — the substance is spontaneously flammable in air or in contact with water or moisture at room temperature, or — the substance meets the classification criteria for skin corrosion leading to classification of the substance as "serious eye damage" (category 1). If results from a first *in vitro* study do not allow a conclusive decision on the classification of the substance or on the absence of eye irritation potential (an)other(s) *in vitro* study(ies) for this endpoint shall be considered. An *in vivo* study for serious eye damage or eye irritation shall be considered only if the *in vitro* study(ies) listed in point (b) in column 1 of this row are not applicable, or the results obtained from these studies are not adequate for classification and risk assessment *In vivo* studies for serious eye damage or eye irritation that were carried out or initiated before 15 April 2022 shall be considered appropriate to address this information requirement

‘8.3	Skin sensitisation The information shall allow to conclude whether the substance is a skin sensitiser and whether it can be presumed to have the potential to produce significant sensitisation in humans (Category 1A). The information should be sufficient to perform a risk assessment where required The assessment shall comprise the following tiers: (a) assessment of the available human, animal and non-animal data; (b) skin sensitisation, *in vitro* testing. Information from *in vitro* or *in chemico* test method(s) referred to in point 5 of the introductory part of this Annex and addressing each of the following key events of skin sensitisation: (i) molecular interaction with skin proteins; (ii) inflammatory response in keratinocytes; (iii) activation of dendritic cells; (c) skin sensitisation *in vivo* testing. The Murine Local Lymph Node Assay (LLNA) is the first-choice method for *in vivo* testing. Another skin sensitisation test may only be used in exceptional cases. If another skin sensitisation test is used, justification shall be provided		The study/ies in column 1 do(es) not need to be conducted if: — the available information indicates that the substance meets the criteria for classification for skin sensitisation or skin corrosion, — the substance is a strong acid (pH≤ 2,0) or base (pH≥ 11,5), or — the substance is spontaneously flammable in air or in contact with water or moisture at room temperature. *In vitro* tests do not need to be conducted if: — an *in vivo* study referred to in point (c) of column 1 of this row is available, or — the available *in vitro or in chemico* test methods are not applicable for the substance or the results obtained from those studies are not adequate for classification and risk assessment. If information from test method(s) addressing one or two of the key events described under point (b) in column 1 of this row allows for classification of the substance and risk assessment, studies addressing the other key event(s) do not need to be conducted An *in vivo* study for skin sensitisation shall be conducted only if *in vitro* or *in chemico* test methods described under point (b) in column 1 of this row are not applicable, or the results obtained from those studies are not adequate for classification and risk assessment *In vivo* skin sensitisation studies that were carried out or initiated before 15 April 2022 shall be considered appropriate to address this information requirement’

(i) row 8.6 is replaced by the following:

'8.6	*In vivo* genotoxicity study The assessment shall comprise the following tiers: (a) If there is a positive result in any of the *in vitro* genotoxicity studies as listed in 8.5 and there are no reliable results available from an appropriate *in vivo* somatic cell genotoxicity study, an appropriate *in vivo* somatic cell genotoxicity study shall be conducted; (b) A second *in vivo* somatic cell genotoxicity study may be necessary depending on the *in vitro* and *in vivo* results, type of effects, quality and relevance of all available data; (c) If there is a positive result from an *in vivo* somatic cell genotoxicity study available, the potential for germ cell mutagenicity should be considered based on all available data, including toxicokinetic evidence to demonstrate whether the substance has the capacity to reach germ cells. If no clear conclusions about germ cell mutagenicity can be made, additional investigations shall be considered	ADS	The study/ies in column 1 do(es) not need to be conducted if: — the results are negative for the three *in vitro* tests listed in 8.5 and no other concern has been identified (e.g. metabolites of concern formed in mammals), or — the substance meets the criteria to be classified as a germ cell mutagen category 1A or 1B. The germ cell genotoxicity test does not need to be conducted if the substance meets the criteria to be classified as a carcinogen, category 1A or 1B and a germ cell mutagen category 2'

(j) rows 8.10 to 8.10.3 are replaced by the following:

'8.10	Reproductive toxicity For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route		The studies do not need to be conducted if: — the substance meets the criteria to be classified as a genotoxic carcinogen (classified both as germ cell mutagen category 2, 1A or 1B and carcinogenic category 1A or 1B), and appropriate risk management measures are implemented including measures related to reproductive toxicity, — the substance meets the criteria to be classified as a germ cell mutagen category 1A or 1B and appropriate risk management measures

		are implemented including measures related to reproductive toxicity, — the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available provided that the dataset is sufficiently comprehensive and informative), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma or blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and the pattern of use indicates that there is no or negligible human or animal exposure, — the substance meets the criteria to be classified as reproductive toxicity category 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for sexual function and fertility will be necessary. A full justification must be provided and documented if investigations for developmental toxicity are not conducted, or — the substance is known to cause developmental toxicity, meeting the criteria for classification as reproductive toxicity category 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. A full justification must be provided and documented if investigations for sexual function and fertility is not conducted.

			Notwithstanding the provisions of this column of this row, studies on reproductive toxicity may need to be conducted to obtain information on endocrine disrupting properties as laid down in 8.13.3.1.
8.10.1	Pre-natal development toxicity study (OECD TG 414) on two species, preferred first species is rabbit (non-rodent) and preferred second species is rat (rodent); oral route of administration is the preferred route		The study on the second species shall not be conducted if the study performed on the first species or other available data indicate that the substance causes developmental toxicity meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment
8.10.2	Extended One-Generation Reproductive Toxicity Study (OECD TG 443), with cohorts 1A and 1B and extension of cohort 1B to include the F2 generation with the aim to produce 20 litters per dose group, F2 pups must be followed to weaning and investigated similarly as F1 pups. Rat is the preferred species and oral route of administration is the preferred route. The highest dose level should be based on toxicity and selected with the aim to induce reproductive and/or other systemic toxicity		A two-generation reproductive toxicity study conducted in accordance with OECD TG 416 (adopted 2001 or later) or equivalent information shall be considered appropriate to address this information requirement, if the study is available and was initiated before 15 April 2022.
8.10.3	Developmental neurotoxicity Developmental Neurotoxicity Study in accordance with OECD TG 426, or any relevant study (set) providing equivalent information, or cohorts 2A and 2B of an Extended One-Generation Reproductive Toxicity study (OECD TG 443) with additional investigation for cognitive functions		The study shall not be conducted if the available data: — indicate that the substance causes developmental toxicity and meets the criteria to be classified as toxic for reproduction category 1A or 1B: May damage the unborn child (H360D), and — are adequate to support a robust risk assessment'

(k) the following row 8.10.4 is inserted:

'8.10.4	Further studies A decision on the need to perform additional studies including those informing on the mechanisms should be based on the outcomes of the studies listed in 8.10.1, 8.10.2 and 8.10.3 and all other relevant available data	ADS'	

(l) row 8.11.2 is replaced by the following:

'8.11.2	Carcinogenicity testing in a second species (a) A second carcinogenicity study should be conducted using the mouse as test species; (b) For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route		The second carcinogenicity study does not need to be conducted if the applicant can justify on the basis of scientific grounds that it is not necessary'

(m) rows 8.12.1 to 8.12.8 are replaced by the following:

'8.12.1	Information on signs of poisoning, clinical tests, first aid measures, antidotes, medical treatment and prognosis following poisoning		
8.12.2	Epidemiological studies		
8.12.3	Medical surveillance data, health records and case reports'		

(n) rows 8.13.2 and 8.13.3 are replaced by the following:

'8.13.2	Neurotoxicity If the active substance is an organophosphorus compound or if there is an indication, knowledge of the mechanism of action or knowledge from acute or repeated dose studies that the active substance may have neurotoxic properties, additional information or specific studies (such as OECD TG 424 or OECD TG 418 or 419 or equivalent) will be required If anticholinesterase activity is detected a test for response to reactivating agents should be considered	ADS	

	For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route		
8.13.3	Endocrine disruption The assessment of endocrine disruption shall comprise the following tiers: (a) An assessment of the available information from the following studies and any other relevant information, including *in vitro* and *in silico* methods: (i) 8.9.1 A 28-day oral toxicity study in rodents (OECD TG 407); (ii) 8.9.2 A 90-day oral toxicity study in rodents (OECD TG 408); (iii) 8.9.4 A repeated dose oral toxicity study in non-rodents (OECD TG 409); (iv) 8.10.1 A prenatal developmental toxicity study (OECD TG 414); (v) 8.10.2 An extended one-generation reproductive toxicity study (OECD TG 443) or two-generation reproductive toxicity study (OECD TG 416); (vi) 8.10.3 A developmental neurotoxicity study (OECD TG 426); (vii) 8.11.1 A combined carcinogenicity study and long-term repeated dose toxicity study (OECD TG 451-3); (viii) A systematic review of the literature including studies on mammals and non-mammalian organisms; (b) If there is any information suggesting that the active substance may have endocrine disrupting properties, or if there is incomplete information on key parameters relevant		Where sufficient weight of evidence to conclude on the presence or absence of a particular endocrine disrupting mode of action is available: — further testing on vertebrate animals for that effect shall be omitted for that mode of action, — further testing not involving vertebrate animals may be omitted for that mode of action. In all cases, adequate and reliable documentation shall be provided'

	for concluding on endocrine disruption, then additional information or specific studies shall be required to elucidate: (1) the mode or the mechanism of action; and/or (2) potentially relevant adverse effects in humans or animals For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to consider the oral route and conduct animal studies by the oral route		

(o) the following row 8.13.3.1 is inserted:

'8.13.3.1	Specific additional studies to investigate potential endocrine disrupting properties may include, but are not limited to the following: (a) the mammalian toxicity studies listed in 8.13.3(a); (b) the *in vitro* assays: (i) Estrogen receptor transactivation assay (OECD TG 455); (ii) Androgen receptor transactivation assay, (OECD TG 458); (iii) H295R steroidogenesis assay (OECD TG 456); (iv) the Aromatase assay (human recombinant) OPPTS 890.1200; (c) Uterotrophic bioassay in rodents (OECD TG 440) and Hershberger bioassay in rats (OECD TG 441); (d) Pubertal development and Thyroid Function in Intact Juvenile or Peripubertal Male Rats (OPPTS 890.1500). The decision to carry out studies in mammals shall be taken based on all available information, including a systematic review of the literature (including information on endocrine disrupting effects in non-target organisms) and the availability of suitable *in silico or in vitro* methods	ADS'	

(p) rows 8.13.4 and 8.13.5 are replaced by the following:

'8.13.4	Immunotoxicity and developmental immunotoxicity If there is any evidence from repeat dose or reproductive toxicity studies that the active substance may have immunotoxic properties, then additional information or specific studies shall be required to elucidate: (1) the mode or the mechanism of action; and/or (2) potentially relevant adverse effects in humans or animals. For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to consider the oral route and conduct animal studies by the oral route	ADS	

8.13.5	Further mechanistic studies A decision on the need to perform additional studies should be based on all relevant data	ADS'	

(q) row 8.18 is deleted;

(r) row 9.1.1 is replaced by the following:

'9.1.1	Short-term toxicity testing on fish When short-term fish toxicity data is required, the threshold approach (tiered strategy) should be applied. A long-term toxicity testing on fish in accordance with point 9.1.6.1 shall be considered if the substance is poorly water soluble, i.e. below 1 mg/L		The study does not need to be conducted if: — a valid long-term aquatic toxicity study on fish is available, — sufficient weight of evidence including the use of other data such as the Fish Embryo Acute Toxicity (FET, OECD TG 236) and/or results obtained from non-animal methods is available for this data requirement'

(s) row 9.1.6.1 is replaced by the following:

'9.1.6.1	Long term toxicity testing on fish The information shall be provided from long-term toxicity testing on fish in which early life-stages (eggs, larvae or juveniles) are exposed	ADS'	

(t) row 9.10 is replaced by the following:

‘9.10	Endocrine disruption The assessment of endocrine disruption properties shall comprise the following tiers: (a) An assessment of the mammalian data set in accordance with 8.13.3 to assess whether the substance has endocrine disrupting properties based on data in relation to mammals; (b) If it cannot be concluded based on the mammalian data in accordance with 8.13.3 or 9.1.6.1 that the substance has endocrine disrupting properties, then studies set out in 9.10.1 or 9.10.2 shall be considered taking account of any other available relevant information, including a systematic review of the literature’		

(u) the following rows 9.10.1, 9.10.2 and 9.10.3 are inserted:

‘9.10.1	Endocrine disruption in fish Specific studies to investigate potential endocrine disrupting properties may include, but are not limited to the following data requirements: (a) Medaka extended one-generation test (MEOGRT, OECD TG 240); (b) Fish life cycle toxicity test (FLCTT, OPPTS 850.1500) covering all the ‘estrogen-, androgen- and steroidogenic-mediated’ (EAS) parameters foreseen to be measured in the MEOGRT study		The study does not need to be carried out if: — there is no indication for endocrine activity or endocrine related effects from a sufficient mammalian data set in accordance with 8.13.3 or from any other relevant information (e.g. literature), and — valid *in vivo* data is available, with no information suggesting that the active substance may elicit endocrine activity or effects potentially related to endocrine activity in either the Fish short term reproduction assay (FSTRA; OECD TG 229), or the 21-days fish assay (OECD TG 230) or Fish sexual developmental test (FSDT, OECD TG 234). If other data are available covering the estrogenic, androgenic and steroidogenic, (EAS) related

			modalities or parameters investigated in OECD TG 229 or OECD TG 230 or OECD TG 234, then those data can be used instead
9.10.2	Endocrine disruption in amphibians Specific additional studies to investigate potential endocrine disrupting properties may include, but are not limited to Larval amphibian growth and development assay (LAGDA; OECD TG 241)		The study does not need to be carried out if: — there is no indication for endocrine activity or endocrine related effects from a sufficient mammalian data set in accordance with 8.13.3 or from any other relevant information (e.g. literature), and — valid *in vivo* data is available, with no information suggesting that the active substance may have endocrine disrupting properties in an Amphibian metamorphosis assay (AMA; OECD 231)
9.10.3	If there is information suggesting that the active substance may have endocrine disrupting properties, or if there is incomplete information on key parameters relevant for concluding on endocrine disruption, additional information or specific studies, as necessary, shall be required to elucidate: (a) the mode or the mechanism of action; and/or (b) potentially relevant adverse effects in humans or animals.	ADS'	

(3) the table in Title 2 is amended as follows:

(a) the heading of the third column is replaced by the following:

		'Column 3 Specific rules for adaptation from column 1'

(b) row 2.4 is replaced by the following:

'2.4	Specification of the technical grade active ingredient'		

(c) the following rows 2.4.1, 2.4.2 and 2.4.3 are inserted:

'2.4.1	Content of the active micro-organism and identity and content of relevant metabolites or toxins		
2.4.2	Identity and content of impurities, additives, contaminating micro-organisms		
2.4.3	Analytical profile of batches'		

(d) row 2.5 is replaced by the following:

'2.5	Method of production and quality control'		

(e) rows 2.6 to 2.9 are deleted;

(f) row 3.5 is replaced by the following:

'3.5	Information on the production of relevant metabolites and toxins'		

(g) rows 4.1 and 4.2 are replaced by the following:

'4.1	Methods, procedures and criteria used to establish the presence and identity of the micro-organism		
4.2	Analytical methods for the analysis of the micro-organism as manufactured'		

(h) the following row 4.3 is inserted:

'4.3	Methods used for monitoring purposes to determine and quantify residues (viable or non-viable)'		

ANNEX II

Annex III to Regulation (EU) No 528/2012 is amended as follows:

(1) the introductory part is amended as follows:

(a) the fourth paragraph of point 2 is replaced by the following:

'For some of the information requirements set out in this Annex, it may be possible to satisfy these requirements based on available information of the properties of the active substance(s) contained in the product and the properties of non-active substance(s) included in the product. For non-active substances, applicants shall use the information provided to them in the context of Title IV of Regulation (EC) No 1907/2006, where relevant, and the information made available by the Agency in accordance with point (e) of Article 77(2) of that Regulation. However, the information may be not sufficient or adequate to determine whether a non-active substance contained in a biocidal product has hazardous properties and the evaluating body may conclude that further data are required.';

(b) the seventh paragraph of point 2 is replaced by the following:

'The applicant shall initiate a pre-submission consultation with the prospective evaluating body. In addition to the obligation set out in Article 62(2), the applicant may also consult with the competent authority that will evaluate the dossier with regard to the proposed information requirements and in particular the testing on vertebrates that the applicant proposes to carry out. The applicant shall document such pre-submission consultations and their outcomes and shall include the relevant documents in the application.';

(c) point 5 is replaced by the following:

'5. Tests submitted for the purpose of authorisation shall be conducted in accordance with the methods described in Commission Regulation (EC) No 440/2008, or any revised version of these methods not yet included in that Regulation.

However, if a method is inappropriate or not described in Commission Regulation (EC) No 440/2008, (*) other methods shall be used which are scientifically appropriate and their appropriateness shall be justified in the application.

When test methods are applied to nano-materials, an explanation shall be provided of their scientific appropriateness for nanomaterials, and where applicable, of the technical adaptations or adjustments that have been made in order to respond to the specific characteristics of these materials.

_____

(*) Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 142, 31.5.2008, p. 1).';

(2) the table in Title 1 is amended as follows:

(a) the heading of the third column is replaced by the following:

		'Column 3 Specific rules for adaptation from column 1'

(b) row 6.6 is replaced by the following:

'6.6	The proposed claims for the product and, where claims are made, for treated articles regarding the biocidal properties conferred to the article'		

(c) row 6.8.2 is replaced by the following:

'6.8.2	Observations on undesirable or unintended side-effects on non-target organisms or on objects and material to be protected'		

(d) Rows 8.1, 8.2 and 8.3 are replaced by the following:

'8.1	Skin corrosion or irritation The assessment shall comprise the following tiers: (a) assessment of the available human, animal and non-animal data; (b) skin corrosion, *in vitro* testing; (c) skin irritation, *in vitro* testing; (d) skin corrosion or irritation, *in vivo* testing		Testing of the product or mixture does not need to be conducted if: — there are sufficient valid data on each component of the product or mixture to allow its classification in accordance with Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected, — the product or mixture is a strong acid (pH≤ 2,0) or base (pH≥ 11,5), — the product or mixture is spontaneously flammable in air or in contact with water or moisture at room temperature, — the product or mixture meets the classification criteria for acute toxicity category 1 by the dermal route, or — an acute toxicity study by the dermal route provides conclusive evidence on skin corrosion or irritation adequate for classification. If results from one of the two studies listed in points (b) or (c) in column 1 of this row already allow conclusive decision on the classification of product or mixture or on the absence of skin irritation potential, the second study does not need to be conducted An *in vivo* study for skin corrosion or irritation shall be considered only if the *in vitro* studies listed in points (b) and (c) in column 1 of this row are not applicable, or the results of these studies are not adequate for classification and risk assessment and the calculation method or

			bridging principles laid down in Regulation (EC) No 1272/2008 are not applicable *In vivo* studies for skin corrosion or irritation that were carried out or initiated before 15 April 2022 shall be considered appropriate to address this information requirement
8.2	Serious eye damage or eye irritation The assessment shall comprise the following tiers: (a) assessment of the available human, animal and non-animal data; (b) serious eye damage or eye irritation, *in vitro* testing; (c) serious eye damage or eye irritation, *in vivo* testing		Testing on the product or mixture does not need to be conducted if: — there are sufficient valid data available on each component of the product or mixture to allow its classification in accordance with Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected, — the product or mixture is a strong acid (pH≤ 2,0) or base (pH≥ 11,5), — the product or mixture is spontaneously flammable in air or in contact with water or moisture at room temperature, or — the product or mixture meets the classification criteria for skin corrosion leading to its classification as "serious eye damage" category 1 If results from a first *in vitro* study do not allow a conclusive decision on the classification of the product or mixture or on the absence of eye irritation potential (an)other(s) *in vitro* study(ies) for this endpoint shall be considered An *in vivo* study for serious eye damage or eye irritation shall be considered only if the *in vitro* study(ies) under point (b) in column 1 of this row are not applicable, or the results obtained from these studies are not adequate for classification and risk assessment and

			the calculation method or bridging principles laid down in Regulation (EC) No 1272/2008 are not applicable *In vivo* studies for serious eye damage or eye irritation that were carried out or initiated before 15 April 2022 shall be considered appropriate to address this information requirement
8.3	Skin sensitisation The information shall allow to conclude whether the substance is a skin sensitiser and whether it can be presumed to have the potential to produce significant sensitisation in humans (Category 1A). The information should be sufficient to perform a risk assessment where required The assessment shall comprise the following tiers: (a) assessment of the available human, animal and non-animal data; (b) skin sensitisation, *in vitro* testing. Information from *in vitro* or *in chemico* test method(s) conducted in accordance with point 5 of the introductory part of this Annex and addressing each of the following key events of skin sensitisation: (i) molecular interaction with skin proteins; (ii) inflammatory response in keratinocytes; (iii) activation of dendritic cells. (c) skin sensitisation *in vivo* testing. The Murine Local Lymph Node Assay (LLNA) is the first-choice method for *in vivo* testing. Another skin sensitisation test may only be used in exceptional circumstances. If another skin sensitisation test is used, scientific justification shall be provided.		Testing on the product or mixture does not need to be conducted if: — there are sufficient valid data available on each component of the product or mixture to allow its classification in accordance with Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected, — the available information indicates that the product or mixture should be classified for skin sensitisation or skin corrosion, — the product or mixture is a strong acid (pH≤ 2,0) or base (pH≥ 11,5), or — the product or mixture is spontaneously flammable in air or in contact with water or moisture at room temperature. *In vitro* tests do not need to be conducted if: — an *in vivo* study referred to in point (c) in column 1 of this row is available, or — the available *in vitro or in chemico* test methods are not applicable for the product or mixture or the results obtained from these studies are not adequate for classification and risk assessment. If information from test method(s) addressing one or two of the key events described in point (b) in column 1 of this row already allows

		for classification of the substance and risk assessment, studies addressing the other key event(s) do not need to be conducted An *in vivo* study for skin sensitisation shall be considered only if *in vitro* or *in chemico* studies referred to in point (b) in column 1 of this row are not applicable, or the results obtained from these studies are not adequate for classification and risk assessment and the calculation method or bridging principles laid down in Regulation (EC) No 1272/2008 are not applicable *In vivo* studies for skin sensitisation that were carried out or initiated before 15 April 2022 shall be considered appropriate to address this information requirement'

(e) row 8.7 is replaced by the following:

'8.7	Available toxicological data relating to: (a) non-active substance(s) (i.e. substance(s) of concern); and (b) a mixture that a substance(s) of concern is a component of Tests listed in Section 8 of the table in Title 1 of Annex II shall be carried out for the substance(s) of concern or a mixture that a substance(s) of concern is a component of if insufficient data are available and cannot be inferred through read-across, *in silico* or other accepted non-testing approaches		Testing on the product or mixture does not need to be conducted if all of the following conditions are met: — there are valid data available on each of the components in the mixture to allow classification of the mixture in accordance with the rules laid down in Regulation (EC) No 1272/2008, — a conclusion can be made whether the biocidal product can be considered as having endocrine disrupting properties, — synergistic effects between any of the components are not expected'

(f) row 9.1 is replaced by the following:

'9.1	Available ecotoxicological data relating to: (a) non-active substance(s) (i.e. substance(s) of concern); (b) a mixture that a substance(s) of concern is a component of		Testing on the product or mixture does not need to be conducted if all the following conditions are met: — there are valid data available on each of the components in the mixture to allow classification of

Tests listed in Section 9 of Title 1 of Annex II shall be carried out for the substance(s) of concern or a mixture that a substance(s) of concern is a component of if insufficient data are available and cannot be inferred through read-across, *in silico* or other accepted non-testing approaches		the mixture in accordance with the rules laid down in Regulation (EC) No 1272/2008, — a conclusion can be made whether the biocidal product can be considered as having endocrine disrupting properties, — synergistic effects between any of the components are not expected.'

(3) the table in Title 2 is amended as follows:

(a) the heading of the third column is replaced by the following:

		'Column 3 Specific rules for adaptation from column 1'

(b) row 2.3 is replaced by the following:

'2.3	Detailed quantitative (g/kg, g/l, % w/w (v/v), cfu/g, cfu/l or IU/mg or any other appropriate unit) and qualitative information on the constitution, composition and function of the biocidal product, e.g. micro-organism, active substance(s) and non-active substances and any other relevant components All relevant information on individual ingredients and the final composition of the biocidal product shall be given'		

(c) rows 3.6.8 to 3.6.12 are deleted

(d) the following rows 3.6.8 and 3.6.9 are inserted:

'3.6.8	Spraying patterns – aerosols		

3.6.9	Other technical characteristics'		

(e) rows 4 to 4.12.3 are replaced by the following

4. PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISITICS		
'4.1. Explosives		
4.2. Flammable aerosols		

4.3. Flammable liquids		
4.4. Flammable solids		
4.5. Oxidising liquids		
4.6. Oxidising solids		
4.7. Corrosive to metals		
4.8. Other physical indications of hazard		
4.8.1. Auto-ignition temperatures of products (liquids and gases)		
4.8.2. Relative self-ignition temperature for solids		
4.8.3. Dust explosion hazard'		

(f) row 10.3 is replaced by the following:

'10.3 Leaching behaviour and/or mobility	ADS'	

COMMISSION DELEGATED REGULATION (EU) 2021/526

of 23 October 2020

correcting the Czech language version of Delegated Regulation (EU) 2015/35 supplementing Directive 2009/138/EC of the European Parliament and of the Council on the taking-up and pursuit of the business of Insurance and Reinsurance (Solvency II)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2009/138/EC of the European Parliament and of the Council of 25 November 2009 on the taking-up and pursuit of the business of Insurance and Reinsurance (Solvency II) ([1]), and in particular Article 111(1), point (c), Article 234, Article 241, points (a) and (c), Article 245(4), Article 248(7) and Article 260(2) thereof,

Whereas:

(1) The Czech language version of Commission Delegated Regulation (EU) 2015/35 ([2]) contains errors in Article 182(1), in Article 190(1) and (2), in Article 331(1), point (a), in Article 332(1), introductory sentence and point (a), in Article 333(1), introductory sentence and point (a), in Article 335(1), points (a), (b) and (d), in Article 343(5), point (a)(iv), in Article 346(1), point (a), in Article 350(1), point (a), in Article 351(1), in Article 351(2), point (c), in Article 352(2), in Article 355(4), point (b), in Article 377(1) and in Article 380, point (b)(i), that alter the meaning of the text.

(2) The Czech language version of Delegated Regulation (EU) 2015/35 should therefore be corrected accordingly. The other language versions are not affected,

HAS ADOPTED THIS REGULATION:

Article 1

(does not concern the English language)

Article 2

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

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

Done at Brussels, 23 October 2020.

For the Commission
The President
Ursula VON DER LEYEN

([1]) OJ L 335, 17.12.2009, p. 1.
([2]) Commission Delegated Regulation (EU) 2015/35 of 10 October 2014 supplementing Directive 2009/138/EC of the European Parliament and of the Council on the taking-up and pursuit of the business of Insurance and Reinsurance (Solvency II) (OJ L 12, 17.1.2015, p. 1).

COMMISSION DELEGATED REGULATION (EU) 2021/527

of 15 December 2020

amending Commission Delegated Regulation (EU) 2017/565 as regards the thresholds for weekly position reporting

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2014/65/EU of the European Parliament and of the Council of 15 May 2014 on markets in financial instruments and amending Directive 2002/92/EC and Directive 2011/61/EU [1], and in particular Article 58(6) thereof,

Whereas:

(1) Commission Delegated Regulation (EU) 2017/565 [2] establishes, in its Article 83, the minimum thresholds referred to in the second subparagraph of Article 58(1) of Directive 2014/65/EU, above which trading venues are required to make public weekly reports as referred to in Article 58(1)(a) of that Directive.

(2) The minimum threshold regarding the size of open positions should be amended to provide transparency to stakeholders on a broader range of commodity derivatives. The publication of weekly position reports should no longer depend on the size of open interest in comparison with the size of deliverable supply but should instead be based on simpler criteria, namely the size of open interest in that commodity derivative.

(3) As regards the open interest threshold, weekly position reports should be published where the total combined open interest in spot contracts and other months' contracts is equal to, or exceeds, 10 000 lots, so as to ensure that there is sufficient interest in a commodity derivative to justify the publication of weekly position reports.

(4) In order to reduce the risk of a breach of confidentiality concerning position holders, for contracts where a category of persons includes fewer than five active position holders, the weekly position report published should include no information regarding that category of persons.

(5) Delegated Regulation (EU) 2017/565 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Article 83 of Delegated Regulation (EU) 2017/565 is amended as follows:

(1) paragraph 1 is amended as follows:

(a) in the first subparagraph, point (b) is replaced by the following:

'(b) the absolute amount of the gross long or short volume of total open interest expressed in the number of lots of the relevant commodity derivative is equal to, or exceeds, 10 000 lots.';

(b) the second subparagraph is replaced by the following:

'For emission allowances and derivatives thereof, point (b) shall not apply.';

[1] OJ L 173, 12.6.2014, p. 349.

[2] Commission Delegated Regulation (EU) 2017/565 of 25 April 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council as regards organisational requirements and operating conditions for investment firms and defined terms for the purposes of that Directive (OJ L 87, 31.3.2017, p. 1).

(2) paragraph 3 is replaced by the following:

'3. For contracts where there are fewer than five position holders in a given category of persons, the aggregate long and short positions, changes thereto since the previous report, the percentage of the total open interest in that category and the number of position holders in that category shall not be published.'.

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,15 December 2020.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION DELEGATED REGULATION (EU) 2021/528

of 16 December 2020

supplementing Regulation (EU) 2017/1129 of the European Parliament and of the Council as regards the minimum information content of the document to be published for a prospectus exemption in connection with a takeover by means of an exchange offer, a merger or a division

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2017/1129 of the European Parliament and of the Council of 14 June 2017 on the prospectus to be published when securities are offered to the public or admitted to trading on a regulated market, and repealing Directive 2003/71/EC ([1]), and in particular Article 1(7) thereof,

Whereas:

(1) In order to provide the highest standards of investor protection across the Union and to enable investors to make an informed investment decision, the document referred to in Article 1(4), points (f) and (g), and Article 1(5), first subparagraph, points (e) and (f), of Regulation (EU) 2017/1129 ('exemption document') should contain sufficient, objective and comprehensible information on the companies involved in the transaction, the rights attaching to the equity securities, the prospects of the issuer of those equity securitiesand, depending on the type of transaction, of the offeree company, of the company being acquired or of the company being divided.

(2) To ensure that investors are provided with the necessary information to take an informed investment decision, a more comprehensive exemption document should be required in case of a takeover by means of an exchange offer that meets the condition of Article 1(6a), point (b), of Regulation (EU) 2017/1129 when, in that case, the equity securities offered are not fungible with existing securities already admitted to trading on a regulated market prior to the takeover and its related transaction, or the takeover is considered to be a reverse acquisition transaction. The expanded content of the exemption document in such situations should be specified.

(3) To limit unnecessary costs for issuers, an exemption document should be lighter where, in connection with a transaction, the equity securities offered to the public or to be admitted to trading on a regulated market are fungible with equity securities already admitted to trading on a regulated market, and represent a small percentage of those equity securities. The reduced content of the exemption document in such a situation should be specified. However, in such a situation an issuer should not be prevented from benefiting from the exemptions laid down in Article 1(5), first subparagraph, points (a) or (b), of Regulation (EU) 2017/1129.

(4) To simplify drafting and to reduce costs of producing an exemption document, issuers should be allowed to incorporate by reference into that document certain information that already has been published in electronic form, provided such information is easily accessible and is written in the same language as the exemption document.

(5) Investors should be able to understand the situation of an issuer with a complex financial history or that has made a significant financial commitment, in which case the disclosure of information about an entity other than the issuer may be necessary. Issuers should therefore be obliged to describe in the exemption document their complex financial history or the effects on the issuer or on the issuer's business of the significant financial commitment undertaken.

(6) In order to ensure that an exemption document is a workable document for investors, it is necessary to specify that it is for the national competent authority to determine in what language that document will be drafted,

([1]) OJ L 168, 30.6.2017, p. 12.

HAS ADOPTED THIS REGULATION:

Article 1

Definitions

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

(a) 'transaction' means a takeover by means of an exchange offer, a merger or a division as referred to in Article 1(4), points (f) or (g), or Article 1(5), first subparagraph, points (e) or (f), of Regulation (EU) 2017/1129, in respect of which the conditions laid down in Article 1(6a) or Article 1(6b) of that Regulation have been fulfilled;

(b) 'exemption document' means a document to be made available to the public in accordance with Article 21(2) of Regulation (EU) 2017/1129 to be entitled to an exemption from the obligation to publish a prospectus in case of a transaction;

(c) 'offeree company' means an offeree company as defined in Article 2(1), point (b), of Directive 2004/25/EC of the European Parliament and of the Council ([2]);

(d) 'company being acquired' means a company transferring assets and liabilities to an acquiring company as a result of any merger in respect of which the conditions laid down in Article 1(6b) of Regulation (EU) 2017/1129 have been fulfilled;

(e) 'company being divided' means a company transferring assets and liabilities to a company receiving contributions as a result of any division in respect of which the conditions laid down in Article 1(6b) of Regulation (EU) 2017/1129 have been fulfilled;

(f) 'offeror' means an offeror as defined in Article 2(i) of Regulation (EU) 2017/1129.

Article 2

Minimum information content of the exemption document

1. An exemption document shall contain the relevant information which is necessary to enable investors to understand:

(a) the prospects of the issuer, and, depending on the type of transaction, of the offeree company, of the company being acquired or of the company being divided, and any significant changes in the business and financial position of each of those companies that have occurred since the end of the previous financial year;

(b) the rights attaching to the equity securities;

(c) a description of the transaction and its impact on the issuer.

The information contained in an exemption document shall be written and presented in an easily analysable, concise and comprehensible form and shall enable investors to make an informed investment decision.

An exemption document shall include the minimum information referred to in Annex I to this Regulation.

An exemption document shall, however, include the minimum information referred to in Annex II to this Regulation where all of the following conditions are met:

(a) the exemption document relates to a takeover by means of an exchange offer in respect of which the conditions laid down in Article 1(6a), point (b), of Regulation (EU) 2017/1129 have been fulfilled;

([2]) Directive 2004/25/EC of the European Parliament and of the Council of 21 April 2004 on takeover bids (OJ L 142, 30.4.2004, p. 12).

(b) the equity securities offered are not fungible with existing securities already admitted to trading on a regulated market prior to the takeover and its related transaction, or the takeover is considered to be a reverse acquisition transaction within the meaning of paragraph B19 of international financial reporting standard (IFRS) 3, Business Combinations, adopted by Commission Regulation (EC) No 1126/2008 ([3]).

2. By way of derogation from paragraph 1 and without prejudice to Article 1(5), first subparagraph, points (a) or (b), of Regulation (EU) 2017/1129, where, in connection with a transaction, the equity securities are offered to the public or are to be admitted to trading on a regulated market and are fungible with and represent no more than 10 % of equity securities already admitted to trading on a regulated market, the exemption document shall only contain the minimum information referred to in sections 1, 3 and 5 and in items 2.2 and 4.2 of Annex I to this Regulation.

Article 3

Incorporation by reference

1. Information may be incorporated by reference in an exemption document where that information has been previously or simultaneously published electronically, drawn up in a language fulfilling the requirements of Article 5 of this Regulation and where that information is contained in one of the following documents:

(a) documents as referred to in Article 19(1) of Regulation (EU) 2017/1129;

(b) documents required by national law transposing Directive 2004/25/EC;

(c) documents required by national law transposing Directive (EU) 2017/1132 of the European Parliament and of the Council ([4]);

(d) other documents that are published in accordance with national law where those documents are relevant to the transaction.

The information referred to in the first subparagraph shall be the most recent that is available to the issuer, the offeree company, the company being acquired or the company being divided.

2. Where only certain items of information are incorporated by reference, the exemption document shall contain a statement that the non-incorporated parts are either not relevant for the investor or are included elsewhere in the exemption document.

3. Persons responsible for the exemption document shall ensure that information incorporated by reference in that exemption document is easily accessible.

4. An exemption document that contains information incorporated by reference shall contain a cross-reference list that enables investors to easily identify specific items of information and shall contain hyperlinks to all documents containing information that is incorporated by reference.

([3]) Commission Regulation (EC) No 1126/2008 of 3 November 2008 adopting certain international accounting standards in accordance with Regulation (EC) No 1606/2002 of the European Parliament and of the Council (OJ L 320, 29.11.2008, p. 1).

([4]) Directive (EU) 2017/1132 of the European Parliament and of the Council of 14 June 2017 relating to certain aspects of company law (OJ L 169, 30.6.2017, p. 46).

Article 4

Complex financial history and significant financial commitment

1. Where the issuer of equity securities has a complex financial history as referred to in Article 18(3) of Commission Delegated Regulation (EU) 2019/980 ([5]), or has made a significant financial commitment as referred to in Article 18(4) of that Regulation, the exemption document shall contain all information referred to in Annex I or, where applicable, Annex II to this Regulation about the entity other than the issuer as if that entity were the issuer of the equity securities, to the extent that investors need that information to make an informed investment decision as referred to in Article 2(1) of this Regulation.

Such additional information shall specify the anticipated effects of the transaction, as defined in Article 1(a) of this Regulation, on the issuer or on the issuer's business, and the effects of the complex financial history or of the significant financial commitment on the issuer or on the issuer's business.

2. The additional information referred to in paragraph 1 shall be accompanied by a clear explanation why investors need that information to make an informed investment decision.

3. An issuer that is unable to provide the additional information referred to in paragraph 1 shall explain in the exemption document why that is the case.

Article 5

Use of languages

An exemption document shall be drawn up in a language accepted by the competent authority as defined in Article 2, point (o), of Regulation (EU) 2017/1129.

Article 6

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, 16 December 2020.

For the Commission
The President
Ursula VON DER LEYEN

([5]) Commission Delegated Regulation (EU) 2019/980 of 14 March 2019 supplementing Regulation (EU) 2017/1129 of the European Parliament and of the Council as regards the format, content, scrutiny and approval of the prospectus to be published when securities are offered to the public or admitted to trading on a regulated market, and repealing Commission Regulation (EC) No 809/2004 (OJ L 166, 21.6.2019, p. 26).

ANNEX I

MINIMUM INFORMATION CONTENT OF THE EXEMPTION DOCUMENT

Article 2(1), third subparagraph, and Article 2(2)

SECTION 1	**PERSONS RESPONSIBLE FOR DRAWING UP THE EXEMPTION DOCUMENT, THIRD PARTY INFORMATION AND EXPERTS REPORT**
Item 1.1	**Identification of persons responsible for drawing up the exemption document** Identify all persons responsible for the information or any parts of it, given in the exemption document with, in the latter case, an indication of such parts. In case of natural persons, including members of the issuer's administrative, management or supervisory bodies, indicate the name and function of the person; in case of legal persons indicate the name and registered office.
Item 1.2	**Responsibility statement** A declaration by those responsible for the exemption document that, to the best of their knowledge, the information contained in the exemption document is in accordance with the facts and that the exemption document makes no omission likely to affect its import. Where applicable, a declaration by those responsible for certain parts of the exemption document that, to the best of their knowledge, the information contained in those parts of the exemption document for which they are responsible is in accordance with the facts and that those parts of the exemption document make no omission likely to affect their import.
Item 1.3	**Expert's statement or report** Where a statement or report attributed to a person as an expert is included in the exemption document, provide the following details for that person: (a) name; (b) business address; (c) qualifications; (d) material interest, if any, in the issuer. Where the statement or report has been produced at the issuer's request, state that such statement or report has been included in the exemption document with the consent of the person who has authorised the contents of that part of the exemption document.
Item 1.4	**Information sourced by a third party** Where information has been sourced from a third party, provide a confirmation that that information has been accurately reproduced and that as far as the issuer is aware and is able to ascertain from information published by that third party, no facts have been omitted which would render the reproduced information inaccurate or misleading. In addition, identify the source(s) of the information.
Item 1.5	**Regulatory statements** A statement that: (a) the exemption document does not constitute a prospectus within the meaning of Regulation (EU) 2017/1129; (b) the exemption document has not been subject to the scrutiny and approval by the relevant competent authority in accordance with Article 20 of Regulation (EU) 2017/1129; (c) pursuant to Article 1(6a), point (b), of Regulation (EU) 2017/1129, where applicable, the supervisory authority that has the competence to review the offer document under Directive 2004/25/EC has issued a prior approval of the exemption document.

SECTION 2	INFORMATION ON THE ISSUER AND ON THE OFFEREE COMPANY, COMPANY BEING ACQUIRED OR COMPANY BEING DIVIDED

Unless stated otherwise, the items listed in Section 2 shall be provided for the issuer and, depending on the type of transaction, the offeree company, the company being acquired or the company being divided. Where one of the aforementioned entities is a group and the consolidated financial statements have already been published, the information listed in this section shall be presented on a consolidated basis.

For equity securities other than shares, the items listed in Section 2 shall also be provided for the issuer of the underlying shares, where different from the issuer of the equity securities.

In case of a takeover by means of an exchange offer, where the requested information on the offeree company is not available, a statement to that effect shall be provided.

Item 2.1	**General information**
Item 2.1.1	Legal and commercial name
Item 2.1.2	(a) domicile and legal form; (b) legal entity identifier ('LEI'); (c) the law of the country of incorporation; (d) country of incorporation, and the address, telephone number of its registered office (or principal place of business where different from the registered office); (e) hyperlink to the website with a disclaimer that the information on the website does not form part of the exemption document unless that information is incorporated by reference into the exemption document.
Item 2.1.3	Names of the auditors for the period covered by the financial statements and the name of the professional body(ies) which they are members of.
Item 2.2	**Business overview**
Item 2.2.1	Principal activities, including the main categories of products sold and/or services performed in the last financial year.
Item 2.2.2	Any significant changes having an impact on the operations and principal activities since the end of the period covered by the latest published audited financial statements.
Item 2.2.3	A brief description of the principal markets, including a breakdown of total revenues by operating segment and geographic market for the last financial year. In case of a division, the description referred to in the first paragraph shall refer to the principal markets where the main assets and liabilities of the company being divided are located.
Item 2.3	**Investments** A description of the material investments made since the date of the last published financial statements and which are in progress and/or for which firm commitments have already been made, together with the anticipated source of funds.
Item 2.4	**Corporate governance**
Item 2.4.1	Names, business addresses and functions within the issuer or, depending on the type of transaction, the offeree company, the company being acquired or the company being divided**,** of the members of the administrative, management or supervisory bodies and, in case of a limited partnership with a share capital, of partners with unlimited liability.
Item 2.4.2	Identity of major shareholders
Item 2.4.3	Number of employees

Item 2.5	**Financial information**
Item 2.5.1	Financial statements Financial statements (annual and half-yearly) that were published over the 12 months prior to the publication of the exemption document. Where both annual and half-yearly financial statements have been published, only the annual statements shall be required where they postdate the half-yearly financial statements. The financial statements shall include the audit reports. Where statutory auditors have refused audit reports on the financial statements or where such audit reports contain qualifications, modifications of opinion, disclaimers or an emphasis of matter, the reason for this shall be given and such qualifications, modifications, disclaimers or emphasis of matter shall be reproduced in full.
Item 2.5.1.a (Mergers only)	By way of derogation from item 2.5.1, where the company being acquired does not have equity securities already admitted to trading on a regulated market, the company shall provide the audited financial statements (annual and half-yearly) that were adopted over the 12 months prior to the publication of the exemption document. Where both annual and half-yearly financial statements have been published, only the annual statements shall be required where they postdate the half-yearly financial statements. The financial statements shall include the audit reports. Where statutory auditors have refused audit reports on the financial statements or where such audit reports contain qualifications, modifications of opinion, disclaimers or an emphasis of matter, the reason for this shall be given and such qualifications, modifications, disclaimers or emphasis of matter shall be reproduced in full. Where the company being acquired does not have audited financial statements, it shall provide financial statements prepared during the past 12 months and a negative statement stating that the financial statements have not been reviewed or audited.
Item 2.5.2	Accounting standards The financial information shall be prepared in accordance with the International Financial Reporting Standards as endorsed in the Union in accordance with Regulation (EC) No 1606/2002 of the European Parliament and of the Council ([1]). Where Regulation (EC) No 1606/2002 is not applicable, the financial information shall be prepared in accordance with: (a) a Member State's national accounting standards for issuers from the EEA, as required by Directive 2013/34/EU of the European Parliament and of the Council ([2]); (b) a third country's national accounting standards equivalent to Regulation (EC) No 1606/2002 for third country issuers. If such third country's national accounting standards are not equivalent to Regulation (EC) No 1606/2002 the financial statements shall be restated in compliance with that Regulation.
Item 2.5.3	A description of any significant change in the financial position which has occurred since the end of the last financial period for which either audited financial statements or interim financial information have been published, or where no such significant change has occurred, a statement to that effect. Where applicable, information on any known trends, uncertainties, demands, commitments or events that are reasonably likely to have a material effect on the issuer and, depending on the type of transaction, the offeree company, the company being acquired or the company being divided for at least the current financial year.

Item 2.5.4	Where applicable, the management report referred to in Articles 19 and 29 of Directive 2013/34/EU.
Item 2.6	**Legal and arbitration proceedings** Information on any governmental, legal or arbitration proceedings (including any such proceedings which are pending or threatened of which the issuer, the offeree company, the company being acquired or the company being divided is aware), during a period covering at least the previous 12 months which may have, or have had in the recent past, significant effects on the issuer, offeree company, company being acquired, company being divided or the group and/or group's financial position or profitability, or provide an appropriate negative statement. In case of a division, the information on legal and arbitration proceedings shall refer to the assets and liabilities that form the object of the division.
Item 2.7	**Summary of information disclosed under Regulation (EU) No 596/2014 of the European Parliament and of the Council** [3] For entities within the scope of Regulation (EU) No 596/2014, a summary of the information disclosed under that Regulation over the last 12 months, where that information is relevant at the date of the exemption document. The summary shall be presented in an easily analysable, concise and comprehensible form and shall not be a replication of information already published under Regulation (EU) No 596/2014. The summary shall be presented in a limited number of categories depending on their subject.
SECTION 3	**DESCRIPTION OF THE TRANSACTION**
Item 3.1	**Purpose and objectives of the transaction**
Item 3.1.1	Purpose of the transaction for the issuer and its shareholders.
Item 3.1.2	Purpose of the transaction for the offeree company, the company being acquired or the company being divided and its shareholders.
Item 3.1.3	Description of any anticipated benefits resulting from the transaction.
Item 3.2	**Conditions of the transaction**
Item 3.2.1	Information on the procedures and terms of the transaction and the governing law of the agreement executing the transaction. In case of a takeover by means of an exchange offer, the exemption document shall contain the information required by Article 6(3) of Directive 2004/25/EC, or an indication of where that information may be found for perusal. In case of a merger, the exemption document shall contain the information required by Article 91(2) or Article 122 of Directive (EU) 2017/1132, depending on the type of merger, or an indication of where that information may be found for perusal. In case of a division, the exemption document shall contain the information required by Article 137(2) of Directive (EU) 2017/1132 or an indication of where this information may be found for perusal.
Item 3.2.2	Where applicable, any conditions to which the effectiveness of the transaction is subject, including any guarantee.
Item 3.2.3	Where applicable, any information on break-up fees or other penalties which may be payable if the transaction is not completed.
Item 3.2.4	Where the transaction is subject to any notifications and/or requests for authorisations, a description of those notifications and/or requests for authorisations.
Item 3.2.5	Where applicable, all information necessary to fully understand the financing structure of the transaction.
Item 3.2.6	Timetable of the transaction.

Item 3.3	**Risk factors** A description, in a limited number of categories, of the material risks that are specific to the transaction, in a section headed 'Risk factors relating to the transaction'. In each category, the most material risk factors in the assessment of the issuer, taking into account the negative impact on the issuer and the probability of their occurrence, shall be mentioned first. The risk factors shall be corroborated by the content of the exemption document.
Item 3.4	**Conflict of interests** Details on any conflict of interests that the issuer, offeree company, company being acquired or company being divided and any of its shareholders may have in respect of the transaction.
Item 3.5	**Consideration of the offer**
Item 3.5.1	The addressees of the offer or allotment of the equity securities connected with the transaction.
Item 3.5.2	The consideration offered for each equity security or class of equity securities, and in particular the exchange ratio and the amount of any cash payment.
Item 3.5.3	Information concerning any contingent consideration agreed in the context of the transaction, including, in case of a merger, any obligation of the acquiring company to transfer additional securities or cash to the former owners of the company being acquired if future events occur or conditions are met.
Item 3.5.4	The valuation methods and the assumptions employed to determine the consideration offered for each equity security or class of equity securities, and in particular regarding the exchange ratio.
Item 3.5.5	Indication of any appraisals or reports prepared by independent experts and information where these appraisals or reports may be found for perusal. In case of a merger, the exemption document shall contain the information required by Articles 96 or Article 125 of Directive (EU) 2017/1132, depending on the type of merger, or an indication of where that information may be found for perusal. In case of a division, the exemption document shall contain the information required by Article 142 of Directive (EU) 2017/1132 or an indication of where that information may be found for perusal.
SECTION 4	**EQUITY SECURITIES OFFERED TO THE PUBLIC OR ADMITTED TO TRADING ON A REGULATED MARKET FOR THE PURPOSE OF THE TRANSACTION**

For equity securities other than shares, the information given shall be comprehensive and include the information listed below for the underlying shares.

Item 4.1	**Risk factors** A description of the material risks that are specific to the equity securities being offered and/or admitted to trading in a limited number of categories, in a section headed 'Risk factors relating to the equity securities'. In each category the most material risks, in the assessment of the issuer, offeror or person asking for admission to trading on a regulated market, shall be set out first, taking into account the negative impact on the issuer and the equity securities and the probability of their occurrence. The risk factors shall be corroborated by the content of the exemption document.

Item 4.2	**Working capital statement** Statement by the issuer that, in its opinion, the working capital is sufficient for the issuer's present requirements or, if not, how it proposes to provide the additional working capital needed.
Item 4.3	**Information concerning the equity securities to be offered and/or admitted to trading**
Item 4.3.1	General information to be provided: (a) a description of the type, class and amount of the equity securities being offered and/or admitted to trading, including the international security identification number ('ISIN'); (b) currency of the equity securities issued.
Item 4.3.2	A statement of the resolutions, authorisations and approvals by virtue of which the equity securities have been or will be created and/or issued.
Item 4.3.3	A description of any restrictions on the free transferability of the equity securities.
Item 4.3.4	An indication of public takeover bids by third parties in respect of the issuer's equity which have occurred during the last financial year and the current financial year. The price or exchange terms attaching to such offers and the outcome thereof shall be stated.
Item 4.4	**Admission to trading and dealing arrangements**
Item 4.4.1	An indication as to whether the equity securities offered are or will be the object of an application for admission to trading, with a view to their distribution in a regulated market, or other equivalent third country markets as defined in Article 1, point (b) of Commission Delegated Regulation (EU) 2019/980 ([4]), with an indication of the markets in question. Where known, the earliest dates on which the equity securities will be admitted to trading.
Item 4.4.2	All the regulated markets, or equivalent third country markets as defined in Article 1, point (b), of Delegated Regulation (EU) 2019/980, on which, to the knowledge of the issuer, equity securities of the same class of the equity securities to be offered or to be admitted to trading are already admitted to trading including, where applicable, depository receipts and underlying shares.
Item 4.4.3	Details of the entities that have given a firm commitment to act as intermediaries in secondary trading, providing liquidity through bid and offer rates and a description of the main terms of their commitment.
Item 4.4.4	Lock-up agreements: (a) the parties involved; (b) content and exceptions of the agreement; (c) indication of the period of the lock-up.
Item 4.5	**Dilution**
Item 4.5.1	A comparison of the net asset value per share as of the date of the latest balance sheet before the transaction and the issue price per share within that transaction.
Item 4.5.2	Additional information where there is a simultaneous or almost simultaneous offer or admission to trading of equity securities of the same class.
Item 4.5.3	A table presenting the number of equity securities and voting rights as well as the share capital for both before and after the transaction. An indication of the dilution (including the dilution in voting rights) that existing shareholders of the issuer will experience as a result of the offer.

Item 4.6	**Advisors** Where advisors connected with an issue are referred to in the exemption document, a statement of the capacity in which the advisors have acted.
SECTION 5	**IMPACT OF THE TRANSACTION ON THE ISSUER**
Item 5.1	**Strategy and objectives** The issuer shall provide a description of its intentions with regard to the future business following the transaction, including an indication of any significant changes impacting the operations, principal activities as well as the products and services as a result of the transaction. Where applicable, that information shall include a description of the business prospects and any restructuring and/or reorganisation.
Item 5.2	**Material contracts** A brief summary of all material contracts of the issuer, offeree company, company being acquired or company being divided, other than contracts entered into in the ordinary course of business, which are materially affected by the transaction.
Item 5.3	**Disinvestment**
Item 5.3.1	To the extent known, information on material disinvestments such as material sales of subsidiaries or any major line(s) of business after the transaction becomes effective, together with a description of possible impacts on the issuer's group.
Item 5.3.2	Information on any material cancellation of future investments or disinvestments previously announced.
Item 5.4	**Corporate governance** (a) to the extent known by the issuer, names, business addresses and functions within the issuer of the persons that are going be, immediately after the transaction, members of the administrative, management or supervisory bodies and, in case of a limited partnership with a share capital, partners with unlimited liability; (b) any potential conflicts of interest that may arise as a result of the carrying out by the persons referred to in point (a) of any duties on behalf of the issuer and their private interests or other duties shall be clearly stated. Where there are no such conflicts, a statement to that effect shall be made; (c) details of any restrictions agreed by the persons referred to in point (a) on the disposal of their holdings in the issuer's equity securities within a certain period of time after the transaction.
Item 5.5	**Shareholding** The shareholding structure immediately after the transaction.
Item 5.6	**Pro forma financial information**
Item 5.6.1	In case of a significant gross change as defined in Article 1, point (e), of Delegated Regulation (EU) 2019/980, a description of how the transaction might have affected the assets and liabilities and earnings of the issuer, had the transaction been undertaken at the commencement of the period being reported on or at the date reported. This requirement will normally be satisfied by the inclusion of pro forma financial information. Such pro forma financial information shall be presented as set out in items 5.7 to 5.9 and shall include the information indicated therein. Pro forma financial information shall be accompanied by a report prepared by independent accountants or auditors.

Item 5.6.2	Where pro forma financial information is not applicable, the issuer shall provide narrative and financial information about the material impacts that the transaction will have on the issuer's financial statements. That narrative and financial information shall not require auditing. The narrative and financial information shall be prepared in a manner consistent with the applicable financial reporting framework and accounting policies adopted by the issuer in its latest or next financial statements. Where that information is audited, it shall be disclosed in the exemption document that this information was audited as well as information about the auditors who proceeded with such audit.
Item 5.7	**Contents of the pro forma financial information** Pro forma financial information shall consist of: (a) an introduction setting out: (i) the purpose for which the pro forma financial information has been prepared, including a description of the takeover by means of an exchange offer, merger or division or significant commitment and businesses or entities involved; (ii) the period and/or date covered by the pro forma financial information; (iii) the fact that the pro forma financial information has been prepared for illustrative purposes only; (iv) an explanation that: (A) the pro forma financial information illustrates the impact of the transaction as if the transaction had been undertaken at an earlier date; (B) the hypothetical financial position or results included in the pro forma financial information may differ from the entity's actual financial position or results; (b) a profit and loss account, a balance sheet or both, depending on the circumstances, presented in a columnar format composed of: (i) historical unadjusted information; (ii) accounting policies adjustments, where necessary; (iii) pro forma adjustments; (iv) the results of the pro forma financial information in the final column; (c) accompanying notes explaining: (i) the sources from which the unadjusted financial information has been extracted and whether or not an audit or review report on the source has been published; (ii) the basis upon which the pro forma financial information is prepared; (iii) the source and explanation for each adjustment; (iv) whether each adjustment in respect of a pro forma profit and loss statement is expected to have a continuing impact on the issuer or not; (d) where applicable, to the extent not covered elsewhere in the exemption document, the financial information and interim financial information of the (to be) acquired businesses or entities used in the preparation of the pro forma financial information shall be included in the exemption document. Similarly, in case of a division, the financial information of the company being divided shall be included.
Item 5.8	**Principles in preparing and presenting pro forma financial information**

Item 5.8.1	The pro forma financial information shall be identified in order to distinguish it from historical financial information. The pro forma financial information shall be prepared in a manner consistent with the accounting policies adopted by the issuer in its last or next financial statements.
Item 5.8.2	Pro forma information may only be published in respect of either of the following: (a) the last completed financial period; (b) the most recent interim period for which relevant unadjusted information has been published or is included in the exemption document.
Item 5.8.3	Pro forma adjustments shall: (a) be clearly shown and explained; (b) present all significant effects directly attributable to the transaction; (c) be factually supportable.
Item 5.9	**Requirements for an accountant/auditor report** The exemption document shall include a report prepared by independent accountants or auditors stating that in their opinion: (a) the pro forma financial information has been properly compiled on the basis stated; (b) that the basis referred to in point (a) is consistent with the accounting policies of the issuer.
SECTION 6	**DOCUMENTS AVAILABLE**
Item 6.1	Information on where the following documents, where applicable, can be perused in the 12 months following the publication of the exemption document: (a) the up-to-date memorandum and articles of association of the issuer; (b) all reports, letters, and other documents, historical financial information, valuations and statements prepared by any expert at the issuer's request any part of which is included or referred to in the exemption document; (c) all reports, letters, and other documents, valuations and statements not covered by points (a) or (b) of this item or by any other points in this Annex, prepared in accordance with Directive 2004/25/EC or Directive (EU) 2017/1132. An indication of the website on which the documents may be perused.

([1]) Regulation (EC) No 1606/2002 of the European Parliament and of the Council of 19 July 2002 on the application of international accounting standards (OJ L 243, 11.9.2002, p. 1).

([2]) Directive 2013/34/EU of the European Parliament and of the Council of 26 June 2013 on the annual financial statements, consolidated financial statements and related reports of certain types of undertakings, amending Directive 2006/43/EC of the European Parliament and of the Council and repealing Council Directives 78/660/EEC and 83/349/EEC (OJ L 182, 29.6.2013, p. 19).

([3]) Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse (market abuse regulation) and repealing Directive 2003/6/EC of the European Parliament and of the Council and Commission Directives 2003/124/EC, 2003/125/EC and 2004/72/EC (OJ L 173, 12.6.2014, p. 1).

([4]) Commission Delegated Regulation (EU) 2019/980 of 14 March 2019 supplementing Regulation (EU) 2017/1129 of the European Parliament and of the Council as regards the format, content, scrutiny and approval of the prospectus to be published when securities are offered to the public or admitted to trading on a regulated market, and repealing Commission Regulation (EC) No 809/2004 (OJ L 166, 21.6.2019, p. 26).

ANNEX II

MINIMUM INFORMATION CONTENT OF THE EXEMPTION DOCUMENT

Article 2(1), fourth subparagraph

SECTION 1	**INFORMATION ON THE ISSUER**
	The following information shall be provided: (a) the information required in Section 1 of Annex I to this Regulation; (b) the information required in Annex 1 to Delegated Regulation (EU) 2019/980, with the exception of Section 1 of that Annex. Where applicable, that information shall also be provided for the issuer of the underlying shares, where different from the issuer of the equity securities. Any reference to 'registration document' or to 'prospectus' contained in Annex 1 to Delegated Regulation (EU) 2019/980 shall be construed as a reference to an exemption document as referred to in this Regulation.
SECTION 2	**INFORMATION ON THE OFFEREE COMPANY, THE COMPANY BEING ACQUIRED OR THE COMPANY BEING DIVIDED**
	The information required in Section 2 of Annex I to this Regulation shall be provided, depending on the type of transaction, for the offeree company, the company being acquired or the company being divided. Where one of the aforementioned entities is a group, and the consolidated financial statements have already been published, the information listed in this section shall be presented on a consolidated basis. In case of a takeover by means of an exchange offer, where the requested information on the offeree company is not available, a statement to that effect shall be provided.
SECTION 3	**INFORMATION ABOUT THE EQUITY SECURITIES OFFERED TO THE PUBLIC OR ADMITTED TO TRADING ON A REGULATED MARKET FOR THE PURPOSE OF THE TRANSACTION**
Item 3.1	The information required in Annex 11 to Delegated Regulation (EU) 2019/980 shall be provided, with the exception of section 1 of that Annex. Where applicable, that information shall also be provided for the underlying shares. Any reference to 'securities note' or to 'prospectus' contained in Annex 11 to Delegated Regulation (EU) 2019/980 shall be construed as a reference to an exemption document as referred to in this Regulation.
Item 3.2	By way of derogation from item 3.1, the following information shall be provided in the following cases: (a) for the securities referred to in Article 19, paragraphs 1 or 2, or in Article 20, paragraphs 1 or 2, of Delegated Regulation (EU) 2019/980, where those securities are not shares or other transferrable securities equivalent to shares, the information required in Annex 14 to that Regulation shall be provided (with the exception of section 1 of that Annex), as well as the additional information referred to in Article 19, paragraphs 1 or 2, or in Article 20, paragraphs 1 or 2; (b) for depository receipts issued over shares, the information required in Annex 13 of Delegated Regulation (EU) 2019/980 shall be provided. Any reference to 'securities note' or to 'prospectus' contained in the relevant Annexes to Delegated Regulation (EU) 2019/980 shall be construed as a reference to an exemption document as referred to in this Regulation.

SECTION 4	**DESCRIPTION OF THE TRANSACTION**
	The information required in Section 3 of Annex I to this Regulation shall be provided.
SECTION 5	**IMPACT OF THE TRANSACTION ON THE ISSUER**
	The information required in Section 5 of Annex I to this Regulation shall be provided.

COMMISSION DELEGATED REGULATION (EU) 2021/529

of 18 December 2020

establishing regulatory technical standards amending Delegated Regulation (EU) 2017/583 as regards adjustment of liquidity thresholds and trade percentiles used to determine the size specific to the instrument applicable to certain non-equity instruments

(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 600/2014 of the European Parliament and of the Council of 15 May 2014 on markets in financial instruments and amending Regulation (EU) No 648/2012 ([1]), and in particular the third subparagraph of Article 9(5) thereof,

Whereas:

(1) Commission Delegated Regulation (EU) 2017/583 ([2]) sets out the transparency requirements applicable to bonds, structured finance products, emission allowances and derivatives. In order to ensure a smooth implementation of those requirements, this Delegated Regulation introduced an annual phase-in of application of certain transparency thresholds over the course of four years, starting from 2019. This phase-in allows gradual broadening of the application of corresponding transparency obligations. In particular this concerns the 'average daily number of trades' criterion used for the determination of bonds for which there is a liquid market and the trade percentiles used for the determination of the size specific to the instrument which allows for pre-trade transparency obligations to be waived.

(2) Under this phase-in approach, moving to the next stage is not automatic. The European Securities and Markets Authority (ESMA) is required to submit to the Commission their annual assessment of the appropriateness of the move to the next stage. ESMA's assessment has to analyse the evolution of trading volumes for the concerned financial instruments under the current stage and to anticipate the possible impact a move to the next stage could have on both available liquidity and market participants. If warranted, ESMA is required to submit, together with its report, a revised regulatory standard to move to the next stage.

(3) ESMA submitted their assessment and revised regulatory standards to the Commission on 23 July 2020. ESMA concludes that between 0,15 % and 0,31 % of bonds traded between the fourth quarter of 2018 and the third quarter of 2019 were considered liquid following the criteria that apply in stage S1. Moving to stage S2 means an increase of approximately 50 %. With regard to the size specific to the instrument ESMA concludes that 16 % of notional trading volume of sovereign bonds and 6 % of other bonds took place under the waiver related to size specific to the instrument in stage S1. The move to stage S2 should ensure that less bond trades are eligible to this waiver.

(4) Taking into account the assessment undertaken by ESMA it is appropriate to move to stage S2 for determining bonds for which there is a liquid market and for the size specific to the instrument for bonds. The move to stage S2 should increase the level of transparency available in the bond market without a negative impact on liquidity. However, considering that for other non-equity instruments than bonds ESMA's first annual transparency calculations have only been published this year, there was not enough evidence to move to stage S2 for other classes of financial instruments.

(5) Delegated Regulation (EU) 2017/583 should therefore be amended accordingly.

([1]) OJ L 173, 12.6.2014, p. 84.

([2]) Commission Delegated Regulation (EU) 2017/583 of 14 July 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council on markets in financial instruments with regard to regulatory technical standards on transparency requirements for trading venues and investment firms in respect of bonds, structured finance products, emission allowances and derivatives (OJ L 87, 31.3.2017, p. 229).

(6) This Regulation is based on the draft regulatory technical standards submitted to the Commission by ESMA.

(7) ESMA 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 Securities and Markets Stakeholder Group established in accordance with Article 37 of Regulation (EU) No 1095/2010 of the European Parliament and of the Council ([3]),

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Delegated Regulation (EU) 2017/583

Article 17 of Delegated Regulation (EU) 2017/583 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. For determining the bonds for which there is not a liquid market for the purposes of Article 6 and according to the methodology specified in point (b) of Article 13(1), the approach for the liquidity criterion "average daily number of trades" shall be taken applying the "average daily number of trades" corresponding to stage S2 (10 daily trades).';

(b) paragraph 3 is replaced by the following:

'3. For determining the size specific to the financial instrument for the purposes of Article 5 and according to the methodology specified under point (b)(i) of Article 13(2), the approach for the trade percentile to be applied shall be used applying the trade percentile corresponding to the stage S2 (40th percentile).

For determining the size specific to the financial instrument for the purposes of Article 5 and according to the methodology specified under points (b)(ii), (iii) and (iv) of Article 13(2), the approach for the trade percentile to be applied shall be used applying the trade percentile corresponding to the stage S1 (30th percentile).'.

Article 2

Entry into force

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

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

Done at Brussels, 18 December 2020.

For the Commission
The President
Ursula VON DER LEYEN

([3]) Regulation (EU) No 1095/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Securities and Markets Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/77/EC (OJ L 331, 15.12.2010, p. 84).

COMMISSION IMPLEMENTING REGULATION (EU) 2021/530

of 22 March 2021

concerning the classification of certain goods in the Combined Nomenclature

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code ([1]), and in particular Article 57(4) and Article 58(2) thereof,

Whereas:

(1) In order to ensure uniform application of the Combined Nomenclature annexed to Council Regulation (EEC) No 2658/87 ([2]), it is necessary to adopt measures concerning the classification of the goods referred to in the Annex to this Regulation.

(2) Regulation (EEC) No 2658/87 has laid down the general rules for the interpretation of the Combined Nomenclature. Those rules apply also to any other nomenclature which is wholly or partly based on it or which adds any additional subdivision to it and which is established by specific provisions of the Union, with a view to the application of tariff and other measures relating to trade in goods.

(3) Pursuant to those general rules, the goods described in column (1) of the table set out in the Annex should be classified under the CN code indicated in column (2), by virtue of the reasons set out in column (3) of that table.

(4) It is appropriate to provide that binding tariff information issued in respect of the goods concerned by this Regulation which does not conform to this Regulation may, for a certain period, continue to be invoked by the holder in accordance with Article 34(9) of Regulation (EU) No 952/2013. That period should be set at three months.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

Article 1

The goods described in column (1) of the table set out in the Annex shall be classified within the Combined Nomenclature under the CN code indicated in column (2) of that table.

Article 2

Binding tariff information which does not conform to this Regulation may continue to be invoked in accordance with Article 34(9) of Regulation (EU) No 952/2013 for a period of three months from the date of entry into force of this Regulation.

Article 3

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

([1]) OJ L 269, 10.10.2013, p. 1.

([2]) Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

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

Done at Brussels, 22 March 2021.

For the Commission
Gerassimos THOMAS
Director-General
Directorate-General for Taxation and Customs Union

ANNEX

Description of the goods	Classification (CN-code)	Reasons
(1)	(2)	(3)
A portable hand-held electromechanical appliance for personal skin care. The appliance is oval shaped and measures approximately 75 × 80 × 30 mm. It has a waterproof housing and a built-in electric motor producing vibrations (so-called sonic pulsations). The outer surface of the appliance is made of silicone, with hypoallergenic silicone brushes on both sides. The surface of the appliance is divided into three zones, each with a different thickness of brushes. On the front side of the appliance there is an on/off button and a button to increase/decrease the intensity of pulsation. The appliance is designed to be used for cleansing the skin on the face with a cleanser and vibrating brushes. When cleansing the skin, a facial massage occurs as an additional effect due to the pulsations. The appliance is of the kind commonly used for domestic purposes, when travelling etc.	8509 80 00	Classification is determined by general rules 1 and 6 for the interpretation of the Combined Nomenclature, by Note 3 to Section XVI in combination with Note 3 to Chapter 90, Note 4 (b) to Chapter 85 and by the wording of CN codes 8509 and 8509 80 00. The appliance performs the function of a domestic facial cleaner (see also the Harmonized System Explanatory Note (HSEN) to heading 8509, first paragraph) as well as a massage function, but the latter is only ancillary. By virtue of Note 3 to Section XVI, machines designed for the purpose of performing two or more complementary functions are to be classified on the basis of the principal function. Therefore, classification under heading 9019 as massage apparatus is excluded. Consequently, the appliance is to be classified under CN code 8509 80 00 as an electromechanical domestic appliance, with self-contained electric motor.

COMMISSION IMPLEMENTING REGULATION (EU) 2021/531

of 22 March 2021

concerning the classification of certain goods in the Combined Nomenclature

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code ([1]), and in particular Articles 57(4) and 58(2) thereof,

Whereas:

(1) In order to ensure uniform application of the Combined Nomenclature annexed to Council Regulation (EEC) No 2658/87 ([2]), it is necessary to adopt measures concerning the classification of the goods referred to in the Annex to this Regulation.

(2) Regulation (EEC) No 2658/87 has laid down the general rules for the interpretation of the Combined Nomenclature. Those rules apply also to any other nomenclature which is wholly or partly based on it or which adds any additional subdivision to it and which is established by specific provisions of the Union, with a view to the application of tariff and other measures relating to trade in goods.

(3) Pursuant to those general rules, the goods described in column (1) of the table set out in the Annex should be classified under the CN code indicated in column (2), by virtue of the reasons set out in column (3) of that table.

(4) It is appropriate to provide that binding tariff information issued in respect of the goods concerned by this Regulation which does not conform to this Regulation may, for a certain period, continue to be invoked by the holder in accordance with Article 34(9) of Regulation (EU) No 952/2013. That period should be set at three months.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

Article 1

The goods described in column (1) of the table set out in the Annex shall be classified within the Combined Nomenclature under the CN code indicated in column (2) of that table.

Article 2

Binding tariff information which does not conform to this Regulation may continue to be invoked in accordance with Article 34(9) of Regulation (EU) No 952/2013 for a period of three months from the date of entry into force of this Regulation.

Article 3

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

([1]) OJ L 269, 10.10.2013, p. 1.

([2]) Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

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

Done at Brussels, 22 March 2021.

For the Commission
Gerassimos THOMAS
Director-General
Directorate-General for Taxation and CustomsUnion

ANNEX

Description of the goods	Classification (CN-code)	Reasons
(1)	(2)	(3)
A camera lens mount made of metal and plastic with a bayonet connection, and with dimensions of approximately 92 × 86 × 35,1 mm. The article is designed to be attached to the front of the digital video camera recorder, being placed between the video camera recorder and the objective lens. It is designed to allow for objective lenses to be used with digital video camera recorders with a different attachment thread size, providing mechanical iris control by moving its iris adjuster.	9002 11 00	Classification is determined by general rules 1 and 6 for the interpretation of the Combined Nomenclature, note 1(m) to Section XVI, note 2 (b) to Chapter 90 and by the wording of CN codes 9002 and 9002 11 00. Classification under heading 8529 as a part suitable for use solely or principally with apparatus of headings 8525 to 8528 is excluded because the article is not essential for the function of the digital camera recorder. As the article allows objective lenses to be used with digital video camera recorders with a different attachment thread size, it increases the range of operations of the objective lenses. Therefore, the article is to be considered an accessory identifiable as suitable for use solely or principally with objective lenses of heading 9002 (see judgment of the Court of 16 June 2011, Unomedical, C-152/10, ECLI:EU:C:2011:402, paragraphs 29, 30 and 34). Consequently, classification under heading 8479 as a machine having an individual function, not specified or included elsewhere in Chapter 84, is excluded because the article is covered more specifically by a heading in another chapter of the Nomenclature (see also the Harmonized System Explanatory Notes to heading 8479, second paragraph (b)). Therefore, the article is to be classified under CN code 9002 11 00 as an accessory for objective lenses of heading 9002.

COMMISSION IMPLEMENTING REGULATION (EU) 2021/532

of 22 March 2021

concerning the classification of certain goods in the Combined Nomenclature

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code ([1]), and in particular Article 57(4) and Article 58(2) thereof,

Whereas:

(1) In order to ensure uniform application of the Combined Nomenclature annexed to Council Regulation (EEC) No 2658/87 ([2]), it is necessary to adopt measures concerning the classification of the goods referred to in the Annex to this Regulation.

(2) Regulation (EEC) No 2658/87 has laid down the general rules for the interpretation of the Combined Nomenclature. Those rules apply also to any other nomenclature which is wholly or partly based on it or which adds any additional subdivision to it and which is established by specific provisions of the Union, with a view to the application of tariff and other measures relating to trade in goods.

(3) Pursuant to those general rules, the goods described in column (1) of the table set out in the Annex should be classified under the CN code indicated in column (2), by virtue of the reasons set out in column (3) of that table.

(4) It is appropriate to provide that binding tariff information issued in respect of the goods concerned by this Regulation which does not conform to this Regulation may, for a certain period, continue to be invoked by the holder in accordance with Article 34(9) of Regulation (EU) No 952/2013. That period should be set at three months.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

Article 1

The goods described in column (1) of the table set out in the Annex shall be classified within the Combined Nomenclature under the CN code indicated in column (2) of that table.

Article 2

Binding tariff information which does not conform to this Regulation may continue to be invoked in accordance with Article 34(9) of Regulation (EU) No 952/2013 for a period of three months from the date of entry into force of this Regulation.

Article 3

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

([1]) OJ L 269, 10.10.2013, p. 1.

([2]) Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

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

Done at Brussels, 22 March 2021.

For the Commission
Gerassimos THOMAS
Director-General
Directorate-General for Taxation and Customs Union

ANNEX

Description of the goods	Classification (CN-code)	Reasons
(1)	(2)	(3)
An apparatus (so-called 'camera station appliance' or 'all-in-one recorder') presented in a single housing with dimensions of approximately 33 × 23 × 8 cm, comprising the following components: — passive and active elements, — a processor, — a graphic card, — an internal memory (hard disc drive). The apparatus does not have a TV tuner. The apparatus is equipped with the following interfaces: RJ45, USB, VGA, SPF and HDMI and integrated eight-port switch with PoE (Power over Ethernet) capability. It is equipped with a 'standard automatic data-processing machine' operating system. It is also preconfigured and preloaded with special 'camera management software' and includes licences for eight channels. The apparatus is designed to receive audio and video data via a telecommunication interface (and Internet Protocol (IP)) from up to eight surveillance cameras (IP cameras). The data can be recorded on the internal hard disc, on an external storage (via the USB interface) or the apparatus can send the data via the telecommunication networks to another IP address (for example, to a server, a switch, a mobile phone, or an automatic data-processing machine). The apparatus can be connected to a monitor or a display and to a keyboard control. It is presented to be used within a security and surveillance system.	8521 90 00	Classification is determined by general rules 1 and 6 for the interpretation of the Combined Nomenclature, note 3 to Section XVI, note 5 (E) to Chapter 84 and by the wording of CN codes 8521 and 8521 90 00. Given its objective characteristics, the apparatus is intended to work together with up to eight cameras for video-surveillance purposes. A machine which, for such purposes, records signals from cameras and can either send them to another IP address or reproduce them on a display or monitor, performs a specific function other than data processing within the meaning of note 5(E) to Chapter 84. (See also judgement of the Court of Justice of 17 March 2005, Ikegami Electronics, C-467/03, ECLI:EU:C:2005:182). Classification under heading 8471 as an automatic data-processing machine is consequently excluded. The apparatus is designed for the purpose of performing two or more complementary functions within the meaning of note 3 to Section XVI, namely transmission and reception of data of heading 8517 and video recording and reproducing of heading 8521. Based on the objective characteristics of the apparatus, the principal function is that of video recording within a security and surveillance system. The transmission and reception of data is merely an ancillary function intended to improve the operation of the system in which the apparatus is incorporated. Classification under heading 8517 is therefore excluded. (See also judgement of the Court of Justice of 25 February 2016, G. E. Security, C-143/15, ECLI:EU:C:2016:115, paragraphs 55 to 57). The apparatus is therefore to be classified as other video recording or reproducing apparatus, whether or not incorporating a tuner, under CN code 8521 90 00.

COMMISSION IMPLEMENTING REGULATION (EU) 2021/533

of 24 March 2021

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

THE EUROPEAN COMMISSION,

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

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

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

Whereas:

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

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

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

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

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

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

Done at Brussels, 24 March 2021.

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

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

ANNEX

'ANNEX I

CN code	Description	Representative price (EUR/100 kg)	Security under Article 3 (EUR/100 kg)	Origin (1)
0207 14 10	Fowls of the species *Gallus domesticus*, boneless cuts, frozen	164,8	48	AR
		146,2	57	BR
		163,7	48	TH
0207 27 10	Boneless turkey cuts, frozen	284,2	4	BR'

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

DECISIONS

COMMISSION DECISION (EU) 2021/534

of 24 March 2021

determining under Article 39(1) of Directive 2014/33/EU of the European Parliament and of the Council whether a measure taken by Germany to prohibit the placing on the market of a lift model manufactured by Orona is justified or not

(notified under document C(2021) 1863)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts ([1]), and in particular Article 39(1) thereof,

Whereas:

1. PROCEDURE

(1) On 10 March 2016, Germany notified the Commission of a measure that it had taken on 26 November 2015 pursuant to Article 7(1) of European Parliament and Council Directive 95/16/EC ([2]) ('the national measure'). That measure prohibited the placing on the market of the lift model M33v3 produced by Orona Sociedad Cooperativa, Hernani, Spain ('the M33v3 lift') and introduced conditions for the placing on the market of equipment.

(2) Germany's justification for adopting the national measure was based on prior market surveillance activities carried out by the Central Authority of the Länder for Safety Technology ('the German authority'). The German authority found the M33v3 lift to be in breach of the essential health and safety requirements set out in section 2.2 of Annex I to Directive 95/16/EC ('the essential requirements').

(3) Orona Sociedad Cooperativa ('Orona') had submitted its objections against the national measure to the Commission already on 11 December 2015, arguing that their innovative M33v3 lift presents alternative safety systems which would amount to an at least equivalent level of safety compared to any lift designed according to the relevant harmonised standards and thus fulfils the essential requirements and invoking the need for the German authority to notify the national measure to the Commission.

(4) In April 2016, the Commission entered into consultation with the Member States and Orona to evaluate the national measure.

(5) Directive 95/16/EC was subsequently recast and repealed by Directive 2014/33/EU with effect from 20 April 2016.

(6) By letter of 20 April 2016, the Commission invited Orona to submit its observations on the national measure, which Orona did by letter of 18 May 2016, which included extensive observations and supporting documents. A follow-up meeting between the Commission and Orona took place on 9 June 2016.

([1]) OJ L 96, 29.3.2014, p. 251.

([2]) European Parliament and Council Directive 95/16/EC of 29 June 1995 on the approximation of the laws of the Member States relating to lifts (OJ L 213, 7.9.1995, p. 1).

(7) By separate letter of 20 April 2016, the Commission also invited Liftinstituut, the notified body chosen by Orona, which in 2012 had certified the compliance of the M33v3 lift with Directive 95/16/EC, to submit its comments. However, as Liftinstituut had already sent to the Commission extensive observations and supporting documents in a letter of 20 January 2016 in line with Orona's observations, it did not provide any further substantial comments.

(8) At a meeting of the Working Group for Administrative Cooperation in the Sector of Lifts on 16 June 2016, which was chaired by the Member States, the German authoritypresented the national measure to the market surveillance authorities of the Member States. The Commission attended the meeting as a member of that working group.

(9) The Commission also conducted an independent expert study (the 'independent study'). The independent study was initially contracted on 29 November 2016, and on 9 February 2017 the German authority, Orona, the independent expert and the Commission attended an on-site inspection of the M33v3 lift. However, the contract was subsequently terminated and a second expert was hired. That expert performed the independent study and issued a final report ([3]) on 10 December 2018. In that final report, it was concluded that the lift 'conclusively meets Essential Requirement 2.2 by achieving at least the equivalent level of safety, at the time of installation, of the harmonised standard which conferred the presumption of conformity to the EHSR 2.2 of Annex I to Directive 95/16/EC'. On 17 December 2018, the Commission invited the German authority, Orona and Liftinstituut to submit observations on the independent study. The Commission received comments from Liftinstituut on 14 January 2019, from Orona on 15 January 2019 and from the German authority on 28 February 2019.

(10) On 16 May 2019, a meeting took place with the Commission, the German authority, Orona and Liftinstituut to clarify the observations received on the independent study. Upon the Commission's request, the German authority sent the clarifications on the observations made on the independent study by email of 28 May 2019. The Commission received comments on those clarifications from Orona on 12 July 2019 and from Liftinstituut on 19 July 2019.

(11) On 14 April 2020, the Commission invited Orona and the German authority to comment on a summary of the parties' positions and the Commission's tentative assessment. All comments were received by 29 May 2020.

2. POSITIONS AND ARGUMENTS OF THE PARTIES

2.1. Position and arguments of the German authority

(12) The German local market surveillance authorities started investigations of the M33v3 lift in October 2014. Subsequently, the German authority took over the investigation.

(13) As stated in the notification to the Commission of the national measure, following a check of documentation in January and February 2015 and a test of a lift installation in Munich on 23 March 2015, the German authority has concluded that the requirements of harmonised standards EN 81-1:1998+A3:2009 ([4]) ('EN 81-1') and EN 81-21:2009 ([5]) ('EN 81-21') ('the harmonised standards') are not met by the lift. The reason for this is that the planned head room in the M33v3 lift of 0,5 m is insufficient, as a distance of 1 m is required by EN 81-1. The German authority did not find the alternative safety measures taken in the design and construction of the M33v3 lift equivalent to the state of the art represented by the harmonised standards, and thus in breach of the essential requirements.

(14) In particular, according to the German authority, while the alternative measures taken by the manufacturer decrease the probability of an accident (namely the unintended movement of the lift car to the upper extreme position), the minimum vertical distance required by the harmonised standards from the car roof to the ceiling of the well is cut by half, which considerably increases the degree of severity of possible injuries. Notwithstanding that, in the case of an emergency, a person on the roof of the car can ensure his or her safety by lying down in the remaining protection area, even though assuming this position would take considerably more time in the M33v3 lift than in a another lift that meets the requirements of the harmonised standards. That time aspect was neither taken into account by the

([3]) Final report of 10 December 2018, Conformance, 'Technical support relating to the Lifts Directive 95/16/EC and the compliance of Orona M33v3 lift, focusing on its essential health and safety requirement 2.2 of Annex I.'.

([4]) OJ C 52, 2.3.2010, p. 5.

([5]) OJ C 263, 5.11.2009, p. 3.

manufacturer, nor by Liftinstituut in the context of the conformity assessment for the EC-type examination. In a lift designed following the implementation of the requirements of the harmonised standards there would, as a result of the higher protection area, be enough free space or refuge to crouch in order to ensure safety of persons using the lift.

(15) During the consultation with the concerned parties, the German authority clarified the arguments provided in the notification to the Commission of the national measure and in the national measure itself.

(16) With respect to the free space or refuge referred to in the essential requirements, the German authority has concluded that the protection against crushing in the M33v3 lift is achieved exclusively by the mechanically protected shelter, which has the dimensions 0,5 m × 0,7 m × 1 m (height × width × length). The German authority also notes that Orona regards this solution as equivalent to the solution set out in the harmonised standard, because the reduction of the vertical distance by 0,5 m is offset by an increase in the width and length of the protective space by 0,1 m and 0,2 m respectively. However, the German authority considers that the shortcoming of the M33v3 lift is not the reduced free space per se but the time it takes a person to ensure his or her safety (namely assuming a lying position) due to that lesser space, which can result in serious injuries. According to the German authority, Orona did not provide evidence, prior to the adoption of the national measure, that the time aspect did not play a role in the M33v3 lift's safety or that there was indeed enough time to assume a safe position.

(17) The German authority specified in its observations sent by email of 28 May 2019 that the vertical distance between the car roof and the well ceiling only drops to 0,5 m in case the lift brake fails. Otherwise, when someone is entering into the well, the lift would be already blocked or stopped at the vertical distance between the car roof and the well ceiling of 1,8 m or, if the two safeguard limit switches in the electric system fail, of 1 m. However, the German authority has subsequently indicated in additional observations of 29 May 2020 that the observations of 28 May 2019 on the vertical distances are incorrect. Instead, the German authority refers to Orona's risk assessment, in which several possible hypotheses based on various events (namely brake failure, control failure, safety switch failure) were foreseen and according to which it is all those events taken together, and not only the brake failure scenario, which could lead to the vertical distance being reduced to 0,5 m. Moreover, the German authority refers to its observations on the independent study of 28 February 2019, in which it stated that there are at least three potential causes of an incident due to the failure of the electronic stopping system: (i) a human error (for example, inspection staff fails to activate or deactivate inspection mode even though there is still a person on the car roof of the lift), (ii) a failure of the limit switch and (iii) a failure of the brake. However, as for the human error, the German authority confirms the conclusion in the independent study that such an error would not lead to a shortening of the vertical distance to 0,5 m.

(18) With respect to the failure of the limit switch, the German authority states in its observations on the independent study of 28 February 2019 that such a scenario is unlikely but cannot be entirely excluded. As for the brake failure cause, the German authority acknowledges that such a failure in the lift would be extremely rare, given that Orona designed the brake as a safety component (a redundant brake, that is to say, a brake that is a protection device both against unintended car movement and ascending car over speed), bearing in mind that the safety components must comply with the essential requirements and go through the conformity assessment and CE marking independently from the lift. Furthermore, the German authority has stated that the brake in the M33v3 lift is safer than the one in the lifts applying the technical specifications set out in EN 81-1, because that harmonised standard requires brakes being certified as safety components for lifts only in particular cases.

(19) When assessing the M33v3 lift, the German authority assumed, in Orona's favour, that the brake of the lift failed less frequently than a non-redundant brake in a lift compliant with EN 81-1. Nonetheless, the German authority considers that despite the low probability of brake failure, the M33v3 lift is not compliant with the essential requirements, because it does not meet the principles of safety integration referred to in Annex I, section 1.1, last sentence, of Directive 95/16/EC. According to those principles, eliminating risks through constructive measures takes clear precedence over merely minimising them.

(20) Finally, in the additional clarifications sent to the Commission by email of 28 May 2019, the German authority stated that when the brake fails, neither the M33v3 lift nor a lift compliant with EN 81-1 can be stopped and a possible failure of the buffers is equally probable for both lifts.

2.2. **Position and arguments of Orona**

(21) During the consultations, Orona stated that, in accordance with Article 8(2) of Directive 95/16/EC, it had assessed the conformity of the lift with the essential requirements via the notified body Liftinstitut. In accordance with Annex V to that Directive, Liftinstituut performed the EC-type examination to assess the safety of the lift. EC-type examination is the procedure whereby a notified body ascertains and certifies that a model lift, or that a lift for which there is no provision for an extension or variant, satisfies the requirements of Directive 95/16/EC. Liftinstituut issued the EC-type examination certificate on 17 July 2012, and revised it on 15 March 2013.

(22) In accordance with Article 8(2) (ii) of Directive 95/16/EC and section 4 of Annex VI to that Directive, a notified body chosen by the installer of the lift is to carry out or have carried out the final inspection of the lift before it is placed on the market. The appropriate tests and checks set out in the standards referred to in Article 5 of Directive 95/16/EC, or equivalent tests, are to be carried out by that notified body in order to ensure conformity of the lift with the essential requirements. Orona chose the notified body TÜV SÜD to perform the final inspection of the M33v3 lift, TÜV SÜD confirmed the conformity of the M33v3 lift and issued the final inspection certificate on 7 August 2014.

(23) Orona requested the market surveillance authorities in the Netherlands to perform an inspection of a M33v3 lift in the city of 's-Hertogenbosch on 20 August 2015 and they concluded that the specific technical measures taken by Orona fulfilled the essential requirements.

(24) Orona argues that the German authority failed to notify the Commission immediately of the national measure, contrary to the requirement to do so under Article 7(1) of Directive 95/16/EC. While the national measure was adopted on 26 November 2015, the Commission only became aware of it through a complaint from Orona of 11 December 2015. The German authority did not notify the Commission of the measure until 10 March 2016. In Orona's view that delay has negatively affected Orona's rights of defence and reputation.

(25) As for the object of the national measure, Orona recalled that the German authority had explained to Orona that it 'did not doubt the EC-type examination in general, but only the version with the smallest headroom in combination with the smallest lift'. The German authority maintained that position until the adoption of the national measure several months later, which consisted of a ban of any M33v3 lift model with reduced headroom, regardless of the size of the lift cabin. Orona considers that the national measure was therefore not only unjustified, but also in breach of the principle of proportionality.

(26) Orona recalled in its observations of 18 May 2016 that rather than focusing merely on how the M33v3 model compares to the harmonised standards concerning vertical headroom, which is merely one factor in evaluating lift safety, an overall safety assessment is required. In this respect, Orona referred to the position paper of NB-L, the coordination group of notified bodies for Directive 95/16/EC of 3 November 2009, entitled 'Crushing danger, free space, criteria', which sets criteria for acceptable free space equivalent to the criteria set out in clause 5.7 of EN 81-1. The criteria set out in that position paper are based on a combination of the free vertical space, a free space volume (cube) and the integration of those spaces in the spatial area. The same position paper contains a non-exhaustive list of additional criteria that must be taken into account during a risk assessment. Those additional criteria include warnings, ergonomic principles, frequency of maintenance and unexpected circumstances.

(27) With respect to the free vertical space between the car roof and the well ceiling, Liftinstsitutt stated, in a letter to Orona of 10 July 2015, supporting Orona's considerations, that 'a guaranteed minimum free space of 0,5 m is generally accepted as sufficient to avoid the danger of crushing the human body […]. That this is also acceptable for application in lifts is reflected in EN 81-1:1998+A3:2009, clause 5.7.3.3 b)'. In any case, Orona stated in its observations of 18 May 2016 that the block above the car of the M33v3 lift has the same vertical clearance (0,5 m) as the vertical clearance required

under EN 81-1 for the rescue space below the car (in the well). As for the free space volume (cube), as described in the technical specifications of the M33v3 lift, the block above the car of the lift has a greater volume (0,5 m × 0,7 m × 1,0 m) than the minimum volume required under EN 81-1 for both the rescue space above the car (0,5 m × 0,6 m × 0,8 m) and the rescue space below the car (0,5 m × 0,6 m × 1,0 m). A study requested by Orona and sent to the Commission on 15 March 2016, carried out by a technology centre specialised in product, process and service innovation named IK4-Ikerlan ('the IK4-Ikerlan study'), shows that all the maintenance personnel tested (representative of the usual variety of maintenance personnel, aged between 18 and 65, and male) fit within the cube above the car of the lift, while this was not the case in the cube dimensioned in accordance with EN 81-1.

(28) According to Orona's observations of 18 May 2016, and as described in the technical specifications sent to the German authority before the national measure was adopted, the M33v3 lift contains a number of additional and specific safety features that substantially exclude human error. Those features include not only the redundant brake EC-type certified safety component, but also a number of other safety features which, altogether, render the lift even safer than lifts designed in accordance with EN 81-1. In that respect, the lift contains (i) a warning sign stating that only one person is allowed on the car roof, and that the correct safety position to prevent the risk of crushing is lying down, (ii) a safety component to switch off normal operation when the car roof is accessed (detection switch) to avoid the car starting upwards when entering the car roof, (iii) a control system which, when an entry into the well is detected, keeps the lift inactive until the inspection switch on top of the car is switched to inspection mode, (iv) an additional inspection limit safety switch which stops the lift when the car is 1,8 m from the ceiling of the well, (v) an additional final limit switch which prevents movement of the car, and (vi) a telescopic balustrade, which prevents normal operation if the balustrade is not fully retracted and prevents inspection operation if the balustrade is not fully extended.

(29) Orona stated in its observations of 18 May 2016 that in the national measure, the German authority argues that it would take 'considerably more time' for a technician on the roof of the car to assume the lying position, which is required to ensure safety in the lift, in contrast to the crouching position. Orona states that this claim was unsubstantiated by any evidence submitted by the German authority and that the need to assume a safe position is not a specific requirement under Directive 95/16/EC. Furthermore, following a meeting between the German authority and Orona on 15 December 2015, it was agreed, in line with the national measure, that Orona would perform some additional trials to further support the safe design of the M33v3 lift. Special emphasis was placed on the influence of the size of the lift roof on reaction time. In this respect, the IK4-Ikerlan study found that the position of the maintenance personnel and the size of the M33v3 lifts is not a factor influencing reaction time. In addition, it is shown that age and body mass index have no effect on the reaction time. Furthermore, the IK4-Ikerlan study concluded that the fact that the reaction time for taking up the squatting position in lifts according to EN 81-20 was on average only 1,26 seconds does not affect the specific potential risk, since this time difference corresponds to a mere 0,9 m with an inspection speed of 0,6 m/s. The different reaction times could be relevant only in the event of a failure of the safety system, for example the redundant brake system. However, in that scenario, the difference in height would not matter, as an accident would be fatal in both the M33v3 lift and a lift meeting the harmonised standards.

(30) As regards the time aspect, Orona stated that, as described in the technical file, the car roof of the M33v3 lift is flat and free from obstacles, and that due to this fact maintenance personnel may assume a safe position faster by lying flat on the roof. Orona pointed out in particular that on a car roof of a lift complying with EN 81-1, there can be many components interfering in the space for the lying position, for example ropes and their attachments, which can delay the time to assume the safe lying position. Furthermore, Orona emphasised that EN 81-1 only states that the safety space must be reachable from the working space. However, in the M33v3 lift, the working space coincides with the safety space, meaning that if something goes wrong and a person must adopt the lying position, the person is already in the correct place, which reduces the time needed to assume the safe position. The differences in the technical specifications (namely the obstacles on the car roof and the access to the safety space) between the M33v3 lift and a lift compliant with EN 81-1 were further clarified in Orona's letter to the Commission of 20 January 2016 and in its email to the Commission of 12 July 2019.

(31) Regarding the brake failure, Liftinstituut explained in a letter sent to Orona on 21 April 2015 that a brake failure, in any lift, would lead to an uncontrolled upward movement of the empty lift car, which would, within a short travel distance, result in a speed causing the lift car to jump into the free space intended to prevent the risk of crushing between the roof of the lift car and the ceiling of the well, that is to say, the lift car continues its upward movement in the well although the counterweight hits the buffers. For a lift with a rated speed of 1 m/s, a headroom of 1 m as required in EN 81-1 would be consumed by the jump where the lift car has travelled uncontrolled over a distance of only 4 m, in other words, only a short travel distance is needed. There would be no free space left implying a fatal crushing of a person on the car roof. The fact that only a short travel distance is needed to accelerate the lift to a speed exceeding 115 % of the rated speed of the lift implies that the buffers are likely to collapse, because their integrity is not guaranteed at speeds exceeding 115 % of the rated speed (EN 81-1 requires that the buffers withstand an impact due to a speed of no more than 115 % of the rated speed).

(32) Furthermore, Orona stated that, in any case, the free space provided (0,5 m vertical distance) and the time aspect are not relevant for the comparison of the safety level between the M33v3 lift and the technical specifications set out in EN 81-1. As explained in Orona's email to the German authority of 22 April 2015, which included the position expressed by Liftinstituut in its letter of 21 April 2015, the risk of crushing would occur only when the brake fails. Orona concluded that if that happens, the risk of crushing is prevented neither by the design of the M33v3 lift, nor by the design of a lift compliant with EN 81-1.

(33) Orona stated in its observations to the Commission of 12 July 2019 that the redundant brake system of the M33v3 lift is in any event far safer than the brake system of a lift compliant with EN 81-1, a fact acknowledged by the German authority in its observations of 28 May 2019. The probability of a brake failure in the M33v3 lift is, unlike in a lift compliant with EN 81-1, an extremely improbable event because the brake is an EC-type certified safety component for unintended car movement protection and ascending car movement protection. Therefore, it is far more unlikely that a brake failure in the M33v3 lift would result in a situation where a person could be confronted with the safe refuge space on the car roof suddenly and non-intentionally.

(34) Orona also stated that the concerns of the German authority in 2015 centered on the issue of risk. Orona provided the German authority with a risk assessment, conducted by Orona according to the ISO/DIS 14798 standard ([6]) ('the risk assessment'), on 16 February 2015, nine months before the national measure was adopted. In the risk assessment it was concluded that, having regard to the protective measures put in place by Orona, the M33v3 lift was safe and no further action to reduce risks needed to be taken since, on the basis of both the probability of harm (graded A-F, F being the least probable) and the degree of seriousness of injury (graded 1-4, 4 being the most minor injury), the result '2F' was obtained.

(35) In particular, it is concluded in the risk assessment that the probability of the brake failing (as an EC-type certified safety component) was so remote that the level of risk was acceptable. Orona stated that in a risk analysis it is not common to consider the failure of EC-type certified safety components because of their intrinsic high level of safety.

(36) As concluded in the risk assessment, there is no difference between the M33v3 lift and lifts compliant with the harmonised standards. The theoretical scenario of a break failure ends invariably fatally for the affected technician due to unrestricted crushing so that it is irrelevant whether the rescue space above the car is 0,5 m or 1 m.

(37) Finally, Orona highlights in its observations to the Commission of 18 May 2016 that Directive 95/16/EC does not require the complete elimination of any possible risk – that is simply impossible – but only compliance with the essential requirements set out in that Directive, which are guaranteed through harmonised standards or equivalent safety measures. Moreover, Orona stated that the equivalent safety measures must be proven to be equally safe to those reflected in the harmonised standards, which does not involve the same standard of proof as the demonstration of a complete lack of risk.

([6]) ISO 14798, lifts (elevators), escalators and moving walks – risk assessment and reduction methodology, international standard, first edition 01-03-2009.

3. **ASSESSMENT**

(38) Based on the extensive consultation with all concerned parties, the Commission has evaluated the national measure.

(39) Article 2(1) of Directive 95/16/EC, as in force when the national measure was taken, required Member States to take all appropriate measures to ensure that lifts covered by that Directive may be placed on the market and put into service only if they are not liable to endanger the health or safety of persons or, where appropriate, the safety of property, when properly installed and maintained and used for their intended purpose.

(40) Article 3 of Directive 95/16/EC provided that lifts covered by that Directive are to satisfy the essential requirements.

(41) Article 7(1) of Directive 95/16/EC required a Member State that ascertains that a lift is liable to endanger the safety of persons and, where applicable, of property, to take all appropriate measures to withdraw it from the market, to prohibit it from being placed on the market or put into service or to restrict its free movement. It follows from the second subparagraph of that Article that the Member State was to immediately inform the Commission of any such measure, indicating the reasons for its decision and in particular whether non-conformity was due to failure to satisfy the essential requirements, incorrect application of standards or shortcomings in the standards themselves.

(42) Article 8(2) of Directive 95/16/EC required that a lift, before being placed on the market, had been made subject to a conformity assessment by a notified body.

(43) The essential requirements were set out in section 2.2 of Annex I to Directive 95/16/EC, which provided that the lift was to be designed and constructed to prevent the risk of crushing when the car is in one of its extreme positions and that that objective was to be achieved by means of free space or refuge beyond the extreme positions.

(44) In accordance with Article 5(2) of the Directive, EN 81-1 gave a presumption of conformity with section 2.2 of Annex I to Directive 95/16/EC at the time the M33v3 lift was placed on the market.

(45) Orona did not rely on harmonised standards to achieve conformity with the essential requirements. Instead, Orona presented to the German authority an alternative technical solution, certified by Liftinstituut in the EC-type examination procedure, and further clarified by Liftinstituut in a letter to the German authority of 12 November 2014. Even though, the minimum free space in the headroom deviates from the requirements set out in clause 5.7.1.1 a) of EN 81-1, in accordance with the EC-type examination certificate NL12-400-1002-035-30 rev.2, issued by Liftinstituut, the free space on the car roof is a larger minimum free space (rectangular volume) than what is required as minimum free space in the pit according to EN 81-1, to prevent crushing risk in the extreme positions of the car. Liftinstituut stated in its letter of 12 November 2014 that in the event that the ropes slip when the traction sheave continues to rotate upward, that free space will be guaranteed by the permanently fixed counterweight buffer. Moreover, that notified body stated that Orona's dimensions of the free space which are alternative to the dimensions set out in EN 81-1 are also compatible with the essential requirements when reliable additional means provide a larger temporary space with dimensions that fulfil the requirements of EN 81-1 and EN 81-21, provided that the crushing risk is always covered by the permanently available free space. Those additional means, ensuring a larger temporary space, include three main elements. First, the application of two additional safety contacts which act directly in the safety circuit of the lift and which are, for additional reliability, checked by the positioning measurement system of the lift. Second, a reliable redundant brake, EC-type certified as a safety component for protection, both against unintended car movement and ascending car over speed that achieves the actual stopping of the lift. Third, a car roof access monitoring, which directly cuts off the normal operation of the lift when a person accesses the car roof via any landing door.

(46) In accordance with Article 8(2) (ii) of Directive 95/16/EC and Annex V to that Directive, Liftinstituut ascertained and certified ([7]) that the reliability of the protection system with respect to crushing risk on top of the car is proved by the EC-type examination for the M33v3 lift to be at least equal compared to a lift fulfilling the EN 81-1 requirements. The M33v3 lift only deviates from the vertical free space dimensions set out in clause 5.7.1.1 a) of EN

([7]) The EC-type examination certificate NL12-400-1002-035-30 rev.2.

81-1. Orona has followed the procedure of EC-type examination set out in part B of Annex V to Directive 95/16/EC. In that procedure, Orona explained how the alternative technical solutions were equivalent to the EN 81-1 requirements with regard to safety. The EC-type examination certificate issued by Liftinstituut follows the position paper of NB-L that sets out general technical criteria for how lifts with free space dimensions deviating from clause 5.7 of EN 81-1 can still be in full compliance with the essential requirements set out in Directive 95/16/EC.

(47) In accordance with Article 8(2)(ii) of Directive 95/16/EC and section 4 of Annex VI to that Directive, TÜV SÜD issued a final inspection certificate declaring that the lift satisfied the requirements set out in Directive 95/16/EC, after having carried out the appropriate tests and checks of the lift before it was to be placed on the market.

(48) According to the German authority, the technical solution provided by Orona does not satisfy the essential requirements mainly because the lift deviates from EN 81-1 in that it provides for only 0,5 m vertical distance instead of 1 m from the car roof to the well ceiling. The German authority considers that this does not allow sufficient time for a person to assume a safe position in case other precautionary measures fail to stop the lift at a greater distance. However, the German authority did not specify in the national measure in which cases the vertical distance in the M33v3 lift would be 0,5 m and consequently, in which cases the risk of crushing may appear.

(49) According to the German authority, the alternative technical specifications applied by Orona do not provide an equivalent level of safety because even if they reduce the probability of an accident (lift car travels unintentionally to the highest extreme position), the degree of severity of possible injuries is clearly increased by the minimal vertical space being reduced by half. A person on the lift car roof can ensure his or her safety if need be by lying down in the remaining refuge space, but it requires more time than in the case of a lift that corresponds to the harmonised standards.

(50) With respect to the free space or refuge, the German authority considers that EN 81-1 requires a vertical distance of 1 m in the entire free space or refuge from the car roof to the well ceiling. This fact is disputed by Orona, Liftinstituut and the Commission, which follows the independent study conclusions in this respect. However, as the German authority does not consider the 0,5 m vertical distance itself as incompatible with the essential requirements but instead the time it takes to assume a safe position, the vertical distance element as such does not need to be further elaborated upon as regards the interpretation of the requirements of EN 81-1.

(51) Regarding the free space or refuge in the M33v3 lift, once in inspection mode, the technician has a minimum working space of 1,8 m (top rescue space). However, the German authority has indicated, during the Commission consultation phase, the three potential causes of an incident in the lift that could lead to the vertical distance dropping to 0,5 m instead of 1,8 m when the lift works properly. Among those three causes, Orona recognises only the brake failure cause. Even in this case, Orona considers that a brake failure is very improbable. As for the human error cause, the German authority did not take this cause into account when adopting the national measure. In this respect, Orona explained in its observations of 15 January 2019 that there is no incentive for a qualified service engineer to ride the lift at a normal operating speed instead of in a maintenance speed mode. For the service engineer to perform his or her work it is of paramount importance to have full control over the movement of the car. If the lift is in normal operation mode it is not possible to stop the lift at any desired location other than a landing to perform the maintenance operations. In any event, in clause 0.3.8 of EN 81-1, it is stated that maintenance personnel are assumed to be instructed and work according to the instructions, meaning that riding the lift in normal operating speed is not genuinely foreseeable. Furthermore, the independent study considers it extremely unlikely that maintenance personnel would deliberately circumvent safety features described in the operating instructions.

(52) Regarding the third potential cause indicated by the German authority that could lead to the vertical distance dropping to 0,5 m, due to the potential failure of the limit switch, Orona explained in its observations of 18 May 2016 that the technician stands on the roof of the car, duly switches on inspection mode on the controller and thereby takes sole control over the lift. The technician then moves the car in the direction of the top of the well. The control system may fail. Due to this failure, the lift continues to move but still only at 0,6 m/s (inspection speed).

Even in the case of uncontrolled movement upwards ('UCMP'), the speed of 1 m/s (normal mode speed) would not be surpassed. The possibility that the technician stops the lift immediately in case of a danger by means of the two emergency limits on the controller remains unchanged. Even if the technician does not operate the emergency stop for unascertainable reasons, the final limit switch will ensure that the lift stops with a minimum free space of 1 m, without any risk of crushing. Therefore, also in this case, the overall probability of serious injury in the M33v3 lift is close to zero and the risk is the same as in a lift compliant with EN 81-1. For those reasons, the human error and the failure of the limit switch cannot be considered as causes leading to the vertical distance dropping to 0,5 m instead of 1,8 m when the M33v3 lift works properly.

(53) As for the complete failure of the braking system, the brake is a mechanical safety device EC-type certified as a UCMP safety component. The brake is a monitored, redundant safety brake and each brake has sufficient force to stop the lift on its own. Both brake circuits brake when the springs are applied, that is to say, in energised operating condition, the electromagnetic brake is open. In case of unforeseeable power failures, both brake circuits automatically close, actuated through spring force, and thus reliably ensures static holding or dynamic deceleration of the moving elevator car in any operating situation. Therefore, the complete failure of the braking system in the M33v3 lift is almost impossible.

(54) Furthermore, NB-L stated that the criteria for acceptable free space equivalent to those set out in clause 5.7 of N 81-1 are based on a combination of free vertical space, free space volume (cube) and the integration of those spaces in the spatial area.

(55) With respect to the time it takes for a person to assume a safe position, according to the national measure, the risk of crushing caused by insufficient time to adopt a safe position appears when the vertical distance is 0,5 m. However, as explained in recital 32, the free space or refuge in the M33v3 lift would have a vertical distance of 0,5 m only in the case that the brake fails. Since Orona provided the German authority with that technical explanation before the adoption of the national measure, specifically in its email of 22 April 2015, the scenario of brake failure is the only one, which will be considered further.

(56) The safety level provided by the technical specifications in EN 81-1 and by the M33v3 lift can only be compared by assessing the same scenario in a lift compliant with EN 81-1 and in the M33v3 lift. This means that, as explained above, the only scenario to be considered when assessing the risk of crushing is the case in which the brake fails in both lifts. Based on the evidence provided by Orona to the German authority before the adoption of the measure, and in particular the letter from Liftinstituut to Orona of 21 April 2015, if the brake fails, the speed of the free acceleration of only few meters would already imply that the travel speed of the lift would, for both lifts, make it impossible for the buffers to stop the lift car and would likely cause the buffers to collapse. In that event, the car would hit the ceiling of the well and crush anyone on the car roof independently of the vertical distance available. As explained by Liftinstituut in its letter, if the brake fails, there is a risk of crushing in both lifts, as the probability that the refuge space could avoid an accident is very small irrespective of the time it takes to assume a certain position on the car roof. In this respect, the German authority stated in its email to the Commission of 28 May 2019, that when the brake fails, neither the M33v3 lift nor a lift compliant with EN 81-1 can be stopped and a possible failure of the buffers is equally probable for both lifts.

(57) Therefore, it can be concluded that the time aspect, namely the time needed to adopt a safety position related to the vertical distance in the car roof, does not play a role in terms of preventing the risk of crushing.

(58) Furthermore, as explained by Orona and admitted by the German authority, the redundant brake used by Orona in the M33v3 lift, which is always an EC-type certified safety component, is safer than the brake used in lifts compliant with the technical specifications set out in EN 81-1, which in most cases do not require the brake to be an EC-type certified safety component.

(59) Indeed, under Article 3 of Directive 95/16/EC, a safety component is to satisfy the essential requirements or enable the lifts in which they are installed to satisfy the essential requirements. This means that the brake system has undergone a thorough independent conformity assessment procedure as referred to in Article 8.1 (ii) of Directive 95/16/EC and that it is thereby fitted with a CE marking, additional to the conformity assessment of the whole lift. A safety component failure is in fact a no risk situation, since it is extremely highly improbable as stated by ISO standard 14798, referred to in recital 33. As the brake failure is the only scenario in which the safe space between the car roof and the well would be reduced to less than what is required by EN 81-1 as vertical distance, and the failure of the brake system is almost impossible, the lift is safer than a lift compliant with EN 81-1, as such a lift does not need to be equipped with a redundant brake, which is a safety component.

(60) As for the principles of safety integration, first, the German authority has not referred to those principles in the national measure. Second, the principles of safety integration are not an abstract concept but are linked to the essential health and safety requirements and the state of the art at the time the lift was placed on the market. This means that the risks presented by the lift must be addressed by the manufacturer considering those elements. Third, the principles of safety integration must be regarded as equally applicable to any lift. In this case, the only scenario to be considered to compare the level of safety is the brake failure and the risk of such a failure in the M33v3 lift is extremely highly improbable, unlike in the case of a lift compliant with EN 81-1.

(61) As for the risks not related to the brake system, in addition to the risk assessment carried out by Orona and its conclusions, the independent study contains a risk assessment based on EN 81-1 and on the technical solution used in the M33v3 lift in order to compare the level of safety achieved by the M33v3 lift and a lift compliant with EN 81-1 with regard to the risk of crushing. A comparison of the level of risk of crushing when applying the measures set out in EN 81-1 and when applying the alternative measures provided by Orona in the M33v3 lift led to the conclusion in the independent study that, when the lift is maintained as intended, 'the alternative measures provided by Orona achieve a level of safety significantly superior to that provided by the application of EN 81-1' ([8]). Moreover, the independent study concluded that even in the highly unlikely event of misuse of the lift (due to a deliberate deviation from the maintenance instructions by the maintenance personnel), the lift 'conclusively achieves at least the same level of safety as the standard' ([9]).

4. **CONCLUSION**

(62) Based on the analysis in recitals 38 to 60, and taking account of the results of the independent study confirming that analysis, it can be concluded that the M33v3 lift was compliant with the essential requirements. The safety level achieved by the M33v3 lift is at least equivalent to the safety level of a lift compliant with EN 81-1, which provided a presumption of conformity at the time the M33v3 lift was placed on the market. Therefore, the national measure should not be considered justified.

HAS ADOPTED THIS DECISION:

Article 1

The measure taken by Germany, which was adopted by the Central Authority of the Länder for Safety Technology on 26 November 2015 and notified to the Commission on 10 March 2016, to prohibit the placing on the market of the lift model M33v3 manufactured by Orona, Sociedad Cooperativa, Hernani, Spain, is not justified.

Article 2

This Decision is addressed to the Member States.

([8]) Task 3 – 'Comparative analysis of the technical specifications of the relevant harmonised standards', section 7.1.1.
([9]) Task 3 – 'Comparative analysis of the technical specifications of the relevant harmonised standards', section 7.1.2.

Done at Brussels, 24 March 2021.

For the Commission
Thierry BRETON
Member of the Commission

CORRIGENDA

Corrigendum to Commission Implementing Regulation (EU) 2021/453 of 15 March 2021 laying down implementing technical standards for the application of Regulation (EU) No 575/2013 of the European Parliament and of the Council with regard to the specific reporting requirements for market risk

(Official Journal of the European Union L 89 of 16 March 2021)

The following Annex III shall be added after Annex II to the Regulation:

'ANNEX III

Part I: Single Data Point Model

All data items referred to in the Annexes I and II shall be transformed into a single data point model which is the basis for uniform IT systems of institutions and competent authorities.

The single data point model shall:

(a) provide a structured representation of all data items set out in Annex I;

(b) identify all the business concepts set out in Annexes I and II;

(c) provide a data dictionary identifying the following labels:

  (i) table labels;

  (ii) ordinate labels;

  (iii) axis labels;

  (iv) domain labels;

  (v) dimension labels; and

  (vi) member labels;

(d) provide metrics which define the property or amount of data points;

(e) provide data point definitions that are expressed as a composition of characteristics that univocally identify the concept;

(f) contain all the relevant technical specifications necessary for developing IT reporting solutions producing uniform supervisory data.

Part II: Validation rules

The data items referred to in the Annexes I and II shall be subject to validation rules ensuring data quality and consistency.

The validation rules shall:

(a) define the logical relationships between relevant data points;

(b) include filters and preconditions that define a set of data to which a validation rule applies;

(c) check the consistency of the reported data;

(d) check the accuracy of the reported data;

(e) set default values to be applied where the relevant information has not been reported.'

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